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3

INSTRUCTIONS FOR REPORTS AND WORKSHEETS

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PREFACE

Retinopathy of Prematurity (ROP) is the leading cause of visual sequelae in the United States for premature infants who survive their initial hospitalization. Visual sequelae such as severe myopia, strabismus, amblyopia, nystagmus and retinal detachments occur more frequently in infants who develop ROP. Basic bench research, animal model studies, and uncontrolled clinical studies have suggested that the retinal hypoxia and ischemia that result from the ROP pathology, plus current medical management of oxygen may aggravate the process. At present, there is no randomized, controlled study which tests the hypothesis that supplemental oxygen will reduce the incidence of progression from Prethreshold ROP to Threshold ROP. To provide such data, the Supplemental Therapeutic Oxygen for Prethreshold Retinopathy for Prematurity (STOP-ROP) is being sponsored by the National Eye Institute, with additional funding from the National Institute for Child Health and Human Development, and the National Institute of Nursing Research, National Institutes of Health, Bethesda, Maryland.

STOP-ROP is a multicenter randomized clinical trial designed to assess the effectiveness of supplemental oxygen in reducing the rate of progression from Prethreshold to Threshold ROP.

The Data Management Handbook is designed for use by Study Center Coordinators and provides each of the STOP-ROP forms and instructions for their implementation and completion. The handbook is divided into the following sections:
Section 1: **GENERAL INFORMATION** - provides general information about the study and outlines study procedures. *The STOP-ROP Manual of Procedures should be consulted for more specific details.*

Section 2: **INSTRUCTIONS FOR DATA FORMS** - provides a copy of each data form and instructions for the implementation and completion of study forms.

Section 3: **INSTRUCTIONS FOR MISCELLANEOUS REPORTS AND WORKSHEETS** - provides samples and descriptions of and instructions for use of miscellaneous reports and worksheets.
SECTION 1: STOP-ROP GENERAL INFORMATION

1.1 DISTRIBUTION AND MAINTENANCE OF THE DATA MANAGEMENT HANDBOOK

This Data Management Handbook is distributed to each Study Center Coordinator (SCC), Study Headquarters, the National Eye Institute, the National Institute for Child Health and Human Development and the National Institute of Nursing Research. Each recipient is responsible for maintaining a current version of the handbook. When the Coordinating Center makes modifications to the handbook because of changes made to the data forms/reports, replacement pages are mailed to each recipient. These pages are identified by the date of modification, and should be inserted in the handbook as soon as they are received. Outdated pages should be immediately discarded. Additional copies of the handbook may be made by individual centers, but the SCC is responsible for tracking the currency of these additional books.

1.2 TRAINING AND CERTIFICATION

[MANUAL OF PROCEDURES Chapter 10]

STOP-ROP requires training and certification for the following activities: (1) ophthalmology examinations, (2) Ohmeda Pulse Oximeter, (3) Laptop Computer, (4) infant randomization, (5) forms completion. Certification is granted and a certification number is assigned by the Coordinating Center when the individual has demonstrated the successful completion of individual training programs. Refer to the Manual of Procedures, Section 6.7.2 regarding coding of certified ophthalmology examinations. When an uncertified examiner completes a data form, code the two-digit STOP-ROP center number followed by 99 as the 4-digit certification number.

1.3 RECRUITMENT LOG

To facilitate tracking of potential enrollees, Study Center Coordinators will attend weekly screening ophthalmology examinations. Infants who reach Prethreshold in either eye will be entered into the Patient Register (STOP 00) and baseline information will be completed and updated by the Study Center Coordinator. This form is submitted to the Coordinating Center on a monthly basis. To maintain confidentiality of infants, the second page of the Patient Register (STOP 00), not the original, is submitted.

1.4 PARENTAL INFORMED CONSENT

Parents or designated legal guardians are required to read the Information for Parents Leaflet and sign the consent forms prior to randomization. Examples of the Leaflet and the consent forms are found in Appendix D and E of the Manual of Procedures.
1.5 INFANT QUALIFICATION

The criteria in 6.1.1 of the STOP-ROP Manual of Procedures should be used to screen infants who are potentially eligible for STOP-ROP. To verify qualification, the SCC will complete questions 1-18 of the Baseline, Eligibility and Randomization form (STOP 01), and call the Coordinating Center. Following verification, the infant will be randomized and the remainder of the Baseline, Eligibility and Randomization Form (STOP 01) will be completed and mailed to the Coordinating Center. If the Coordinating Center is not available and randomization occurs by use of sealed envelope alone, the SCC will follow the process outlined in Section 6.5 of the Manual of Procedures. When randomization is completed, the Baseline, Eligibility and Randomization form (STOP 01) should be completed up to question 19 and faxed to the Coordinating Center.

All questions concerning qualification and eligibility should be directed to the Protocol Monitor at the Coordinating Center, (301) 299-8655.

1.6 INFANT RANDOMIZATION

Following review of the Baseline, Eligibility and Randomization Form (STOP 01) and verification of eligibility, the Coordinating Center will randomize the study infant based upon stratification on the severity of the Prethreshold disease. During the telephone call to the Coordinating Center to randomize an infant, the Coordinating Center will ask the Study Center Coordinator to open the envelope corresponding to the stratification code and lowest sequence number within the stratum. Within the sealed envelope will be a folded, postcard size, two-part, tear-apart card imprinted on one half with the treatment arm designation and a 3-digit patient number. The other half will be imprinted with the Coordinating Center’s address. The SCC will record the date and time of randomization, hospital code, patient number, and name and certification number of person enrolling the infant on each section of the tear-apart card, and mail one half to the Coordinating Center and retain the other half in the infant’s study chart. The opened envelope will be maintained in the infant’s STOP-ROP file. The SCC will then record the 7-digit STOP-ROP identification number on the appropriate sequence line of the Randomization Log corresponding to the proper stratum, and complete the information requested on the Randomization Log.

When the Coordinating Center cannot be reached by telephone, randomization will be accomplished by means of the sealed envelope alone. This procedure is outlined in section 6.5 of the Manual of Procedures.

1.7 INFANT IDENTIFICATION

The infant’s study identifier consists of three elements: a 7-digit STOP-ROP identification number, name code and hospital ID number. The first two digits of the STOP-ROP identification number represent the Study Center number assigned to each Study Center at the beginning of the study, the next two digits represent the hospital code
assigned at the beginning of the study, and the last three digits represent the infant number assigned at the time of randomization.

In addition, each infant will be identified by a name code and hospital ID number. The name code is six letters in length and includes, in order, the first three letters of the infant’s last name, the first two letters of the first name and the first letter of the middle name. If the last name is 2 letters, an "X" will be used for the last letter of the 3 letters. When the infant has a hyphenated last name (e.g. Gonzales-Ramirez), use the first 3 letters of the first component of the last name (e.g. GON). If the infant has no first name, "XX" is used. If the infant has no middle name an "X" is used. The hospital ID number is the medical record number issued to the infant at the time of birth. Once the STOP-ROP identification number is assigned, it remains with the infant throughout the study, unless the infant is transferred to another institution; this would change the identification number [see section 1.14 below].

| Neonatal Network Centers will use their 4-digit Network number and 2-digit Network Center number in addition to the STOP-ROP identifiers on all data forms. |

1.8 INFANT INELIGIBILITY

Infants are ineligible for randomization if one or more of the exclusion criteria (Section 6.1.2) have been met or if one of the items on the Baseline, Eligibility and Randomization form (STOP 01) is incomplete. If the infant is found to be ineligible by the Coordinating Center during the randomization telephone call, the Coordinating Center will inform the Study Center of infant ineligibility indicating the reason for ineligibility, and, when appropriate, data required from the Study Center to qualify the infant for randomization.

1.9 STOP-ROP DATA FORMS

STOP-ROP data forms must be completed in black or blue ink and submitted to the Coordinating Center. The STOP-ROP order form should be mailed or submitted by facsimile (301) 299-3991 to the Protocol Monitor to obtain additional copies of data forms.

1.10 STOP-ROP STUDY EQUIPMENT

The Ohmeda 3740 pulse oximeter used in conjunction with Oxytip neonatal probes, Zenith laptop computer with customized Profox software program and PC Guardian security cable with anti-theft kit are the components of the STOP-ROP study equipment. Specific instructions for the proper assembly and operation of the study equipment are contained in section 1.10.1 and 1.10.2. The SCC will call the Coordinating Center if questions arise during the assembly or operation of study equipment.
The Oxytip oximeter probes should be changed every seven days. Any problems that occur before seven days should be reported to the Coordinating Center. These problems may lead to changes in policy. Such changes will be communicated by the Coordinating Center to the Study Centers.

The Ohmeda interconnect cable should be changed every 6 months. Those centers which have unused cables should use them before requesting replacements.

1.10.1 Laptop Computer Assembly and Operation

Save the box and wrapping in case you ever need to ship the laptop computer.

Unpacking. Carefully take each component out of the box and remove its protective wrapping. The components include:

- Laptop computer
- Battery pack (already attached to the laptop computer)
- Oximeter cable (already attached to the laptop computer)
- Computer AC power supply pack
- Power cord
- Floppy diskette

Additionally, the oximeter is being shipped separately.

Orientation (see Figure 1). The top of the laptop computer has the words "Zenith data systems" and "Super Sport" on its front. The rear of the laptop computer has the oximeter cable extending from it. Position the laptop computer so that the front of the laptop computer is toward you.

Locate the important devices, latches, cables and indicators on the laptop computer:

- **Display panel release latches**
  These two latches, located near the front on both sides of the top of the laptop computer, are used to raise the display panel. Simply slide these latches forward. This display panel may be raised or lowered during use to obtain the best possible viewing angle (0 to 180 degrees). To close the display panel, simply lower it until the latches engage automatically.

- **Battery pack release button**
  In the unlikely event that you need to disconnect the battery pack from the laptop computer, this rear-most button on the right side of the laptop computer will disengage the battery pack.

- **Battery pack AC input connector**
  Located on the back of the battery pack, toward the right side, this connector is labeled "DC". The cord leading from the computer's AC power supply pack will be connected here.
FIGURE 1

Oximeter
AC power
supply

Interconnect
cable

Probe

Oximeter cable

DC

Computer AC
Power Supply

Battery Pack

Laptop
Computer

Inserting a Diskette

Laptop RHS
Power switch
This switch, on the bottom of the right side in front of the battery pack release button, is used to turn the laptop computer on and off. The "off" position is designated as "0". The "on" position is designated as "1". This switch should be in the off position until AC power has been supplied from the AC power supply pack.

Floppy diskette drive
This drive, located directly in front of the power switch on the right side, will be used for data collection. A diskette has been shipped along with the computer for this purpose; any additional diskettes required for data collection will be supplied by each institution. See the oximetry collection software documentation for further details.

Oximeter cable
This cable extends from the rear of the laptop computer and will be connected to the oximeter.

Initial setup, powering up and additional orientation.

A. Set the laptop computer and the oximeter on a level surface near a dual AC outlet. This surface should be sturdy and stable so as to minimize damage due to fall or mechanical shock. It should also be in an environment protected from temperature extremes; the equipment will function best at room temperature.

B. Security lock assembly
For the installation of your universal anti-theft kit, you may choose either of the two methods described in step 9 of the instructions included with the kit; method A is probably more desirable, depending on your circumstances. The recommended placement of the Perma-Plate on the lap-top computer and the oximeter are:

- lap-top computer

Place the Perma-Plate on top of the lap-top computer, as follows (see Figure 2):
- The cylindrical "curl" of the Plate should be toward the rear of the computer, facing up.
- The Plate should be centered from left to right
- There should be approximately three inches between the front of the lap-top computer and the flat edge of the Plate.

- oximeter

Place the Perma-Plate on the bottom of the oximeter, as follows see Figure 2):
- The cylindrical "curt" of the Plate should extend laterally to the left of the left side of the oximeter (as you face the system), and should face up.

- The Plate should be even with the left side of the oximeter.

- The Plate should be just behind the plastic piece containing the stand-up bracket. This bracket should be moved out of the way before affixing the Plate.

C. Connect the oximeter cable from the computer to the oximeter. Line up the cable plug from the laptop computer with the opening on the oximeter located at the rear on your right side (note that there is only one way in which the cable plug and the opening can mate). Push the cable plug into the opening until it fits snugly. Turn the two cylindrical knobs located at either side of the cable plug clockwise until they are hand-tight to secure the cable to the oximeter.

D. Slide the two display panel release latches toward you and raise the display panel to an appropriate height. Centered directly below the display panel is a sliding control to adjust the screen CONTRAST. To its right is another sliding control to adjust the screen BRIGHTNESS.

E. Connect the cord from the computer's AC power supply to the battery pack AC input connector. Push in until it fits snugly.

F. Connect the AC power cord to the computer's AC power supply.

G. Connect the AC power cord to an AC wall outlet.

Note that when AC power is supplied in this fashion, the battery pack is being charged whether the laptop computer is on or not. Therefore, you should not leave the power cord plugged in to the wall outlet when the laptop computer will not be used for an extended period of time as this can decrease battery performance and waste electricity. The battery will allow at least 2 hours of operation without power, and requires a similar recharge time.

H. Turn the laptop computer on by sliding the power switch toward you. Within 15 seconds, the oximetry software main menu will be displayed. If a display is not visible or you wish to adjust the screen appearance, adjust the CONTRAST and BRIGHTNESS controls.
To the left of the contrast control are three indicators. The two left-most indicators will flash periodically during power-up and during study operation and may largely be ignored. The right-most indicator will glow continuously; the color indicates the source of power under which the laptop computer is operating, as follows:

♦ AMBER       Power is being supplied by the AC power supply. This should be the color of this indicator at all times except when moving the laptop computer between AC outlets while it is operating.

♦ GREEN       Power is being supplied by the battery pack. This means that AC power is no longer being supplied; this should be the color of the indicator only when moving the laptop computer between AC outlets while it is operating.

♦ RED         A flashing red indicator means that the battery pack is supplying power and needs to be charged, as the laptop computer will shut down in 3 to 5 minutes. The laptop computer also begins "beeping". A steady red indicator means that no AC power is being supplied, the battery pack is dead and the laptop computer is shutting down. The indicator should not be red (flashing or steady). If this should occur, please contact the Coordinating Center (301-299-8655).

Connect and turn on the oximeter. You are now ready to learn how to run the Stop-Rop data collection program. Please follow the directions given in the User Manual.

NOTE: If the battery pack is exhausted and you try to keep using the equipment without connecting it to an external power source, you may damage the battery pack. This is true of both laptop and oximeter. The oximeter uses the message PLEASE CONNECT POWER SUPPLY TO RECHARGE BATTERY, and an audible alarm, to indicate exhausted battery pack.

1.10.2    STOP-ROP Data Collection Program User's Guide

Sessions. A session is defined as the complete set of pulse and oxygen saturation readings taken from an Ohmeda 3740 Pulse Oximeter while it is attached to a single infant during the infant's entire period as a STOP-ROP participant. The oximeter may be disconnected during the infant's entire period as a STOP-ROP participant. The oximeter may be disconnected during transportation, surgical procedures, etc. The interrupted periods are still considered collectively as a single session for STOP-ROP purposes. The STOP-ROP data collection program collects, displays, and stores sessions as they are generated.

Floppies. The program stores each session on a 3.5" high-density diskette (floppy). [See Figure 1.] The floppy should remain inserted in the laptop during the entire
session. Since a floppy has room for about 300 days, a typical session will fit easily on a single floppy. Each floppy should bear a gummed paper label stating the STOP-ROP ID, Infant Name Code, and start date for the session contained therein. The laptop also stores its last 20 sessions on the hard disk. These serve as a backup in case a floppy gets lost. Each center should maintain a paper log detailing all the disks it has processed, or is currently processing. The log should give the paper label information, the date data collection ended, and the date the diskette was shipped to the Coordinating Center.

The Main Menu. The very first time you run your computer, you will be in the Main Menu. For subsequent power-ups, you will automatically be in Continuation Mode (option 1). In Continuation Mode, if you respond 'N' to the question about whether you actually wish to be in this mode, the Main Menu appears. From the Main Menu, you have access to all 6 of the program options. To learn how to run the program, try options (3) and (4), which do not require a floppy. For routine work, you will probably use options (1) and (2) the most.

The Data Screen. While collecting data, the laptop displays its data screen. This graphically shows (from left to right): the percent of time in target over the last 20 minutes and the last 4 hours, and saturation levels for the last hour. If you hit the left or right arrow keys, you will see the percent of time in target in the past 8 hours. Additionally, if you hit the [Tab] key, the top part of the data collection screen will be replaced with a table showing the percent time in target for each hour of the preceding six days of data collection. Percents less than 50% will be highlighted. If you then press the [C] key, the total compliance, preceded by the letters "TC: :", will be displayed in the upper left corner of the screen. Hitting [Tab] again will make this table vanish. The screen can also display various error messages. A message at the screen bottom reminds you that you can exit from the screen by holding down the [Ctrl] key and then pressing the [E] key.

The Alarm. Every minute, the computer decides whether to alarm you that the infant is out of target. It sounds the alarm only if the following 3 conditions are all true at the same time:

1) The infant is out of target.
2) The infant has been out of target more than 50% of the last 20 minutes.
3) The alarm has not sounded in the last 20 minutes.

Since the laptop stores the current session on the hard disk, you can do two things that would otherwise be impossible. (a) You can collect data even when the floppy drive is inoperable. The laptop allows this type of data collection if it tries and fails to read a floppy three times in a row. If this happens, the laptop is broken. Only as a last resort should one collect data with a broken laptop. Call the Coordinating Center for a replacement immediately. (b) You can send an incomplete session to the Coordinating Center, while still continuing to collect additional data for the same session. This will be useful at the outset of the trial, to quickly ensure that our data collection system has no further problems. We will be requesting this from selected centers.
You can silence the alarm for 20 minutes by pressing the space bar, or disable the alarm for 4 hours by holding down [Ctrl], and pressing [A]. You cannot re-enable the 20-minute alarm; the alarm will not reset itself until the entire time period has passed. You can re-enable the 4-hour alarm by holding down [Ctrl], and pressing [A].

The Options

1. **Continue the current infant’s session.** Use this to continue the session when the infant has been temporarily off the oximeter. For example, this might occur because of medical procedures, transportation, etc. You should re-insert the correct floppy for that session, if the floppy has been (improperly) removed. If you insert a new unused floppy, the laptop will assume that you have lost the floppy for the current session. Therefore, it will transfer the stored portion of the most recent session (i.e., the current session) from the hard disk to the floppy. If this happens, you should label the new floppy correctly, and dispose of the old floppy to avoid confusion.

Note: to stop collecting data and take the infant off for a procedure, hold down the [Ctrl] key and press the [E] key – see the section above on The Data Screen.)

2. **Begin a new infant session.** Use this option to start a new session, that is, to begin recording from a new infant. Enter the STOP-ROP ID code, Infant Name Code, and start date. Also write these on a paper label and stick it to an unused floppy. (If necessary, the program can format the floppy). Insert the floppy in its drive, and respond to various other computer queries. The laptop will insist, if necessary, that the floppy be blank, and also check for other disk errors. Finally, it will display its data screen.

3. **Demonstration of an infant session.** Use this option first, to familiarize yourself with the program. You need not connect the oximeter; the program manufactures its own fake saturation and pulse data, but does not save any data to disk. You can move the fake saturation value up and down by using the up-arrow and down-arrow keys.

4. **Practice session or monitor only.** In this mode, the laptop reads the oximeter and displays its data screen, but does not save any data to disk. Therefore a diskette is not required. Use this mode to practice collecting data, or to determine whether an infant is eligible.

5. **See what’s on a floppy disk.** This reports number and identities of session files, and number of non-session files, on a floppy. You should have 0 or 1 session file, and 0 non-session files, on a STOP-ROP floppy. Anything else is an error. Send allfloppies with session data to the Coordinating Center upon completion of Oxygen treatment.

6. **Transfer a session to a floppy disk.** If the program has stored only one session on its hard disk, it transfers this to the floppy. If more than one, it tells you what it has stored, and asks you which to transfer.
1.11 DATA CORRECTIONS

Corrections to STOP-ROP data should be made on the hard copy of the form. Corrections are made by placing a line through the incorrect item, recording the correct response, and dating and initializing the correction. All corrections must be done utilizing an ink pen; correction fluid should never be used.

1.12 DOCUMENTATION AND VERIFICATION

The completed original of all STOP-ROP data forms must be sent to the Coordinating Center and will be retained in the STOP-ROP file. The exception is Patient Register (STOP 00) which requires submission of the second carbon copy, with the name of the infant omitted. Mail completed data forms to:

STOP-ROP Data Manager
11325 Seven Locks Road, Suite 214
Potomac, MD 20854

Individual Study Centers should retain a copy of each form in the infant's STOP-ROP file.

1.13 MISSING DATA/QUERIES

Errors, possible errors, and missing items detected by the Coordinating Center generate a query message for the Study Center. These queries are sent to the Study Center in the form of a Missing Data Report. The Missing Data Report is generated following an update and will be sent with a corresponding Query Inventory on a regular basis. The Query Inventory is a list of the Missing Data Reports sent to a Study Center since the last update. The STOP-ROP master database will be updated on the 1st and the 15th of each month.

1.14 MISSING FORMS REPORT

The Coordinating Center generates a Missing Forms Report on a bi-monthly basis that serves to notify each Study Center of forms that are not in the infant's file. A response should be returned within two weeks to the Coordinating Center.

1.15 INFANT TRANSFER TO/FROM ANOTHER STOP-ROP CENTER

When an infant is transferred from one STOP-ROP Study Center to another STOP-ROP Study Center on a permanent basis, the existing file for that infant must be transferred as well. The Study Center Coordinator at the transferring Study Center must
notify the Coordinating Center to which Study Center the infant is to be transferred. The data diskette must be sent to the Coordinating Center. NO STOP-ROP equipment will accompany the infant to the new STOP-ROP Study Center. A copy of all the material in the infant’s STOP-ROP file must be maintained by the sending Study Center.

When the infant has been transferred to the new Study Center, a new 7-digit STOP-ROP identification number is assigned. The infant’s original STOP-ROP identification number is maintained in the new Study Center record and at the Coordinating Center.

1.16 INFANT TRANSFER TO A NON STOP-ROP CENTER

When an infant is transferred for his or her primary care to a non STOP-ROP Center on a permanent basis and no further follow-up is possible, the Study Center must notify the Coordinating Center by completing a Protocol Anomaly (STOP 06 form). Infants receiving primary care at a non STOP-ROP Center for whom follow-up information is obtainable are NOT considered transferred.

1.17 PROTOCOL MONITOR REVIEW CALLS

To assure adequate intercommunication between the Coordinating Center and the Study Centers, a regularly scheduled telephone call is made to each Study Center Coordinator by the Protocol Monitor at the Coordinating Center. An agenda listing topics of discussion is mailed in advance. The confidentiality of the call allows for discussion of any topic of interest to the Study Center Coordinator (see Chapter 10 of the Manual of Procedures).
SECTION 2: STOP-ROP DATA FORMS

Section 2 provides instructions for the implementation and completion of data forms. A sample of each form is provided, followed by instructions for completion. The tab dividers are red for this section to easily distinguish it from the main body of the handbook. Every data form has its own tab and a listing of forms has been provided immediately following this introduction (Exhibit 1).

A STOP-ROP Order Form to obtain new forms and worksheets is provided in this section. In the event a question is not answered in this section, in the main body of this Handbook or in the Manual of Procedures, call the Coordinating Center at (301) 299-8655.
<table>
<thead>
<tr>
<th>NUMBER AND TITLE OF FORM</th>
<th>WHEN TO SUBMIT</th>
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<tr>
<td>STOP 00: Patient Register</td>
<td>Submit second page of NCR form at end of each month</td>
</tr>
<tr>
<td>STOP 01: Baseline, Eligibility and Randomization</td>
<td>If randomization by sealed envelope only, fax form immediately. For both methods of randomization, mail original after completing question # 21</td>
</tr>
<tr>
<td>STOP 02: Retinal Examination</td>
<td></td>
</tr>
<tr>
<td>STOP 03: Weekly Outcome</td>
<td></td>
</tr>
<tr>
<td>STOP 04: Three-Month Ophthalmic Outcome</td>
<td>At 3 month corrected age visit</td>
</tr>
<tr>
<td>STOP 05: Three-Month Neonatal Outcome</td>
<td>At 3 month corrected age visit</td>
</tr>
<tr>
<td>STOP 06: Protocol Anomaly (e.g., missed weekly examination; transfer to non-STOP-ROP study facility; infant off study monitoring equipment; parent refusal of assigned treatment; parent refusal of further follow-up; treatment of an eye not at endpoint)</td>
<td>Following notification of a protocol anomaly</td>
</tr>
<tr>
<td>STOP 07: Transfer</td>
<td>At time of transfer from one STOP-ROP Study Center to another STOP-ROP Study Center</td>
</tr>
<tr>
<td>STOP 08: Adverse Experience</td>
<td>Within 24 hours of notification of life-threatening adverse experiences or treatment-related death; within 1 week of unexpected serious adverse experiences.</td>
</tr>
<tr>
<td>STOP 09: Revised Denver Prescreening Developmental Questionnaire</td>
<td>At 3 month corrected age visit</td>
</tr>
<tr>
<td>STOP 10: Initial Discharge</td>
<td></td>
</tr>
<tr>
<td>STOP 10A: Parent/Caretaker Interview</td>
<td></td>
</tr>
<tr>
<td>STOP 11: Rehospitalization</td>
<td></td>
</tr>
<tr>
<td>STOP 12: Death</td>
<td>Within 24 hours of notification of death of infant, either at home, or during initial or subsequent hospitalizations prior to 3 month corrected age visits</td>
</tr>
<tr>
<td>STOP 13: Cryo-Risk</td>
<td>When both eyes have attained endpoint</td>
</tr>
</tbody>
</table>
## EXHIBIT 1

### LISTING OF STOP-ROP FORMS

<table>
<thead>
<tr>
<th>NUMBER AND TITLE OF FORM</th>
<th>WHEN TO SUBMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STOP 00:</strong> Patient Register</td>
<td>Submit second page of NCR form at end of each month</td>
</tr>
<tr>
<td><strong>STOP 01:</strong> Baseline, Eligibility and Randomization</td>
<td>If randomization by sealed envelope only, fax form immediately. For both methods of randomization, mail original after completing question # 21</td>
</tr>
</tbody>
</table>
| **STOP 02:** Retinal Examination | • At baseline  
• When each eye attains an ophthalmic endpoint |
| **STOP 03:** Weekly Outcome | • At weekly evaluation  
• Completion of assigned oxygen treatment  
• Parents refuse further follow-up |
| **STOP 04:** Three-Month Ophthalmic Outcome | At 3 month corrected age visit |
| **STOP 05:** Three-Month Neonatal Outcome | At 3 month corrected age visit |
| **STOP 06:** Protocol Anomaly (e.g., missed weekly examination; transfer to non-STOP-ROP study facility; infant off study monitoring equipment; parent refusal of assigned treatment; parent refusal of further follow-up; treatment of an eye not at endpoint) | Following notification of a protocol anomaly |
| **STOP 07:** Transfer | At time of transfer from one STOP-ROP Study Center to another STOP-ROP Study Center |
| **STOP 08:** Adverse Experience | Within 24 hours of notification of life-threatening adverse experiences or treatment-related death; within 1 week of unexpected serious adverse experiences. |
| **STOP 09:** Revised Denver Prescreening Developmental Questionnaire | At 3 month corrected age visit |
| **STOP 10:** Initial Discharge | • At initial discharge to home  
• At time of transfer to non-STOP-ROP facility (if hospitalized)  
• Hospitalized at 3 month corrected age visit  
• Death during initial hospitalization |
| **STOP 10A:** Parent/Caretaker Interview | • At initial discharge to home  
• Transfer to non-STOP-ROP Study Center  
• In rare instances, at 3 month corrected age visit |
| **STOP 11:** Rehospitalization | • At discharge(s) following rehospitalization  
• At time of transfer(s) to non-STOP-ROP facility (if rehospitalized)  
• Rehospitalized at 3 month corrected age visit  
• Death during rehospitalization |
| **STOP 12:** Death | Within 24 hours of notification of death of infant, either at home, or during initial or subsequent hospitalizations prior to 3 month corrected age visits |
### PATIENT REGISTER [STOP 00]

**DATE COMPLETED:**

**STUDY CENTER NAME:**

**CENTER #**

**HOSPITAL NAME:**

**HOSPITAL #**

*To be completed for each infant - at the time the infant first reaches Prethreshold as modified from CRYO-ROP.*

<table>
<thead>
<tr>
<th>1) Name¹</th>
<th>2) Hospital ID #</th>
<th>3) Date of Birth M/D/Y</th>
<th>4) Birth Weight (in grams)</th>
<th>5) Gender M-male, F-female, A-ambiguous</th>
<th>6) Race of Mother²</th>
<th>7) Gest. Age (in weeks)</th>
<th>8) Date of Exam M/D/Y</th>
<th>9) Examination Results</th>
<th>10) Right Eye</th>
<th>11) Left Eye</th>
<th>12) Pulse Oximetry Saturation</th>
<th>13) Oxygen Code³</th>
<th>14) Exclusion Criteria⁴</th>
<th>15) Treatment Assignment⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

### NOTES:

¹ This column will not copy through to page two of NCR form, to protect confidentiality of patient.

² Race Code: W-White, not of hispanic origin, B-Black, not of hispanic origin, H-Hispanic, A-Asian, P-Pacific Islander, N-Native American, O-Other, specify

³ Oxygen Code: 0-No oxygen, 1-Nasal cannula or hood, 2-Nasal CPAP (prongs) 3-ETT (vent or CPAP), 4-Other, specify

⁴ Exclusion Criteria: 0-No exclusion criteria apply, 1-Parent refusal, 2-Physician refusal, 3-Infant enrolled in conflicting study, 31-Sats >94% in room air, 32-Too ill to maintain sats >95% in O₂, 4-Infant transferred to non-STOP-ROP center, 5-Fatal congenital anomaly, 6-Congenital eye anomaly, 7-Second exam does not confirm Prethreshold, 8-Threshold ROP OU, 9-Unable to maintain follow-up if enrolled, 99-Other, specify on log.

⁵ Treatment Assignment code: C-Conventional, S-Supplemental, H-Hope-Rop.

*Signature of Study Center Coordinator:*

*Certification Number: ____________________________*

*STOP 00 V02, 01/01/96*
MODIFIED CRYO-ROP DEFINITION OF PRETHRESHOLD ROP

The modified CRYO-ROP definition of prethreshold ROP is used to define zones and stages.

ZONE 1
- Any number of clock hours of stage 1 or 2 without PLUS disease

ZONE 2
- Any number of clock hours of stage 3 without PLUS disease
- Any number of clock hours of stage 2 with PLUS disease
- PLUS disease with less than 5 contiguous and less than 8 composite clock hours of stage 3

ZONE 3
- ROP that is in Zone 3 cannot be Prethreshold
INSTRUCTIONS FOR STOP 00 FORM

PATIENT REGISTER

GUIDELINES

With the exception of infants diagnosed outside your institution as having Threshold ROP OU and referred to your institution for treatment, every infant with Prethreshold ROP or greater in at least one eye on at least one screening examination must be recorded on the Patient Register. Infants referred to your institution for treatment of Threshold ROP OU, and infants who are less than Prethreshold OU on all screening exams, should not be entered on the Patient Register. Results of screening examinations will be obtained by the Study Center Coordinator. The Study Center Coordinator will maintain a separate Patient Register for each hospital within a Study Center. Once enrolled in STOP-ROP, an infant should never again appear on the register.

It is possible to enter an infant on the Patient Register more than once. For example, an infant with Prethreshold ROP OS has a median pulse oximetry exceeding 94% in room air. The infant is excluded, using code 31. One week later, both eyes are at Prethreshold and the median saturation is 92%: the Study Center Coordinator completes a new line in which columns 3-7 may be omitted, and if the infant meets all other eligibility criteria, the exclusion code is 0. The date of the initial screening exam should be completed in addition to today’s examination date in column 8.

At the end of each month, the Study Center Coordinator is required to sign and mail or fax this form, indicating the date the form was completed, and Study Center name and number. When the Study Center is a consortium, the member hospital name and code in the consortium should be recorded.

The following guidelines are numbered to represent each column commencing with Name and proceeding horizontally. These guidelines serve to supplement the instructions on the form, not replace them. Not all columns are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, call the Coordinating Center.

1. Name - To maintain confidentiality of the infant, the second page of this form, not the original, will be submitted to the Coordinating Center. This page will not contain name of infant. If the SCC is required to submit this form after first submission, the SCC will cover the name column prior to copying, in order to maintain confidentiality of the infant.
6. Race of mother - Enter the appropriate code based on the choices list at the bottom of the form. If race of mother is mixed, code according to what she considers her predominant race.

7. Gestational age at birth - Use early ultrasound dating (at or before 15 weeks), unless unavailable or when there are other widely discrepant (greater than 3 weeks) estimates. In this case, the admitting neonatologist should decide. If the admitting neonatologist is unavailable, the STOP-ROP neonatologist should decide. When gestational age is recorded in weeks and days, do not record days; round to the nearest number of weeks. If the number of days is four or more, round to next week, e.g. 31 weeks 4 days (31 4/7) is 32 weeks, however, 30 weeks 2 days (30 2/7) is 30 weeks.

8-11. Examination results - If infant is enrolled in HOPE-ROP, enter information obtained from the infant's second screening ophthalmology examination that indicates Prethreshold in either eye. Otherwise, enter information obtained from the infant's first screening ophthalmology examination that indicates Prethreshold in either eye. Enter the total composite number of clock hours of worst stage, and then, the total contiguous number of clock hours of worst stage. Record the status of each eye using the modified CRYO-ROP criteria listed on the reverse side of the form. The ophthalmologist should be consulted if questions arise regarding exam results prior to completion of this form. When no disease is present in an eye, record 0 for lowest zone, highest stage and clock hours and N for plus disease.

12. Pulse oximetry saturation - If the infant is not receiving oxygen, record the median pulse oximeter reading in room air. If the infant is receiving oxygen, record the median saturation value (e.g. 92% or 95%) at which the infant is maintained prior to randomization. The Study Center Coordinator can obtain either of these readings by the following methods, which are listed by decreasing order of preference:

Note: Please refer to your Study Center policy regarding parental consent to place infant on pulse oximeter

a) 4 hours of continuous monitoring of pulse oximetry by a study oximeter and laptop computer. This will permit an objective percent of time to be determined. The laptop program has a practice/monitoring option in which the oximetry data are collected normally, but not saved to disk. This option allows monitoring of oximetry status prior to randomization. The laptop data collection program displays in the middle of the data collection screen a graph titled: "% time:4 hours". This graph uses horizontal bars to show the percents of time spent, over the past four hours, at various saturation values. The height of each bar (on the vertical axis) gives the saturation value, while the length of the bar (measured on the horizontal axis) gives the percent time spent at that saturation value. The bar corresponding to the median is
identified by a dotted line drawn through it. Enter the saturation (vertical axis) value for this bar.

b) 4-8 hours of continuous monitoring of pulse oximetry on an Ohmeda oximeter with a computer printout of trends. Ohmeda 3700 and 3740 can produce such a printout. There are also commercial programs that produce such analyses based on a "dump" of continuous data. To obtain the median:

**If the median is displayed**, record it.

If percents of time spent at various saturation levels are displayed, calculate a median as follows: Starting from the lowest saturation value and moving upward, add together the percents time. When this sum exceeds 50, stop. The saturation value for the last percent you have added is the median. Record this value. For example, suppose the percents time at various saturation values are:

<table>
<thead>
<tr>
<th>sat</th>
<th>% time</th>
<th>sat</th>
<th>% time</th>
<th>sat</th>
<th>% time</th>
</tr>
</thead>
<tbody>
<tr>
<td>88</td>
<td>5</td>
<td>90</td>
<td>30</td>
<td>92</td>
<td>20</td>
</tr>
<tr>
<td>89</td>
<td>10</td>
<td>91</td>
<td>20</td>
<td>93</td>
<td>15</td>
</tr>
</tbody>
</table>

The percents for 88, 89, and 90 are 5 + 10 + 30 = 45. Adding the percent for 91 brings the sum up to 65, so the median is 91. Notice that the median is not necessarily the most frequent value (90, in this case, with 30% of the time), nor is it equal to the average (90.85, in this case).

If the saturation values are displayed, sort them in order and record the middle saturation value as the median.

c) 4-12 hours of continuous monitoring of pulse oximetry on a pulse oximeter other than an Ohmeda, with a computer printout of summary data giving the percent time at various levels of saturation. Some oximeters can do such a printout, others have such data in memory that can be recalled (but not printed) and there are also commercial programs that produce such analyses based on a "dump" of continuous data. Obtain the median as per b). If the oximeter in question is a Nellcor, subtract 1 from the median; Nellcor consistently reads 1-2% above Ohmeda.

d) 2-4 hours of continuous monitoring analyzed as per b) with an Ohmeda.

e) 2-4 hours of continuous monitoring analyzed as per c) with a pulse oximeter other than an Ohmeda.
f) 4 hours of sitting at the bedside watching a continuous monitoring of saturation using the Ohmeda pulse oximeter. Write down the subjective "most frequent" oximetry every 5 minutes for the preceding 5 minutes. You will have 48 values. Sort them in order. Record the middle saturation value as the median.

g) 4 hours of sitting at the bedside watching a continuous monitoring of saturation using a pulse oximeter other than an Ohmeda. Write down the subjective "most frequent" oximetry every 5 minutes for the preceding 5 minutes. You will have 48 values. Sort them in order. Record the middle saturation value as the median. If using Nellcor, subtract 1% from the median.

h) If nursing staff have been determining and charting pulse oximetry in this infant on room air, take all values for the preceding 24 hours saturation. These must include at least 5 values in the 24-hour period. Sort them in order. Record the middle saturation value as the median. If using Nellcor, subtract 1% from the median.

13. Oxygen code - Enter the appropriate code based on the mode of oxygen administration listed at the bottom of the form.

14. Exclusion criteria - Enter the appropriate code for exclusion from STOP-ROP based on the exclusion criteria listed at the bottom of the form. If there are several exclusion reasons, use the reason which falls highest in the following hierarchy: ophthalmic reasons overrule other medical reasons, which overrule procedural reasons.

- Ophthalmic
  - congenital eye anomaly
  - Threshold OU
  - second exam does not confirm Prethreshold

- Other medical
  - fatal congenital anomaly
  - cannot attain ranges

- Procedural
  - parent/physician refuses
  - conflicting study
  - transferred
  - cannot follow

Following are some definitions for some exclusion criteria:
• Category 11: parent refusal

• Category 12: physician refusal

• Category 31: infant cannot be randomized to conventional range (89-94%): median pulse oximetry exceeds 94% in room air.

• Category 32: physician determines infant is too ill to maintain pulse oximetry in supplemental range (96-99%).

• Category 6: congenital eye anomaly. Refers to any ocular disease or condition, the presence of which may now or in the future complicate evaluation of ROP. Example: CMV Retinitis.

• Category 7: second examination does not confirm Prethreshold ROP. Although a screening examination indicated Prethreshold ROP in at least one eye, a subsequent examination of that eye failed to confirm this diagnosis.

• Category 8: Threshold OU. The infant was found to have Threshold OU on a first or subsequent screening examination. Do not use this category to record infants who have had a diagnosis of Threshold ROP OU at another institution and are transferred in to receive cryo or laser surgery; omit these infants from the log.

15. Treatment assignment - If enrolled in STOP-ROP, after verifying eligibility using the Baseline, Eligibility and Randomization form (STOP 01), enter the treatment assignment as C for conventional or S for supplemental.

Reminder: consent for randomization must be obtained from the parents prior to treatment assignment.

If enrolled in HOPE-ROP, enter H. In so doing, you are certifying that the infant is eligible for HOPE-ROP. That is:

a) infant has Prethreshold in at least one eye on two successive screening examinations, at least one by a certified examiner;

b) most recent certified screening examination documenting Prethreshold is within 48 hours of enrollment in HOPE-ROP;

c) infant has oxygen saturation greater than 94% in room air;

d) parental consent has been obtained (if required by institution).
Complete this form to confirm eligibility for infants with Prethreshold ROP. Answer questions 1-13. If randomizing by telephone, call the Coordinating Center at 301/299-8655 and complete questions 14-20 while on the telephone. If randomizing by sealed envelope alone, complete questions 14-20, and fax questions 1-20 to the Coordinating Center. For both methods of randomization, complete question 21 and mail original form to the Coordinating Center.

1. Date of Birth M D Y
2. Infant’s Gender
   (M-male
   F-female
   A-ambiguous) __________
3. Birth weight grams
4. Gestational age at birth ___ and ___/7 days weeks
5. Race or ethnic background of mother
   (W-White, not of Hispanic origin
   B-Black, not of Hispanic origin
   H-Hispanic
   A-Asian
   P-Pacific Islander
   N-Native American
   O-Other, specify ________________)
6. First Study Examination
   a) Date M D Y
   b) Time of first exam (24 hour clock) Hours Minutes
   c) Study Eye Status
      (1-Before Prethreshold
      2-Prethreshold
      3-Threshold or beyond
      4-Fully vascularized or Zone 3
      9-Other, specify _____________)
   Name of Ophthalmologist
   d) Cert. #

7. Confirmatory Study Examination
   a) Date M D Y
   b) Time of second exam (24 hour clock) Hours Minutes
      Right Eye Left Eye
   c) Study Eye Status
      (1-Before Prethreshold
      2-Prethreshold
      3-Threshold or beyond
      4-Fully vascularized or Zone 3
      9-Other, specify ________________)
      Name of Ophthalmologist
      d) Cert. #

8. Growth Assessment
   a) Current weight grams
   b) Length cms
   c) Head circumference cms

9. Apnea Assessment
   a) Is the infant on an apnea monitor? (N-No, Y-Yes) __
   b) Is the infant on any methylxanthines? (N-No, Y-Yes) __
   c) Number of apnea/bradycardia episodes requiring stimulation in past 24 hours __
10. Respiratory Support

a) Is the infant currently on oxygen? 
   (1-No, skip to c)
   2-Yes, but intermittently
   3-Yes, on nasal cannula
   4-Yes, on hood
   5-Yes, on nasal CPAP [prongs]
   6-Yes, on ETT (vent or CPAP)
   9-Yes, other, specify ____________________________

b) Pulse oximeter saturation on O₂ 
   _______________________ 

c) Pulse oximetry in room air recorded today 
   _______________________ 

   If infant is on oxygen with sats ≥90%,
   discontinue for 20 minutes before recording
   saturation. If saturation drops below 85%,
   return to ordered oxygen immediately, and
   record 84%.

   Record 999 if the infant is medically unstable
   to place in room air.

11. Is the infant on diuretics? 
   (1-No
    2-Intermittently
    3-Daily) ______________________

12. Within the past week, has the infant received steroids that were other than topical? 
   (1-No
    2-Systemic for BPD
    3-Systemic, not for BPD
    4-Inhaled
    5-Unknown, enrolled in masked steroid clinical trial) ______________________

13. All of the following must be verified prior to randomization. Code: (N-No, Y-Yes)

   To be eligible, question 13.a-d must be answered Yes and either e or f must be answered Yes.

   a) Consent form for randomization

   b) Does the neonatologist caring for the infant agree that both study saturation ranges (89-94% and 96-99%) can be attained without medical complications?

   c) A pulse oximeter and laptop are available within 24 hours for full time study use

   d) Infant was verified to have Prethreshold ROP by two examiners at least one of whom was certified

   e) Infant was first diagnosed with Prethreshold ROP within the past 24 hours [If Yes, skip to 14]

   f) Late Entry. The last certified ophthalmic examination which confirmed Prethreshold ROP was performed within the past 48 hours but the first exam diagnosing Prethreshold ROP occurred more than 24 hours ago

14. Is infant eligible to be randomized? 
   (N-No, Y-Yes) __________

15. Method of randomization 
   (1-Telephone call,
    2-No telephone call) __________
STOP-ROP
BASELINE, ELIGIBILITY AND RANDOMIZATION [01]

STOP-ROP ID: _______ _______ _______ _______
Center # Hosp. Code Patient #

NOTE: Certified ophthalmologist must complete Retinal Examination Form (STOP 02) and provide the following for last certified examination:

### ROP SEVERITY

<table>
<thead>
<tr>
<th></th>
<th>No stage</th>
<th>Stage 1</th>
<th>Stage 2</th>
<th>Stage 3</th>
<th>Stage 4/5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plus disease</td>
<td>N/A</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Zone 1</td>
<td>&lt;P</td>
<td>P</td>
<td>T</td>
<td>P</td>
<td>T</td>
</tr>
<tr>
<td>Zone 2</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>P</td>
</tr>
<tr>
<td>Zone 3</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
<td>&lt;P</td>
</tr>
</tbody>
</table>

**Key:**
- +: plus disease (at least 2 quadrants)
- 3+: 5 contiguous and <8 composite clock hours of stage 3 with plus disease
- 3++: ≥5 contiguous hours or ≥8 composite clock hours of stage 3 with plus disease
- <P: less than Prethreshold
- P: Prethreshold
- T: Threshold
- >T: Beyond Threshold

### STRATUM DEFINITIONS

**STRATUM A**

- **One Eye**
  - Prethreshold ROP any zone
  - AND
  - Worse than Prethreshold any zone
- **OR**
  - Prethreshold ROP zone 1
  - AND
  - Prethreshold ROP any zone

**STRATUM B**

- **One Eye**
  - Prethreshold ROP zone 2
  - AND
  - Less than Prethreshold ROP zone 2
- **OR**
  - Prethreshold ROP any zone
  - AND
  - Prethreshold ROP any zone

16. **PRETHRESHOLD SEVERITY STRATUM** .................................................. (Code A or B)

17. **TREATMENT ASSIGNMENT**
    (C-Conventional, S-Supplemental)

18. **ASSIGNED STOP-ROP ID NUMBER** ..........................................................

19. Randomization Completed

   Date ...................................................... M D Y
   Time (24 hour clock) ................................ Hours Minutes

Signature of Study Center Coordinator ...

ON COMPLETION OF ITEMS 1-21, MAIL TO: DATA MANAGER, STOP-ROP COORDINATING CENTER, 11325 SEVEN LOCKS ROAD, SUITE 214, POTOMAC, MD 20854. IF RANDOMIZING BY SEALED ENVELOPE ALONE, ALSO FAX FORM TO COORDINATING CENTER AT 301/299-3991 ON COMPLETION OF ITEMS 1-20.

STOP 01 V03, 01/01/96
21. COMPLETE THIS FORM USING DATA OBTAINED AT TIMES SHOWN

<table>
<thead>
<tr>
<th>Randomization date:</th>
<th>READING 1</th>
<th>READING 2</th>
<th>READING 3</th>
<th>READING 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomization time:</td>
<td>4 hrs prior to randomization</td>
<td>8 hrs post randomization</td>
<td>16 hrs post randomization</td>
<td>24 hrs post randomization</td>
</tr>
</tbody>
</table>

a) Month/Day/Year

b) Hour: Minutes (24 hour clock)

c) Is infant Receiving Oxygen by hood? N = No, Skip to e, Y = Yes

d) Oxygen Concentration (%)

e) Is infant Receiving Oxygen by Cannula? N = No, Skip to f, Y = Yes

f) Cannula Oxygen Concentration (%)

g) Cannula Oxygen Flow L/min

h) Is the infant on vent? N = No, if No skip to i, Y = Yes

i) Vent PIP/PEEP, cm H₂O

j) Vent Rate/min

k) Oxygen Concentration (%)

l) Is the infant on CPAP? (N = No, skip m and n, Y = Yes)

m) Oxygen Concentration (%)

n) CPAP, cm H₂O

* Submit original to Coordinating Center by mail.
* RETAIN COPY FOR YOUR FILES.

REMEMBER: Enter STOP-ROP ID Number, Name Code and Date of Randomization in the RANDOMIZATION LOG.
INSTRUCTIONS FOR STOP 01 FORM

BASELINE, ELIGIBILITY AND RANDOMIZATION

This form is used to screen for an infant's eligibility to be randomized. If all criteria in question #13, a through d, are answered "YES", and either e or f is answered "YES", the infant can be randomized. Following randomization, the Study Center Coordinator is required to complete the remainder of the form. Questions 1-16 must be answered, and a completed Retinal Examination form (STOP 02) must be available before randomizing.

GUIDELINES

Instructions for adding new data or modifying old data are found in Section 1 of this Handbook. The instructions are universal for all data forms, except where noted below. The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 6 of the Manual of Procedures or call the Coordinating Center.

3. Birth weight must be in grams, not pounds/ounces.

4. Gestational age at birth - Use early dating ultrasound (at or before 15 weeks), unless unavailable or when there are other widely discrepant (greater than 3 weeks) estimates. In this case, the admitting neonatologist should decide. If the admitting neonatologist is unavailable, the STOP-ROP neonatologist should decide. Gestational measurement may be recorded in fractions (e.g., 32 4/7) if this detail is available. If fractions are not available, enter X for the days. A range may not be recorded.

5. Race of mother - If race of mother is mixed, code according to what she considers her predominant race.

6. First study exam - The Study Center Coordinator will record the date, time and eye status.

6.c Code each eye:
   • 1-when the eye is at risk of Prethreshold; zone 1 or 2 immature vessels, or zone 2 ROP at stage 1 or at stage 2 without plus disease.
   • 2-when an eye is Prethreshold as defined by STOP-ROP, modified from the CRYO-ROP study
   • 3-when an eye is at Threshold or beyond (includes retinal detachment, retinal fold, obscuring hemorrhage or status post cryo or laser treatment)
   • 4-when an eye is fully vascularized (no active ROP and with vessels reaching within one disc diameter of the ora serrata both nasally and temporally), or in zone 3 (vessels within one
disc diameter of the ora serrata on the nasal meridians with no nasal ROP of fully regressed ROP).

In addition, the name of the ophthalmologist and certification number (if applicable) will be entered.

7.

Confirmatory study exam - The Study Center Coordinator will record the date and time, and the name and certification number, if applicable, of the ophthalmologist.

7.c Code each eye:
• 1-when the eye is at risk of Prethreshold; zone 1 or 2 immature vessels, or zone 2 ROP at stage 1 or at stage 2 without plus disease.
• 2-when an eye is Prethreshold as defined by STOP-ROP, modified from the CRYO-ROP study
• 3-when an eye is at Threshold or beyond (includes retinal detachment, retinal fold, obscuring hemorrhage or status post cryo or laser treatment)
• 4-when an eye is fully vascularized (no active ROP and with vessels reaching within one disc diameter of the ora serrata both nasally and temporally), or in zone 3 (vessels within one disc diameter of the ora serrata on the nasal meridians with no nasal ROP of fully regressed ROP).

If more than 48 hours have elapsed between the time of expected randomization and the last exam by a certified ophthalmologist, a repeat eye examination by a certified ophthalmologist must document continued eligibility prior to randomization. The results of this confirmatory examination should be recorded in this space. The certified ophthalmologist will complete a Retinal Examination form (STOP 02). The name and certification number of the certified ophthalmologist are required. Responses to questions 8 through 11 should reflect the infant’s status on the day of randomization or during the 48 hours prior to randomization.

8.

Growth assessment -
8.a Weight - Record the infant’s weight in grams. If the infant is wearing a cast and is getting weighed daily, the estimated dry weight of the casts can be calculated and subtracted from each applicable day’s weight.

8.b Length - Record the infant’s length in centimeters, with one decimal place (e.g., 43.5). If the infant’s length can not be measured (legs in bent cast, etc.), this data item will be missing for this examination, and should be recorded as N/A. Attach a note to the data form explaining why the data item is not available.
8.c Head circumference - To obtain, wrap the measuring tape around the head just above the brow and past the back of the head just above the base of the neck, at the maximal prominence of the occiput. Adjust the tape and remeasure two more times. Record the largest of the 3 measurements in centimeters with one decimal place (e.g., 32.5). If the infant has been diagnosed as having hydrocephalus and is receiving treatment for it (diamox, shunt or ventricular drainage), head circumference will not be analyzed and should be coded as N/A. Attach a note to the data form explaining why the data item is not available. If there is no ongoing treatment for diagnosed hydrocephalus, it is considered "arrested hydrocephalus" and the head circumference should be measured and recorded.

9. Apnea assessment -
9.b Methylxanthines include drugs such as aminophylline, caffeine (Cafegrot) and theophylline.

9.c Record the total number of apnea and/or bradycardia episodes which required stimulation or intervention in the past 24 hours. Example: if there were 2 apneic episodes requiring gentle stimulation, 1 combined apnea/bradycardic episode requiring bag and mask ventilation, and 3 bradycardia episodes but only one requiring stimulation, this would be recorded as 2+1+1=4.

10. Respiratory support -
10.a If infant is on oxygen intermittently, (e.g., with feeds), record 2; if on continuous oxygen, indicate the method of receiving oxygen as 3, 4, 5, 6 or 9. Code hooded isoelette as 4-hood. Code masked CPAP as 5-nasal CPAP. If the infant is receiving mixed respiratory support, code the highest level of support, e.g., infant is on hood alternating with periods of nasal CPAP, code 5-nasal CPAP. For study purposes, the hierarchy is ETT > nasal CPAP > nasal cannula > hood. If infant has a tracheostomy, select 9 and specify trach, CPAP or vent on form.

10.b Pulse oximeter saturation recorded while on oxygen. Indicate the median value recorded within the past 24 hours. *Do not record recent changes in pulse oximeter saturation in this space (e.g., during eye exams or other procedures).*

10.c If the infant is not receiving oxygen, there are several ways to determine the median pulse oximeter reading in room air. The Study Center Coordinator will obtain this reading as per 10.b above:

*Note: Please refer to your Study Center policy regarding parental consent to place infant on pulse oximeter*
a) 4 hours of continuous monitoring of pulse oximetry by a study oximeter and laptop computer. This will permit an objective percent of time to be determined. The laptop program has a practice/monitoring option in which the oximetry data are collected normally, but not saved to disk. This option allows monitoring of oximetry status prior to randomization. The laptop data collection program displays in the middle of the data collection screen a graph titled: "% time:4 hours". This graph uses horizontal bars to show the percents of time spent, over the past four hours, at various saturation values. The height of each bar (on the vertical axis) gives the saturation value, while the length of the bar (measured on the horizontal axis) gives the percent time spent at that saturation value. The bar corresponding to the median is identified by a dotted line drawn through it. Enter the saturation (vertical axis) value for this bar.

b) 4-8 hours of continuous monitoring of pulse oximetry on an Ohmeda oximeter with a computer printout of trends. Ohmeda 3700 and 3740 can produce such a printout. There are also commercial programs that produce such analyses based on a "dump" of continuous data. To obtain the median:

If the median is displayed, record it.

If percents of time spent at various saturation levels are displayed, calculate a median as follows: Starting from the lowest saturation value and moving upward, add together the percents time. When this sum exceeds 50, stop. The saturation value for the last percent you have added is the median. Record this value. For example, suppose the percents time at various saturation values are:

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<td>15</td>
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</table>

The percents for 88, 89, and 90 are 5 + 10 + 30 = 45. Adding the percent for 91 brings the sum up to 65, so the median is 91. Notice that the median is not necessarily the most frequent value (90, in this case, with 30% of the time), nor is it equal to the average (90.85, in this case).

If the saturation values are displayed, sort them in order and record the middle saturation value as the median.

c) 4-12 hours of continuous monitoring of pulse oximetry on a pulse oximeter other than an Ohmeda, with a computer printout of summary data giving the percent time at various levels of saturation. Some oximeters can do such a printout, others have such data in memory that can be recalled (but not printed) and there are also
commercial programs that produce such analyses based on a "dump" of continuous data. Obtain the median as per b). If the oximeter in question is a Nellcor, subtract 1 from the median; Nellcor consistently reads 1-2% above Ohmeda.

d) 2-4 hours of continuous monitoring analyzed as per b) with an Ohmeda.

e) 2-4 hours of continuous monitoring analyzed as per c) with a pulse oximeter other than an Ohmeda.

f) 4 hours of sitting at the bedside watching a continuous monitoring of saturation using the Ohmeda pulse oximeter. Write down the subjective "most frequent" oximetry every 5 minutes for the preceding 5 minutes. You will have 48 values. Sort them in order. Record the middle saturation value as the median.

g) 4 hours of sitting at the bedside watching a continuous monitoring of saturation using a pulse oximeter other than an Ohmeda. Write down the subjective "most frequent" oximetry every 5 minutes for the preceding 5 minutes. You will have 48 values. Sort them in order. Record the middle saturation value as the median. If using Nellcor, subtract 1% from the median.

h) If nursing staff have been determining and charting pulse oximetry in this infant on room air, take all values for the preceding 24 hours saturation. These must include at least 5 values in the 24-hour period. Sort them in order. Record the middle saturation value as the median. If using Nellcor, subtract 1% from the median.

If the infant is receiving oxygen by CPAP, vent, hood, or cannula, the oxygen should be decreased by 10% decrements to room air to ensure a gradual transition. The pulse oximeter will be watched continuously and the test in room air will be continued for 20 minutes, provided that the saturation does not fall below 85%. If the saturation falls below 85%, the infant is immediately returned to the prior oxygen setting and the results of the test are recorded as 84%. If the saturation does not fall below 85% in the 20 minutes, the lowest saturation obtained in that time period will be entered in the space provided.

11. Diuretics - Include drugs such as Lasix (furosemide), Diuril (chlorothiazide), Aldactone (spironolactone), and Edecrine (ethacrynic acid).

12. Review the medication sheets for the previous week. Systemic steroids are given for BPD if they are given for chronic lung disease; code 2 in this case. Laryngeal edema is not lung disease. If steroids are given for a few days around the time of extubation, the neonatologist must determine if the primary purpose is for the lungs (code 2), or for laryngeal edema (code 3).
If an infant has been on more than one category of steroid administration during the past week, record only the highest category; systemic for BPD > systemic non-BPD > inhaled > unknown.

Note: steroids administered by intraocular injection or nasal drops (e.g. Beclomethasone or Dexamethasone) are not considered systemic steroids; rather, they are to be considered topical.

13. Randomization eligibility - In order for the infant to be randomized, questions # 13a through d must be answered Y=YES, and either e or f must be answered Y=YES.

13.b In answering question 13b, use the following approximation: if the answer to question 10c, "pulse oximetry recorded in room air today", exceeds 94, then assume that the answer to question 13b is No; the infant cannot attain the lower range and is therefore ineligible. The neonatologist need not be consulted in this case. On the other hand, if the answer to question 10c is not greater than 94, the neonatologist must be consulted to obtain an answer to question 13b.

Signature of Neonatologist certifies that, given the proper amounts of oxygen, the infant can attain the lower range at least half of the time, and separately, attain the upper range at least half the time.

13.f If more than 24 hours pass from the first diagnosis of Prethreshold ROP to randomization, the infant may still be randomized, but will be designated a "Late Entrant." If more than 48 hours have elapsed from the last certified ophthalmic examination which confirmed Prethreshold ROP, a repeat ophthalmic examination is required to document current continued eligibility prior to randomization.

15. Method of Randomization - Randomization usually is performed by placing a telephone call to the Coordinating Center to confirm eligibility, and receiving instructions for selecting the next lowest sequentially numbered envelope in a designated stratum. On rare occasions, it may be necessary to randomize an infant without a phone call to the Coordinating Center - see Section 3 of this handbook for instructions on how to randomize an infant using envelopes when the Coordinating Center is unavailable. Record the method of randomization.

16. Prethreshold severity stratum - Code A or B based on the stratum definitions provided. The ROP severity table should be used to confirm the diagnosis of Prethreshold disease in at least one eye.

19. Date of randomization - Enter the randomization date and time using military time (e.g., 4:20 pm is 16:20) on the form. Randomization time is when the envelope is opened, not the time the infant is placed on the study oximetry monitoring equipment. The time between opening of the envelope
and placement of the infant on the assigned oxygen treatment should be minimal.

20. When randomizing by sealed envelope alone, once questions 1 through 20 are complete, the Study Center Coordinator should sign, enter certification number and fax this form to the Coordinating Center. Retain original for later submission.

21. The initial reading should be completed 4 hours prior to randomization, and subsequent readings within 24 hours after randomization. Readings # 2, 3 and 4 will be obtained at 8-hour spans and at 3 different times (e.g., if participant is randomized at 9 am, obtain reading #2 at 5 pm, reading #3 at 1 am, reading #4 at 9 am). The window for readings will be 4 hours -- readings should be obtained as close to the target time as possible.

Reading #1 - Record the most frequent value, e.g., oxygen concentration, L/min cannula flow, vent rate/min in the 4 hours prior to randomization. Do not record recent changes in this column which are related to a procedure or other atypical status.

21.f When an infant is receiving oxygen by cannula, record the % oxygen the cannula is attached to, not the measurement of oxygen at the infant's nostril area.

Mail the original form with all questions completed to the Coordinating Center. Retain a copy in the infant's STOP-ROP file.

INFANTS RANDOMIZED AFTER INITIAL DISCHARGE

When an infant has been randomized after initial discharge:

1) Submit an Initial Discharge Form (STOP 10) when you submit the Baseline Form (STOP 01). The date of discharge specified in question 1 on the STOP 10 should precede the date of randomization specified in question 19 on the STOP 01. The answer to question 1a on the STOP 10 should be 1-initial discharge to home. Cost tracking questions 4-10 on the STOP 10 should be all zero. Question 12 should be answered No. Other questions on the STOP 10 should be answered using information from the infant's medical record.

2) Subsequent hospitalizations should be documented with Rehospitalization Forms (STOP 11).
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Certified ophthalmologist: complete entire form at Baseline and when each eye first reaches an endpoint.

1. Visit number ........................................ (Code 00-Baseline, 01-Week 1, 02-Week 2, 88-Treatment Completion)

2. Date of Examination ........................................ M D Y

3. EYE EXAMINATION SKETCH (to be completed by certified ophthalmologist)

Provide Findings by Clock Hours
[Mark highest stage in each sector]

(CODE: 0-No information 1-Demarcation line 2-Ridge 3-Extraret prolif 4-Retinal detach 5-Avascular 6-Incompl. vessels 7-Fully vascularized 8-Regressing 9-Regressed)

STOP 02 V02, 01/01/96
STOP-ROP
RETINAL EXAMINATION FORM [02]

4. Stage 3 disease .................................. (Code: 0-None, 1-Mild, 2-Moderate, 3-Severe) _______ _______

5. Hemorrhages (vitreous/retinal) ........ (Code: 0-None, 1-Small, retina, 2-Large, retina, 3-Vitreous) _______ _______

6. Is active ROP present in Zone 1 or Zone 2? ........ (Code N-No Skip to 8, Y-Yes) _______ _______

7. STOP-ROP ophthalmic summary of active ROP
   a) Lowest zone with ROP .................................. _______ _______
   b) Worst stage in lowest zone with ROP .............. _______ _______
   c) Total clock hours of worst stage in lowest zone with ROP .... _______ _______
   d) Longest number contiguous hours of worst stage in lowest zone with ROP .... _______ _______
   e) Plus disease (at least two quadrants) ................. (N-No, Y-Yes) _______ _______

8. Study Eye Status (use codes 01-99 below) .................. _______ _______

   ** Adverse Eye Endpoint **
   01) * Threshold ROP *
   02) * Beyond Threshold ROP *
      (retinal fold, detachment, or obscuring hemorrhage)

   ** Favorable Eye Endpoint **
   03) * Fully Vascularized within 1 disc diameter of ora
       (may be quiescent old disease present) - No active ROP *
   04) ** In zone 3 for the 2nd time in a row or more: immature vessels
       or less than Prethreshold ROP with/without regression **

Eye not yet at endpoint - continue to examine weekly
05) Zone 3 for the 1st time: immature vessels or less than Prethreshold ROP with/without regression
06) Zone 1 or 2: immature vessels or less than Prethreshold ROP with/without regression
07) Prethreshold present with or without some regressing ROP
08) Status post cryo or laser (no detachment)
99) Other (comment)

* If present for FIRST TIME, submit Retinal Examination form
** If in zone 3 for the SECOND TIME, submit Retinal Examination form

THRESHOLD VERIFICATION
Complate the first time answer to question 8 = 01 or 02 for an eye
Verification of Threshold disease or retinal fold or detachment was performed by: ______________________________

Certification Number 9. _______ _______

Name of Certified Ophthalmologist

Signature of Examining Certified Ophthalmologist

Signature of Study Center Coordinator

Certification Number 10. _______ _______

Certification Number 11. _______ _______

STOP 02 V02, 01/01/96
INSTRUCTIONS FOR STOP 02 FORM

RETINAL EXAMINATION

This form is completed at the following times during the STOP-ROP study:

- **Prerandomization**: Infant reaches Prethreshold status on 2 examinations, one of which was performed by a certified examiner.

  *Note: Informed Consent must be obtained prior to completion of this form at the Baseline examination.*

- **Postrandomization**: Endpoint for each eye after randomization (defined as the first time each eye reaches Threshold, retinal fold or detachment, or is fully vascularized, or second time regressing in zone 3)

The Study Center Coordinator and certified ophthalmologist are responsible for the completion and accuracy of information on this form. The Study Center Coordinator will complete the top portion of the form and submit it to the examining ophthalmologist. Following completion of the Retinal Examination form (STOP 02), the original should be submitted to the Coordinating Center and 2 copies maintained (1 for the infant's medical record if locally applicable, 1 for the infant's STOP-ROP study file).

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form and to assist you in understanding the interpretation of the findings and how to record them on these forms using study conventions. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 8 of the Manual of Procedures or call the Coordinating Center or Study Headquarters. If a generic issue is identified, explanations will be provided for all centers.

3. **Eye examination sketch** - Provide a diagrammatic sketch of the ROP in each eye. These are not meant to be a "photograph", but are to be used to record the findings on paper and facilitate the coding by clock hour of the observed disease. Use the study conventions of coding the stages of active ROP according to the examples provided (see Figure 1).

   **Plus disease** - This question refers to the presence or absence of dilatation and tortuosity of the posterior pole vessels seen around the disc prior to initiating scleral depression. This subjective determination is made more objective by comparing the
INSTRUCTIONS FOR STOP 02 FORM

RETINAL EXAMINATION

This form is completed at the following times during the STOP-ROP study:

- **Prerandomization:** Infant reaches Prethreshold status on 2 examinations, one of which was performed by a certified examiner.

  *Note: Informed Consent must be obtained prior to completion of this form at the Baseline examination.*

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The Study Center Coordinator and certified ophthalmologist are responsible for the completion and accuracy of information on this form. The Study Center Coordinator will complete the top portion of the form and submit it to the examining ophthalmologist. Following completion of the Retinal Examination form (STOP 02), the original should be submitted to the Coordinating Center and 2 copies maintained (1 for the infant's medical record if locally applicable, 1 for the infant's STOP-ROP study file).

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form and to assist you in understanding the interpretation of the findings and how to record them on these forms using study conventions. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 8 of the Manual of Procedures or call the Coordinating Center or Study Headquarters. If a generic issue is identified, explanations will be provided for all centers.

3. **Eye examination sketch** - Provide a diagrammatic sketch of the ROP in each eye. These are not meant to be a "photograph", but are to be used to record the findings on paper and facilitate the coding by clock hour of the observed disease. Use the study conventions of coding the stages of active ROP according to the examples provided (see Figure 1).

   *Plus disease* - This questions refers to the presence or absence of dilatation and tortuosity of the posterior pole vessels seen around the disc prior to initiating scleral depression. This subjective determination is made more objective by comparing the
findings to standard photographs provided. Although when present, it usually involves all four arteriovenous pairs of vessels, it is possible that fewer than four pairs of vessels will be involved and therefore the presence of plus disease in each quadrant will be recorded by circling $\bigcirc$ in each Zone 1 quadrant where it is present and circling $\bigtriangleup$ in each quadrant where it is not present.

An eye is considered to have plus disease if at least two of the four quadrants of the posterior pole vessels seen around the disc have dilatation and tortuosity that meets or exceeds the degree shown in the standard photographs.

**Zone** - Extremely immature eyes with vessels terminating in zone 1 are easily recognized. Zone 1 has a radius of twice the distance from the disc to the center of the macula (fovea) and is centered on the disc. The examiner will next visualize the ora serrata on the nasal side of the retina, that is, at 3:00 and 4:00 in the right eye, and 9:00 and 10:00 in the left eye. Ophthalmic findings in these two clock hours determine how the eye is classified and sectors are drawn and coded, as follows:

If vessels terminate well within one disk diameter of the ora serrata in both nasal clock hours, and there is either no nasal ROP or only fully regressed nasal ROP in these two clock hours, then the summary eye status is coded in zone 3 (codes 04 or 05) or fully vascularized (code 03). In any sector, all findings (i.e., any ROP or immature vessels, no matter how posterior) are drawn and coded in zone 3. Mature vessels are drawn and coded in zone 3.

If, in either of the two nasal clock hours, there is either active nasal ROP no matter how close it is to the ora serrata, or, in either of the two nasal clock hours, the anterior border of immature vascularization does not reach well within one disk diameter of the ora, then the eye is classified as a zone 2 eye (unless it is so posterior that it is a zone 1 eye), and immature vascularization and ROP are drawn and coded in every sector as zone 2 (or zone 1). However, sectors without active ROP that are completely vascularized to the ora serrata are drawn and coded on the Retinal Examination form (STOP 02) as completely vascularized in zone 3.

These definitions indicate that there cannot be active ROP in zone 3 in the nasal horizontal meridians. The conventions are summarized in the table below.
<table>
<thead>
<tr>
<th>Ophthalmic findings</th>
<th>How to code the summary eye status</th>
<th>How to draw and code the sectors</th>
</tr>
</thead>
<tbody>
<tr>
<td>In both nasal clock hours, vessels reach within 1 DD of the ora, and ROP is either absent or fully regressed</td>
<td>Zone 3 or Fully Vascularized</td>
<td>ROP, immature vessels, and mature vessels are in zone 3.</td>
</tr>
<tr>
<td>In at least one of the two nasal clock hours, there is either active ROP, or vessels do not reach within 1 DD of the ora.</td>
<td>Zone 2 or Zone 1</td>
<td>ROP and immature vessels are in zone 2 or 1. Mature vessels (within 1 DD of ora) without ROP are in zone 3.</td>
</tr>
</tbody>
</table>

**Stage by clock hours** - Using the sketches to guide you, in every zone of each eye, complete the stage in individual clock hours according to the 0-9 key provided using the condition observed for each sector. If an entire zone contains a single stage, the corresponding number may be inserted in the space provided directly to the left or right of the zone diagram. Otherwise, when more than one stage or condition occur within a zone, the corresponding number must be placed in each sector of the zone diagram. If more than one stage or condition are present within a sector, record the most severe stage or condition. For example, if within a sector of a zone, there is evidence of regression but there is active ROP anterior to the regression, the stage of the active ROP should be recorded in the sector.

0  No information is used when you can not get information about the eye (eg, pupil would not dilate, view obscured)

1-3  Stage 1, 2 and 3 per ICROP definitions. If within a sector of a zone there is any active ROP, disregarding any regressed or regressing disease, code the most severe stage of active ROP present at the border of the vascularized and avascularized retina (the leading edge of vessel growth).

4  Retinal detachment may be of any degree, but must involve at least one 30 degree section (full clock hour) of the vascularized retina and extend at least one disc diameter posterior to the ridge.

5  Avascular means that the entire clock hour within that zone has no vessels (this will usually be zone 3)
Incomplete vessels is used when there is no ROP in the clock hour and there are vessels, but they have not crossed the entire zone. This is common in zone 2.

Fully vascularized means that the vessels have fully crossed the zone in that clock hour. If the nasal vessels are fully vascularized, any disease or even partially vascularized retina on the temporal side is recorded in zone 3 by study convention.

Regressing ROP is used (rather than "regressed" — see below) in a zone when there is evidence of ROP in the zone, with vessels extending anterior to it, but not attaining the zone boundary. In zone 3, the vessels are not within one disc diameter of the ora serrata.

The designation regressed ROP is used in any zone in which there is evidence of earlier ROP (cicatrix), but the vessels have now progressed to the next zone (for zones 1 or 2) or within one disc diameter of the ora serrata both nasally and temporally (for zone 3). Evidence of ROP (cicatrix) seen in zone 2 in an eye which now has vessels progressing into zone 3 is coded as regressed ROP in zone 2. There may be old cicatrix in the retina, but the active disease is gone. Fully regressed ROP in all 3 zones has complete vessels within one disc diameter of the ora serrata in both the nasal and temporal sides. If there is no evidence of old ROP in a fully vascularized eye, you may use code 7 or 9 if you are aware that ROP previously existed.

Examples of stage at clock hours:
A. All sectors were fully vascularized (7)
B. Sectors 11-6 contain a demarcation line while Sectors 7-10 are immature vessels without ROP. Numbers appear in each sector.
4. Stage 3 disease - Ophthalmologists should utilize their clinical experience and standard photographs located in Appendix 1 of the Manual of Procedures to describe as accurately as possible the severity of stage 3 in each eye. Record 0=none, 1=mild, 2=moderate, 3=severe.

5. Hemorrhages (vitreous/retina) - Small: one or more hemorrhages, with each having diameter less than 1 disc diameter at the narrower dimension and less than 2 disc diameters at the larger dimension. Large: any hemorrhage larger than these definitions is considered large. Vitreous hemorrhage is reserved for unequivocal bleeding in the vitreous. If several types of hemorrhage are present, code the most important: vitreous > large retinal > small retinal.

6. If the ROP is active and in zone 1 or 2, disregarding any regressed or regressing ROP, code Yes. If the ROP is not active or is in zone 3 (i.e. mature, cicatricial, regressed, regressing in all clock hours), code No and skip to Study Eye Status.

7. ICROP - For each eye: record the lowest zone of active ROP in any clock hour, worst active ROP stage in any clock hour, the number of clock hours of this worst stage, and the longest number of contiguous hours of the worst stage.

NOTE: when the total number of clock hours of worst stage is 01, for study convention purposes, the longest number of contiguous hours is also 01.

Record N or Y for plus disease. For STOP-ROP, the eye is considered to have plus disease if at least two of four quadrants have dilatation and tortuosity that meet or exceed the degree shown in the standard photographs.

8. Study Eye Status - Select the category which best describes the worst ophthalmic finding of each eye, and record that code. If other, specify findings on form in space provided.

Threshold ROP is defined by the following criteria:

a) zone 1 ROP, with plus disease, irrespective of stage of ROP as long as at least 1 clock hour of ROP is present
b) zone 1, no plus disease, stage 3 ROP
c) zone 2, with plus disease at the posterior pole and stage 3 for 5 or more contiguous clock hours or 8 or more composite clock hours.
Prethreshold ROP is defined by the following criteria:

a) zone 1, any stage ROP less than Threshold.
b) zone 2, stage 2 ROP with plus disease, or
c) zone 2, stage 3 ROP any amount without plus, or if plus disease is present, <5 contiguous clock hours and <8 composite clock hours.

Fully vascularized is defined by both the following criteria:

a) no active ROP, and
b) vessels reach within one disc diameter of the ora serrata nasally and temporally

NOTE: When an eye has been previously reported as fully vascularized, while its fellow eye is not yet at endpoint, further examinations of the fully vascularized eye are unnecessary for the study protocol (until the 3-month follow-up) and eye status may be left blank. However, examinations may be performed, and status recorded, if the ophthalmologist so desires.

9. Threshold disease, retinal fold, or detachment must be confirmed by a certified ophthalmologist when observed for the first time in an eye. The SCC will enter the name and certification number (if applicable) of the confirming ophthalmologist in the space provided.

10. Signature of the Certified Ophthalmologist and Certification Number - Indicates form is completed and verified for accuracy of information.

11. Signature of Study Center Coordinator and Certification Number - Indicates form is completed and verified for accuracy of information.
FIGURE 1
DRAWING SCHEME

Incomplete Vessels

STAGE 1 - Demarcation Line

STAGE 2 - Ridge

STAGE 3 - Ridge with EFP

STAGE 4 - Retinal Detachment

HEMORRHAGED
WEEKLY OUTCOME FORM

STOP-ROP ID: ____________________________

HOSPITAL ID NUMBER: _________________________

NAME CODE: ____________________________

1. Date of Examination ____________________________ M D Y

2. Status of infant at time of form completion
   1- Routine weekly examination prior to oxygen treatment completion
   2- Routine treatment completion: both eyes at endpoint, and at least 2 weeks post randomization
   3- Treatment prematurely terminated, but weekly follow-up continues
   4- Treatment prematurely terminated and weekly follow-up will not continue
   9- Other, please specify ____________________________

3. Follow-up visit number ____________________________ (Code: 01-week 1, 02-week 2, 99-not weekly exam)

RESPIRATORY SUPPORT

4. Is the infant on oxygen? ____________________________ (N-No, Y-Yes)
   
   If NO, enter the last date the infant received oxygen and skip to e
   ____________________________ M D Y

   a) Mode of delivery
      1- Yes, but intermittently, skip to d
      2- Yes, on nasal cannula
      3- Yes, on hood
      4- Yes, on nasal CPAP [prongs]
      5- Yes, on ETT [vent or CPAP]
      9- Yes, other, specify ____________________________

   b) Oxygen concentration ____________________________ %

   c) If on cannula, enter cannula flow ____________________________ L/min

   d) Pulse oximeter saturation on O2 ____________________________

   e) Pulse oximetry in room air recorded today ____________________________

   If infant is on oxygen with sats ≥90%, discontinue for 20 minutes before recording saturation. If saturation drops below 85% return to ordered oxygen immediately, and record 84%.

   Record 999 if the infant is too medically unstable to place in room air.

APNEA ASSESSMENT

5. a) Is the infant on an apnea monitor? ____________________________ (N-No, Y-Yes)

   b) Number of apnea and/or bradycardia episodes requiring stimulation recorded in past 24 hours ____________________________

   c) Is the infant on any methylxanthines? ____________________________ (N-No, Y-Yes)

PHARMACOLOGICAL SUPPORT

6. Is the infant on diuretics?
   1- No
   2- Intermittently
   3- Daily ____________________________

STOP 03 V03, 01/01/96
7. Within the past week, has the infant received any steroids other than topical? (1-No, 2-Yes, systemic for BPD, 3-Yes, systemic, not for BPD, 4-Yes, inhaled, 5-Unknown, infant enrolled in masked steroid clinical trial)

GROWTH ASSESSMENT

8. a) Current weight ............................................ grams
b) Length ............................................................. cms
  c) Head circumference ........................................... cms

Right eye Left eye

9. Study Eye Status (use codes 01-99 below) ...........................................

The ophthalmologist will use conventional eye examination form/chart notes to record the weekly eye findings for clinical purposes and determine the current eye status as below. The purpose is to determine if an eye has reached either the adverse or favorable endpoint, or needs to continue in follow-up. Confirm study eye status with the ophthalmologist and record below. If answer is 1, 2, 3, or 4, Retinal Examination form must be submitted.

Adverse Eye Endpoint

01) * Threshold ROP *
02) * Beyond Threshold ROP *
  (retinal fold, detachment, hole or obscuring hemorrhage)

Favorable Eye Endpoint

03) * Fully Vascularized within 1 disk diameter of ora (may be quiescent old disease present) - No active ROP *
04) ** In zone 3 for the 2nd time in a row or more; immature vessels or less than Prethreshold ROP with/without regression **

Eye not yet at endpoint - continue to examine weekly

05) Zone 3 for the 1st time: immature vessels or less than Prethreshold ROP with/without regression
06) Zone 1 or 2: immature vessels or less than Prethreshold ROP with/without regression
07) Prethreshold present with or without some regressing ROP
08) Status post cryo or laser (not detached)
09) Other (comment) ____________________________

* If present for FIRST TIME, submit STOP 02 form *
** If in zone 3 for the SECOND TIME, submit STOP 02 form **

10. Was ophthalmologist masked to treatment assignment at the time of the exam? (N-No, Y-Yes) __________

Name of Examining Certified Ophthalmologist ________________________

11. Certification Number ________________________

12. Has a new episode of any of the following occurred since completion of the last STOP-ROP weekly outcome form? (N-No, Y-Yes) __________

- Excessive Apnea and Bradycardia (number of episodes in a 24 hour period is triple the baseline and > 3)
- Documented hypoxemia (paO₂ > 120 torr) while in the target range
- Documented hypoxemia (paO₂ < 45 torr) while in the target range
- Seizures (new onset)
- Necrotizing Enterocolitis
- Pneumonia/Sepsis with positive culture or requiring antibiotic treatment for more than five days
- Other serious events or events thought to be treatment-related

Reminder: If YES, complete an Adverse Experience (STOP 08) for each item.

Signature of Study Center Coordinator ________________________________ Date __________

Certification Number ________________________
INSTRUCTIONS FOR STOP 03 FORM

WEEKLY OUTCOME

This form is completed at the following times during the STOP-ROP study:

- **Weekly, while on treatment or following, to document infant’s progress**
- **Completion of oxygen treatment assignment** (assigned oxygen treatment and study equipment at least for two weeks and until both eyes reach endpoints).
- **Parents refuse further follow up** (reminder: also complete the Protocol Anomaly form (STOP 06))

If a scheduled eye examination is cancelled and cannot be later performed within the visit time window, a Protocol Anomaly form (STOP 06) must be completed.

The Study Center Coordinator should attend the ophthalmic examination and obtain the study eye status from the certified ophthalmologist for recording on the Weekly Outcome form.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 9 of the Manual of Procedures or call the Coordinating Center.

1. For routine treatment completion (both eyes at endpoint and at least 2 weeks of assigned oxygen), the date of examination must be the date the infant is removed from assigned oxygen and study equipment.

2. Indicate the status of the newborn at the time of this exam, using the codes provided. Use codes (1) and (2) for routine exams. (1) indicates that other weekly exams will follow, while (2) indicates that no other weekly exams will follow.

Use codes (3) and (4) for non-routine situations, that is, situations in which treatment and/or follow-up are refused, or oxygen treatment is otherwise prematurely terminated. (3) indicates that other weekly exams will follow, for example, both eyes are not at endpoint and:
• parents refuse further treatment but allow follow-up (Protocol Anomaly, form STOP 06, question 2a=Y).

• follow-up is possible but oxygen treatment is prematurely terminated for other reasons (Protocol Anomaly, form STOP 06, question 2f=Y).

(4) indicates that no other weekly exams will follow, for example:

• Both eyes are now at endpoint but:
  - parents refused further treatment prior to both eyes reaching endpoints but allowed follow-up for at least the first two weeks (Protocol Anomaly, form STOP 06, question 2a=Y).

  - follow-up was possible but oxygen treatment was prematurely terminated and study equipment removed for other reasons (Protocol Anomaly, form STOP 06, question 2f=Y).

• Weekly follow-up is impossible because:
  - parents refuse (Protocol Anomaly question 2b=Y)
  - the infant will be permanently transferred to a non STOP-ROP facility (Protocol Anomaly question 2d=Y)

Note that, except for death and parental refusal of follow-up, the infant must be on assigned oxygen for at least 2 weeks before coding status 2 or 4.

3. The timing of follow-up visits begins from the day of randomization which is day 0. The window for a one week examination is ± 3 days [e.g., Week 1 examination can occur between Day 4 and Day 10; Week 2 examination can occur between Day 11 and Day 17]. If form is completed at times other than weekly exams, (e.g. parents refuse follow up, ophthalmologic endpoints attained in both eyes 2 days after a weekly exam) code 99.

4. Use of oxygen - If the infant is receiving oxygen, enter Y. If infant is not receiving oxygen, the last date that the infant received oxygen (even intermittently for procedures) will be recorded, unless it is an isolated event in the middle of a long period of days (>7) when no oxygen is needed.

4.a If infant is receiving oxygen intermittently, code 1; if continuously, select 2, 3, 4, or 5 to indicate mode of oxygen delivery. Code flooded isolette as 3- hood. Code masked CPAP as 4-nasal CPAP. If infant has a tracheostomy, select 9 and record trach, CPAP or vent. If the infant is receiving mixed respiratory support, code the highest level of support, e.g., infant is on
hood alternating with periods of nasal CPAP, code 4-nasal CPAP. For study purposes, the hierarchy is ETT > nasal CPAP > nasal cannula > hood.

4.b Oxygen concentration expressed as a %. When an infant is receiving oxygen by cannula, record the % oxygen the cannula is attached to, not the measurement of oxygen at the infant's nostril area.

4.c L/min cannula flow - If infant is receiving 1/4 liter, record 0.25.

4.d Pulse oximeter saturation on O₂ - Indicate the median value recorded in the past 4 hours. Do not record recent acute changes in pulse oximeter saturation in this space (e.g. during eye exams or other procedures).

The laptop data collection program displays in the middle of the data collection screen a graph titled "% time: 4 hours". This graph uses horizontal bars to show the percents of time spent, over the past four hours, at various saturation values. The height of each bar (on the vertical axis) gives the saturation value, while the length of the bar (measured on the horizontal axis) gives the percent time spent at that saturation value. The bar corresponding to the median is identified by a dotted line drawn through it. Enter the saturation (vertical axis) value for this bar.

4.e Pulse oximetry in room air recorded today (within the past 24 hours) - If the infant is not receiving oxygen, record the median value in the past 4 hours. To obtain the median, follow the general directions given in 4.d above.

If the infant is receiving oxygen by CPAP, vent, hood, or cannula, the oxygen should be turned down to room air. The pulse oximeter will be watched continuously and the test in room air will be continued for 20 minutes, provided that the saturation does not fall below 85%. If the saturation falls below 85%, the infant is immediately returned to the prior oxygen setting and the results of the test are recorded as 84%. If the saturation does not fall below 85% in the 20 minutes, the lowest saturation obtained in that time period will be entered in the space provided.

5. Apnea assessment -

5.b Number of apnea/bradycardia episodes - Record the total number of apnea and/or bradycardia episodes which required stimulation or intervention in the past 24 hours. Example: if there were 2 apneic episodes requiring gentle stimulation, 1 combined apnea/bradycardic episode requiring bag
and mask ventilation, and 3 bradycardia episodes, but only one requiring stimulation, this would be recorded as 2+1+1=4.

5.c Methylxanthines - Review the medical sheets for the past week in response to this question. Include drugs such as aminophylline, caffeine (Cafergot) and theophylline.

6. Diuretics - Drugs such as Lasix (furosemide), Diuril (chlorothiazide), Aldactone (spironolactone), and Edecrine (ethacrynic acid). Code 1-No, if the infant has not received a diuretic in the past week. Code 2-Intermittently, if the infant receives diuretics less often than once every other day, or if diuretics are ordered and have been given on a PRN basis in the past week (i.e. ordered PRN with blood transfusion). Code 3-Daily, if the infant receives diuretics once or more times per day, or every other day on a regular basis, or when the infant receives diuretics 5 days a week with two days off.

7. Review the medication sheets for the previous week. Systemic steroids are given for BPD if they are given for chronic lung disease; code 2 in this case. Laryngeal edema is not lung disease. If steroids are given for a few days around the time of extubation, the neonatologist must determine if the primary purpose is for the lungs (code 2), or for laryngeal edema (code 3).

If an infant has been on more than one category of steroid administration during the past week, record only the highest category; systemic for BPD > systemic non-BPD > inhaled > unknown.

Note: steroids administered by intraocular injection or nasal drops (e.g. Bectamethasone or Dexamethasone) are not considered systemic steroids; rather, they are to be considered topical.

8. Growth assessment - These measurements should be performed on the day of the follow-up visit or within 48 hours prior to follow-up visit.

8.a Weight - Record the infant's weight in grams. If the infant is wearing a cast and is getting daily weights, the estimated dry weight of the casts should be calculated and subtracted from each applicable day's weight.

A conversion chart is attached to these instructions, to use when a gram scale is unavailable.

8.b Length - Record the infant's current length in centimeters, with one decimal place (e.g. 43.5). If the infant's length can not be measured (legs in bent cast, etc.), this data item will be missing for this examination, and should
be recorded as N/A. Attach a note to the data form explaining why the
data item is missing.

8.c Head circumference - To obtain, wrap the measuring tape around the head
just above the brow and past the back of the head just above the base of
the neck, at the maximum prominence of the occiput. Adjust the tape and
remeasure two more times. Record the largest of the 3 measurements in
centimeters with one decimal place (e.g. 32.5). If the infant has been
diagnosed as having hydrocephalus and is receiving treatment for it
(diamox or shunt or ventricular drainage), head circumference will not be
analyzed and should be coded as N/A. Attach a note to the data form
explaining why the data item is missing. If there is no ongoing treatment
for diagnosed hydrocephalus, it is considered "arrested hydrocephalus" and
the head circumference should be measured and recorded.

9. Study Eye Status - If scheduled retinal exam not performed, code N/A. Complete
a Protocol Anomaly form, and attach explanatory note. In addition, skip questions
# 10 and # 11. Otherwise, select the category which best describes the worst
ophthalmic finding of each eye, and record that code. Choose the category that
describes the worst sector in that eye. If other, specify findings on form in space
provided.

Threshold ROP is defined by the following criteria:

a) zone 1, with plus disease, irrespective of stage of ROP as long as at least
1 clock hour of ROP is present
b) zone 1, no plus disease, stage 3 ROP
c) zone 2, with plus disease and stage 3 for 5 or more contiguous clock hours
or 8 or more composite clock hours.

Prethreshold ROP is defined by the following criteria:

a) zone 1, any stage ROP less than Threshold.
b) zone 2, stage 2 ROP with plus disease, or
c) zone 2, stage 3 ROP any amount without plus, or if plus disease is
present, <5 contiguous clock hours and <8 composite clock hours.
Fully vascularized is defined by the following criteria:

a) no active ROP, and
b) vessels reach within one disc diameter of the ora serrata nasally and temporally.

When an eye has been previously reported as fully vascularized, while its fellow eye is not yet at endpoint, further examinations of the fully vascularized eye are unnecessary for the study protocol (until the 3-month follow-up), and eye status may be left blank. However, examinations may be performed, and status recorded, if the ophthalmologist so desires.

11. Provide certification number and name of certified ophthalmologist who performed retinal examination.

12. Report only adverse experiences that occur before the date you complete the weekly outcome form. When an adverse experience occurs prior to the first weekly examination, report it on the first weekly examination form. Events that happen on the date you complete the weekly outcome form should be reported on the next weekly outcome form. This will help us better track missing Adverse Experience reports.

Do not report adverse experiences that are continuations of previously unresolved adverse experiences. The Coordinating Center will periodically query you for the resolutions of ongoing adverse experiences.

13. Certification number and signature of Study Center Coordinator indicates form is completed and checked for accuracy.
## Conversion of Pounds and Ounces to Grams

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THREE MONTH OPHTHALMIC OUTCOME
EXAMINATION FORM [04]
(To be completed by a Certified Ophthalmologist)

STOP-ROP ID:  __________  __________  __________  __________  ________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ___________________

NAME CODE:  __________  __________  __________  __________  __________

1. Date of Examination  _____________________________  __________  __________  __________

M  D  Y

2. Is this visit outside the three-month examination window? [10-14 weeks post due date]
   (N-No, Y-Yes)  __________

   If YES, code REASON:

   (1-Infant unable to maintain scheduled appointment due to illness or hospitalization,
   2-Parents unable to maintain scheduled appointment,
   3-Certified ophthalmologist not available,
   9-Other, specify ____________________________ )  __________

   RIGHT EYE  LEFT EYE

3. Vitreous opacity on or near visual axis

   a) Hemorrhage  __________  __________

   (0-Absent, 1-Slight, 2-Moderate, 3-Extensive, 9-View obscured)

   b) Membranes/orrganization  __________  __________

   (0-Absent, 1-Slight, 2-Moderate, 3-Extensive, 9-View obscured)

4. Fundus

   a) Macular heterotopia  __________  __________

   (0-Absent, 1-Questionable, 2-Present, 9-View obscured)

   b) Optic nerve atrophy  __________  __________

   (0-Absent, 1-Questionable, 2-Present, 9-View obscured)

   c) Other  __________  __________

   (0-Absent, 1-Present, 9-View obscured)

   If other is present in RIGHT EYE, specify: ____________________________

   If other is present in LEFT EYE, specify: ____________________________
STOP-ROP
THREE MONTH OPHTHALMIC OUTCOME EXAMINATION [04]

STOP-ROP ID: ________________________

Center #  Hosp. Code  Patient #

RIGHT EYE  LEFT EYE

d) Retina

1) Fold ........................................ (0-Absent, 1-Present*, 9-View obscured) □ □
* If present, record clock hour orientation and extent.
Always indicate clock hour limit clockwise.

   a. Radial ....................... (clock hours) ___ to ___  ___ to ___

   b. Zones involved (0-Absent, 1-Present) ___ Z1 ___ Z2 ___ Z3 ___ Z1 ___ Z2 ___ Z3

   c. Circumferential ............ (clock hours) ___ to ___  ___ to ___

   d. Zones involved (0-Absent, 1-Present) ___ Z1 ___ Z2 ___ Z3 ___ Z1 ___ Z2 ___ Z3

2) ROP cicatrix (old line) without fold (0-Absent, 1-Present, 9-View obscured) □ □

3) Chorioretinal scars [document by drawings on pages 4 and 5 of this form]

   a. Cryo or laser .................. (0-Absent, 1-Present, 9-View obscured) □ □

   b. Other than cryo or laser ... (0-Absent, 1-Present, 9-View obscured) □ □

4) Detachment or retinoschisis .... (0-Absent, 1-Present, 9-View obscured) □ □

If detachment or retinoschisis, code location as follows: if some but not all hours detached, leave "all" blank and code 0 (absent), 1 (present), or 9 (View obscured) under each hour. If no (or all) hours detached, code 0 (or 1) under "all" and leave hours 1-12 blank.

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STOP 04 V03, 01/01/96
STOP-ROP
THREE MONTH OPHTHALMIC OUTCOME EXAMINATION [04]

STOP-ROP ID: [Center #] [Hosp. Code] [Patient #]

5. Summary [Note: codes differ from CRYO-ROP forms]
   a. View (1-Complete to ora serrata, 2-Out to vortex veins, 3-Only zone 1, 4-No fundal view) ______                    ______
   b. Most severe abnormality found for each eye ________________________________________                        ________________________________________
      01-Essentially normal
      02-Minor finding(s) (e.g. cicatrix, laser cryo scars) and/or abnormal angle of temporal vessels
      03-Macular ectopia
      04-*Partial retinal detachment, retinoschisis, or fold in near periphery (sparring fovea)*
      05-*Partial retinal detachment, schisis, or fold involving fovea*
      06-Cataract, retrolental membrane, or corneal opacity blocking view of macula (draw if possible)
      07-Total retinal detachment or schisis, or total retrolental membrane
      08-Status post vitrectomy
      09-Enucleation
      88-Unable to determine (e.g., corneal opacity unrelated to ROP, or miotic pupil making view impossible). Explain:
      RIGHT EYE: ______________________________________________________________
      LEFT EYE: ______________________________________________________________
      99-Other, specify: RIGHT EYE: ____________________________________________
      LEFT EYE: ______________________________________________________________

* Complete appropriate Fundus Sketches on pages 4 and 5 of this form

6. Are fundus drawings prepared? _____________________________________________ (N-No, Y-Yes) ______
   If partial detachment or chorioretinal scars, but no drawings, specify reasons:
   ____________________________
   RIGHT EYE: ____________________________ LEFT EYE: ____________________________

7. Are you masked to the assigned oxygen treatment of this infant? _____________________________ (N-No, Y-Yes) ______

8. Whether or not you think you know the treatment assignment, what is your best guess, or intuition? _____________________________ (C=Conventional, S=Supplemental) ______

   RIGHT EYE                  LEFT EYE

9. Did infant have cryotherapy? __________________________________________ (N-No, Y-Yes) ______
   If Yes, specify initial date __________ M __________ D __________ Y __________
   __________ M __________ D __________ Y __________

10. Did infant have argon or diode laser therapy? __________ (N-No, Y-Yes) ______
    If Yes, specify: type of laser __________ (A=Argon, D=Diode) ______
        initial date __________ M __________ D __________ Y __________
        __________ M __________ D __________ Y __________

11. Did infant have any other surgical treatment on the eyes? (N-No, Y-Yes) ______
    If YES, specify:
    RIGHT EYE: ____________________________ DATE: __________ M __________ D __________ Y __________
    LEFT EYE: ____________________________ DATE: __________ M __________ D __________ Y __________

   ____________________________ Certification Number ____________________________ Certification Number
   Signature of Certified Ophthalmologist
   ____________________________
   Signature of Study Center Coordinator

STOP 04 V03, 01/01/96
14. DRAWINGS AT THREE MONTH EXAMINATION

COMPLETE IF PARTIAL DETACHMENT OR CHORIORETINAL SCAR PRESENT, OR AT THE DISCRETION OF THE OPHTHALMOLOGIST. Use Figure 1 of instructions for symbols. Black pen or dark colored pencils may be used.

RIGHT EYE

Sagittal View
DRAWINGS AT THREE MONTH EXAMINATION

COMPLETE IF PARTIAL DETACHMENT OR CHORIORETINAL SCAR PRESENT, OR AT THE DISCRETION OF THE OPHTHALMOLOGIST. Use Figure 1 of instructions for symbols. Black pen or dark colored pencils may be used.

LEFT EYE

CLOCK HOURS

ORA SERRATA

Sagittal View
INSTRUCTIONS FOR STOP 04 FORM

3-MONTH OPHTHALMIC OUTCOME

This form is used to assess ophthalmological study outcomes in the infant at 10-14 weeks post due date. Examinations which occur in this time frame are considered within the examination window. Example: an infant is born at 28 weeks gestation - 12 weeks post due date would be 40 weeks later (40 weeks is when the infant would have been born if he or she was full term; the 3-month examination is performed 10-14 weeks post due date: 12+12=24 weeks later). If it proves impossible to perform the examination within the window, it should be performed as close to the window as possible. The Study Certified Ophthalmologist is responsible for completion of the form. The Study Center Coordinator assures that the form is completed.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form and to assist you in understanding the interpretation of the findings and how to record them on these forms using study conventions. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 8 of the Manual of Procedures or call the Coordinating Center or Study Headquarters. If a generic issue is identified, explanations will be provided for all centers.

2. Examination window - The examination window is 10-14 weeks post due date. If the examination is outside the window, record the reason it was performed outside the window.

3. Vitreous opacity on or near visual axis - Consider findings within or overlying zone 1 to answer this question. Use 9-View obscured when there is a corneal or lens opacity blocking the view.

3.a Hemorrhages: slight range is 1 or 2 separate hemorrhages per eye, with each having neither a larger diameter than 1 disc diameter at the narrower dimension, nor 2 disc diameters at the larger dimension. Moderate range is 3-5 separate hemorrhages per eye, also with each having neither a larger diameter than 1 disc diameter at the narrower dimension, nor 2 disc diameters at the larger dimension. Any hemorrhages larger than these definitions either in size or quantity are considered extensive.
3.b Membranes/Organization: slight is considered to be anything the ophthalmologist feels is insignificant to visual acuity, moderate is potentially visually significant, and extensive means that this is obviously an obstacle to good visual acuity.

4. a) Macular heterotopia - Record 0 (absent) if the center of the fovea is positioned 2-3 disc diameters from the temporal disc margin and appears essentially undisturbed. If the macula is still 2-3 disc diameters from the disc margin but appears unequivocally dragged, record 1, (questionable). If the macula is 2 disc diameters or less from the temporal disc margin, or 3 or more disc diameters from the disc margin, record 2 (present). If the view of the fundus is obscured, then record 9 (view obscured).

b) Optic nerve - Record 2 if atrophy is unequivocally present. Record 1 (questionable) if you feel presence of atrophy is highly suspicious. Record 0 if only a slight question (please err on the side of under, not over-diagnosis). If the view of the fundus is obscured, then record 9 (view obscured).

c) Other - includes edema or 50% or greater cupping of the disc, or unequivocally larger cupping in one eye than the fellow eye. The question is left non-deductive in case there should be some other change you feel should be noted as a possible effect of ROP or cryotherapy (or unrelated but of potential prognostic significance). If the view of the fundus is obscured, then record 9 (view obscured).

d) 1) Retinal fold here may be located anywhere. For this item please err on the side of over-call, since something that looks like a fold may represent a significant disturbance. If you think "probably a fold" mark "present." The asterisk after "present" refers to the lines immediately following. If the view of the fundus is obscured, then record 9 (view obscured).

For the instructions under the asterisk, "clockwise" means that a fold from 11:00 to 2:00 represents 3 sectors, not 9, and should be recorded as

```
1 1  to  0 2
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A fold from 2:00 to 11:00, however unlikely, represents 9 sectors and should be recorded as
2) At times there are residual membranes or cicatrix within the retina, but without a fold and with nothing near the visual axis. Record the observed presence or absence of such findings here. If the view of the fundus is obscured, then record 9 (view obscured).

3) If there are chorioretinal scars, determine if they are from cryotherapy or laser ablation for treating ROP and record accordingly. If they are not related to cryo or laser, use the "other than cryo or laser" choice. If the view of the fundus is obscured, then record 9 (view obscured).

4) Code 1 if there is an unequivocal retinal detachment involving at least one 30 degree section (full clock hour) of the vascularized retina and extending at least one disc diameter posterior to the ridge. Old circumferential cicatrices and tented vessels rising to the top of the ridge are not considered folds or detachments.

For zone 1, if detachment and/or retinoschisis is suspected, enter 1. For zones 2 and 3, if detachment and/or retinoschisis is questionable, record 0.

If the view of all zones is obscured, then record 9 (view obscured), and skip to question 4.

If the view is obscured in some zones, but not all zones, code 1 if detachment/retinoschisis is present in any of the zones viewed or code 0 if detachment/retinoschisis is not present in any of the zones viewed. Complete the individual zone coding indicating the detachment/retinoschisis status of each sector (0-absent, 1-present, 9-view obscured).

If detachment and/or retinoschisis is present and extends 360°, you should use the first column "all" for simplicity for each zone; otherwise, enter 1 for each detached clock hour. Clock hour involvement should be coded using the labels for each hour as illustrated below:
5. Summary - Code using only the listed numbers on the form. These are NOT identical to summary diagnosis codes used in previous forms or CRYO ROP classification codes.

   a) View - use the appropriate choice that best describes the amount of view that was obtained in each eye.
      1. Complete to the ora means that the view was to the ora in effectively all clock hours.
      2. If the ora cannot be seen, use this code if a good view was obtained at least out to the vortex veins.
      3. If it is possible only to examine the posterior pole, effectively only zone 1, use this code.
      4. If there is no view, use code 4. In the summary diagnosis in part b), this will mean that the summary diagnosis will be 88 and you will be asked to write in the reason.

   b) Summary diagnosis -

      01 Essentially normal, or minimally abnormal. Minor variations are tolerated here, particularly when they don't relate to ROP. Visible cryo or laser scars should not be considered essentially normal.

      02 Abnormal angle of the temporal vessels, or even abnormal angle of the nasal vessels--although if the nasal vessels are abnormal it is more likely there is a fold or macular ectopia present, in which case you should use the higher codes below. Other minor findings could
include peripheral cicatrix, and cryo or laser scars if there are no other more severe findings present.

03 Macular (or fovea) ectopia or distortion without retinal detachment or fold.

04 Partial retinal detachment, schisis, or fold sparing the fovea (including partial retrolental tissue opacity incorporating the retina)
NOTE: If this code is used, please prepare a fundus drawing.

05 Partial retinal detachment or schisis or fold involving the fovea. This includes partial retrolental tissue opacity incorporating retina (detachment) and obscuring view of the fovea.
NOTE: If this code is used, please prepare a fundus drawing.

06 Cataract, retrolental membrane, or corneal opacity from ROP blocking the view of the macula (draw if possible). This code can also be used for other ROP related pathology that results in the same blockage of the visual axis. This is used when it can be seen that there is not complete retinal detachment (see 07).

07 Used when there has been complete retinal detachment or there is such a complete retrolental membrane that you can not determine the condition of the remaining retina.

08 Use if the eye has had vitreoretinal surgery for ROP -- if for another diagnosis, the 99 code for "other" should be used and an explanation provided.

09 Use if the eye has been enucleated for complications of ROP -- if for another diagnosis, the 99 code for "other" should be used and an explanation provided.

88 Avoid using "unable to determine" if at all possible. Try to best categorize the eye according to the choices given. If you must use code 88, be certain to explain the circumstances. You may attach an additional note if necessary.

99 If other, please specify as a write in. In the rare event that an eye is at Threshold or still in the active stages of ROP at this 3 month examination, use code 99 and specify.
6. Fundus drawings - If partial detachment or chorioretinal scars, fundus drawings are required. At the discretion of the ophthalmologist, these drawings may also be used to illustrate unusual or positive findings.

7. If you think you know the infant's assigned oxygen, then you are not masked.

8. Whether or not you think you know the infant's assigned oxygen, use your knowledge, best guess, or intuition in choosing the oxygen treatment assignment of the infant.

12. Signature and certification number of the ophthalmologist indicates form is completed and checked for accuracy.

13. Signature and certification number of the Study Center Coordinator indicates form is completed and checked for accuracy.
Fundus Drawings

Use the last two pages of the form for drawings if you feel there is a partial detachment or chorioretinal scar, or if there are other findings that should be recorded. Conventions for regressing and regressed ROP and cicatricial changes are shown in Figure 1. Color is optional.

In using the sagittal sections, show elevated or intravitreous lesions; if it should be necessary to show a cross section other than sagittal, cross out "sagittal" and indicate opposing clock hours of section selected.
FIGURE 1

CODE FOR CICATRICIAL ROP

Single hatching = Blue = RD

White = Red = Attached Retina

G with arrow = Green = Vitreous Traction

Y = Yellow = Exudate

P = Pigment

H = Blood

Remnant of ridge or demarcation line

Regression with vessels growing through ridge

Double cross-hatching: neovascularization

skipped area

Cryo scars
THREE MONTH NEONATAL OUTCOME FORM [05]

STOP-ROP ID: __________________________

HOSPITAL ID NUMBER: _______________________

NAME CODE: __________________________

Infant examination should be performed 10-14 weeks post due date.

1. Date of Examination ___________________________ M D Y

2. Weeks post due date ____________________________ weeks __________

CURRENT PHYSICAL STATUS

3. 
   a) Weight ___________________________ grams __________
   
   b) Length ___________________________ cms __________
   
   c) Head circumference ___________________________ cms __________

RESPIRATORY SUPPORT

4. Is the infant currently on oxygen? ___________________________ (N-No, Y-Yes) __________
   
   If NO, enter last date the infant received oxygen, and skip to 5 ___________________________ M D Y
   
   a) Mode of delivery
   (1-Yes, but intermittently, skip to 5
   2-Yes, on nasal cannula
   3-Yes, on hood
   4-Yes, on nasal CPAP (prongs)
   5-Yes, on ETT (vent or CPAP)
   6-Yes, other, specify ___________________________)

   b) Oxygen concentration ___________________________ % __________

   c) If on cannula, enter cannula flow rate ___________________________ L/min __________

   d) Pulse oximeter saturation on O₂ ___________________________

5. Pulse oximetry in room air recorded today ___________________________
   
   Code 999 if infant is medically unstable to place in room air.

   If infant is on oxygen with sats ≥ 90%, discontinue oxygen for 20 minutes before recording lowest saturation value.
   If saturation drops below 85% at any time, return to ordered oxygen immediately and record 84%.

6. Status of home apnea monitor use
   (1-Never used
   2-Currently on monitor
   3-Previously used
   4-Infant never discharged to home)
   
   If 3-Previously used, provide: ___________________________ Date ended __________
   
   M D Y

STOP 05 VO4, 01/01/96
STOP-ROP ID: ____________________________

PHARMACOLOGICAL SUPPORT

7. Since the week before randomization, when did the infant last receive any steroids, other than topical?
(1-Never, 2-Currently daily or every other day, 3-In past 2 weeks, 4-Since the last weekly study examination, but more than 2 weeks ago, 5-Before or on the last weekly study examination, 6-Unknown, infant enrolled in masked steroid trial) ____________________________

If 4, estimate the date last received ____________________________

8. Since randomization, when did the infant last receive any methylxanthines?
(1-Never, 2-Currently daily or every other day, 3-In past 2 weeks, 4-Since the last weekly study examination, but more than 2 weeks ago, 5-Before or on the last weekly study examination) ____________________________

If 4, estimate the date last received ____________________________

9. Since randomization, when did the infant last receive any diuretics?
(1-Never, 2-Currently daily or every other day, 3-In past 2 weeks, 4-Since the last weekly study examination, but more than 2 weeks ago, 5-Before or on the last weekly examination) ____________________________

If 4, estimate the date last received ____________________________

HEALTH STATUS SINCE INITIAL DISCHARGE

10. REMINDER: Initial Discharge Form (STOP 10) must be completed for initial hospitalization, and Rehospitalization Form (STOP 11) must be completed for each hospitalization following initial discharge.

   a) Is the infant currently at home? ____________________________ (N-No, Y-Yes) ___

   b) Including initial discharge, how many times has the infant been discharged to home?
      (If never discharged to home, code 00 and skip to 11) ____________________________

   c) Since initial discharge to home, did the infant:
      1-Have any illness or breathing problem, but no oxygen was required ____________________________ (N-No, Y-Yes) ___
      2-Require oxygen to be started or increased, but did not need to be hospitalized ____________________________ (N-No, Y-Yes) ___
      3-Require oxygen to be started or increased and needed to be hospitalized for a cardio-pulmonary condition ____________________________ (N-No, Y-Yes) ___
      4-Require hospitalization for a non-cardio-pulmonary condition ____________________________ (N-No, Y-Yes) ___

NEURO/DEVELOPMENTAL STATUS

11. a) Have parents and SCC completed the modified RPDQ Form (STOP 09)? ____________________________ (N-No, Y-Yes) ___

   b) Was the infant able to maintain oral feedings for 3 consecutive days at the time of initial discharge to home? ____________________________ (N-No, Y-Yes) ___

   c) Is the infant able to maintain oral feedings for 3 consecutive days now?
      Provide the first date of the first 3 consecutive days at which the infant was able to maintain oral feedings, if not previously provided. Leave blank if previously provided. ____________________________

   M  D  Y

Signature of Study Center Coordinator or Neonatologist ____________________________
Date Completed ____________________________

12. Certification Number ____________________________

STOP 05 V04, 01/01/96
INSTRUCTIONS FOR STOP 05 FORM

3-MONTH NEONATAL EXAMINATION

This form is used to assess secondary study outcomes in the infant at approximately 10-14 weeks post due date. Examinations which occur in this time frame are considered within the examination window. Example: an infant is born at 28 weeks gestation - 12 weeks post due date would be 24 weeks later (40 weeks is when the infant would have been born if he or she was full term; the 3-month examination is performed 10-14 weeks post due date: 12 + 12 = 24 weeks later). The information is obtained by direct examination and through communication with the parents. Information about which the parents are unsure should always be verified by the infant's pediatrician. The Study Center Coordinator or Neonatologist is responsible for completion of this form.

When reporting infant history information, consider any previously undocumented information. For example, this might arise from unreported rehospitalizations at non STOP-ROP facilities. Obtaining the information may require telephone calls to these hospitals, or a review of the infant's medical record. If possible, complete a Rehospitalization form (STOP 11) for each such rehospitalization. If the infant has died at a non STOP-ROP hospital, and this was previously undocumented, complete a Death (STOP 12) form.

REMINDER: If the infant has never been discharged, complete an Initial Discharge (STOP 10) form with the 3-month Neonatal Examination form.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult Chapter 9 of the Manual of Procedures or call the Coordinating Center.

2. Weeks post due date - Record by counting the number of weeks from the time the infant would have begun 40 weeks term gestation to today (eg. an infant born at 30 weeks gestation who is being seen in the clinic today at 52 weeks post conception is at a corrected age of 52-40, or 12 weeks post due date).

3. Current physical status -

3.a Weight - Record the infant's weight in grams. If the infant is wearing a cast at the 3-month visit, the parents' report of the most recent weight can be accepted in lieu of the current weight including the cast. A conversion chart is attached to these instructions, to use when a gram scale is unavailable.
3.b Length - Record the infant's length in centimeters, with one decimal place (e.g. 43.5). If the infant's length can not be measured (legs in bent cast, etc.), this data item will be missing for this examination, and should be recorded as zeros. Attach a note to the data form explaining why the data item is missing.

3.c Head circumference - To obtain, wrap the measuring tape around the head just above the brow and past the back of the head just above the base of the neck, at the maximal prominence of the occiput. Adjust the tape and remeasure two more times. Record the largest of the three measurements in centimeters with one decimal place (e.g. 32.5). If the infant has been diagnosed as having hydrocephalus and is receiving treatment for it (diamox or shunt or ventricular drainage), head circumference will not be analyzed and should be coded as zeros. If there is no ongoing treatment for diagnosed hydrocephalus, it is considered "arrested hydrocephalus" and the head circumference should be measured and recorded.

4. Use of oxygen - If the infant is receiving oxygen, enter Y. If infant is not receiving oxygen, the last date that the infant received oxygen (even intermittently for procedures) will be recorded, unless it is an isolated event in the middle of a long period of days (>7) when no oxygen is needed.

4.a If infant is receiving oxygen intermittently, code 1; if continuously, select 2, 3, 4 or 5 to indicate mode of oxygen delivery. Code flooded isorlette as 3-hood. Code masked CPAP as 4-nasal CPAP. If the infant is receiving mixed respiratory support, code the highest level of support, e.g., infant is on hood alternating with periods of nasal CPAP, code 4-nasal CPAP. For study purposes, the hierarchy is ETT > nasal CPAP > nasal cannula > hood. If infant has a tracheostomy, select 9 and record trach, CPAP or vent.

4.b Oxygen concentration expressed as a %. When an infant is receiving oxygen by cannula, record the % oxygen the cannula is attached to, not the measurement of oxygen at the infant's nostril area.

4.c L/min cannula flow - If infant is receiving 1/4 liter, record 0.25.

4.d Pulse oximetry saturation on O₂ - Place oximeter on infant. If using study equipment: Monitor oximeter data for at least 5 minutes. If the infant is off treatment assignment, use the practice/monitoring option, in which the oximetry data are collected normally, but not saved to disk. The laptop data collection program displays at the left of the data collection screen a graph titled "% time: 20 mins". This graph uses horizontal bars to show the percents of time spent, over the past 20 minutes, at various saturation values. The height of each bar (on the vertical axis) gives the saturation value, while the length of the bar (measured on the horizontal axis) gives
the percent time spent at that saturation value. The bar corresponding to
the median is identified by a dotted line drawn through it. Enter the
saturation (vertical axis) value for this bar.

If using non-study equipment: Some oximeters can produce analyses of
output, while others require you to periodically note readings from the
oximeter display. If the oximeter in question is a Nellcor, subtract 1 from
the median; Nellcor consistently reads 1-2% above Ohmeda.

If recording continuously, base your assessment of the median on at least
5 minutes of data. If the median is displayed, record it. If percents of time
spent at various saturation levels are displayed, calculate a median as
follows: Starting from the lowest saturation value and moving upward, add
together the percents time. When this sum exceeds 50, stop. The
saturation value for the last percent you have added is the median. Record
this value. For example, suppose the percents time at various saturation
values are:

<table>
<thead>
<tr>
<th>sat</th>
<th>% time</th>
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<th>% time</th>
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<tr>
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<td>15</td>
</tr>
</tbody>
</table>

The percents for 88, 89, and 90 are 5 + 10 + 30 = 45. Adding the percent
for 91 brings the sum up to 65, so the median is 91. Notice that the median
is not necessarily the most frequent value (90, in this case, with 30% of the
time), nor is it equal to the average (90.85, in this case).

If noting values at discrete intervals, gather at least 11 oximeter values (an
odd number is best), spaced at 30-second intervals in time. Sort them in
order and record the middle saturation value as the median.

5. Pulse oximetry in room air - If the infant is not receiving oxygen, place the pulse
oximeter on infant and establish a consistent reading. To obtain the median, follow
the general directions given in 4.d above.

If infant is receiving oxygen and saturations are <90%, or if the infant is unstable
to place in room air, record 999.

If the infant is receiving oxygen and saturations are ≥90%, place oximeter on infant,
establish a consistent reading, then discontinue oxygen for 20 minutes or until the
infant’s saturations drop below 85%. When this occurs, restart oxygen supply
immediately and record 84%. If the infant’s saturations do not drop below 85%,
record the lowest saturation obtained in this 20 minute period.
6. Status of home apnea monitor - Record the code that describes home apnea monitor usage. If 3, provide the last date on a monitor.

7. If the infant is hospitalized, review the medication sheets. Otherwise, ask the parents about steroid use. If estimating dates, precision is unnecessary; accuracy of ± 1 week suffices.

Note: steroids administered by intraocular injection or nasal drops (e.g. Beclomethasone or Dexamethasone) are not considered systemic steroids; rather, they are to be considered topical.

8. Use of methylxanthines - Methylxanthines include aminophylline, caffeine (Cafergot) or theophylline. If the infant is hospitalized, review the medication sheets. Otherwise, ask the parents about methylxanthine use. If estimating dates, precision is unnecessary; accuracy of ± 1 week suffices.

9. Use of diuretics - Drugs such as Lasix (furosemide), Diuril (chlorothiazide), Aldactone (spironolactone), and Edecrine (ethacrynic acid). If the infant is hospitalized, review the medication sheets. Otherwise, ask the parents about diuretics use. If estimating dates, precision is unnecessary; accuracy of ± 1 week suffices.

10. b. Number of times discharged to home - Count the initial discharge to home as 1, even if the discharge occurred before randomization. Also count any other discharge to home prior to this visit. Do not count a transfer as a discharge to home.

10. c. Answer these questions irrespective of whether the initial discharge to home occurred before or after randomization.

11. a. Modified Revised Denver Prescreening Developmental Questionnaire (RPDQ) - The Study Center Coordinator will complete this form with the parents either at the time of this visit, or by phone prior to this visit. (REMINDER - THE RPDQ IS PROVIDED IN ENGLISH). Additional assistance may be required if the parents are unable to read the instructions.

b. If the infant was able to maintain oral feedings for 3 consecutive days at the time of initial discharge to home, code "Y". If the infant was not able to maintain feedings at the time of initial discharge to home or has never been discharged to home, code "N".
c. Oral feedings are feedings taken from a bottle, cup, or at the breast. Oral feedings do not include NG, NJ, OG, OJ, or gastrostomy feedings. If infant is now able to maintain feedings, enter the first date of the first 3 consecutive days on which the infant was able to maintain oral feedings.

12. Signature and certification number of person completing form indicates form is completed and checked for accuracy.
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PROTOCOL ANOMALY [06]

STOP-ROP ID: ____________________ ____________________ ____________________
Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ____________________

NAME CODE: ____________________

Complete this form whenever a protocol anomaly occurs.

1. Date of anomaly ____________________ ____________________ ____________________ M  D  Y

2. Cause(s) of anomaly ____________________ Code each: (N-No, Y-Yes)
   a) Signed consent, infant randomized, weekly or 3 month follow-up possible, 
      but parents refuse assigned treatment or monitoring ____________________
      If Yes, indicate treatment plan

   b) Signed consent, infant randomized, but parents refuse follow-up ____________________

   c) Scheduled STOP-ROP weekly examination or its ophthalmic portion not performed 
      If YES,
      1) which weekly exam? ____________________ (Code: 01-Week 1, 02-Week 2, 03-Week 3, etc) ____________________
      2) reason for not performing exam (1-Medically unstable
         2-Unavailability of certified ophthalmologist
         3-Parents unable to keep scheduled appointment
         4-Transferred to a non STOP-ROP facility on a temporary basis
         9-Other, please specify)

   d) Permanent transfer to non-STOP-ROP facility, no follow-up of infant is possible ____________________
      If YES, where:

   e) Infant not permanently transferred to non-STOP-ROP facility, but temporarily off study oxygen treatment 
      monitoring equipment for over 4 hours ____________________
      If YES, code reason:
      0-In operating room
      1-Prolonged radiology examination
      2-Transportation to/from home
      3-Transportation to/from other facility
      4-Medically unstable
      9-Other, please specify)

   f) Oxygen treatment prematurely permanently terminated, but not by parent ____________________
      If YES, indicate why:

   g) Lasar/cryo treatment of ROP in an eye not yet at Threshold ____________________

   h) Moved/lost to follow-up without explicit refusal/termination ____________________

   z) Other cause(s) ____________________
      If YES, specify:

Signature of Certified Neonatologist/Ophthalmologist ____________________ ____________________
Date  Certification Number

Signature of Study Center Coordinator ____________________ ____________________
Date  Certification Number

STOP 06 V04, 01/15/98
INSTRUCTIONS FOR STOP 06 FORM

PROTOCOL ANOMALY

This form is used to record a protocol anomaly whenever it occurs. Multiple anomalies must be recorded on one form if they occurred on the same date. A certified Neonatologist or Ophthalmologist is responsible for completion of the form. The Study Center Coordinator is responsible for verifying completion of this form.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

For the purposes of this study, a "permanent transfer" is a transfer to a non STOP-ROP institution that does not allow any follow up, and that will not culminate in return to a STOP-ROP institution. All other transfers to non STOP-ROP institutions are defined as "temporary". That is, a "temporary" transfer is a transfer to a non STOP-ROP institution that allows some follow up, and/or that will culminate in return to a STOP-ROP institution, either at the 3-month examinations or earlier.

1. Date of the anomaly - Enter the date the anomaly is first discovered (e.g. date congenital eye anomaly was found, or the date parents refused treatment).

2. Cause(s) of anomaly - There may be more than one cause of anomaly, e.g. if the infant's parents refuse further participation in the study after signing the initial informed consent form, and the infant is transferred on a permanent basis to a non STOP-ROP center, record Y=YES for b and d.
   a. Refuse treatment or monitoring: report this cause of anomaly only once per infant.
   b. Refuse follow-up: report this cause of anomaly only once per infant.
   c. Scheduled STOP-ROP weekly exam or ophthalmic portion not performed (either in whole or in part) - If Y, enter which weekly examination was not performed (e.g. 01 = week 1, 02 = week 2, etc) and indicate the reason for not performing it (e.g. code 1 for periods of time during which the infant was too medically unstable for an examination to be performed). Code 4 if the infant has been transferred to a non-STOP-ROP facility on a temporary basis and no weekly exam is able to be performed. If other (9), specify reason.
d. If transferred on a permanent basis to a non-STOP-ROP Study Center and no follow-up is possible, indicate center where infant was transferred. The Coordinating Center will expect no further forms to be submitted for this infant.

e. If infant is required to be temporarily off study equipment for more than 4 hours, record Y and code reason in space provided. If several reasons apply, select the most clinically relevant condition, e.g., if an infant is transported to another facility for a surgical procedure, select 0-in operating room, not 3-transportation to/from other facility.

f. Choose this if the assigned oxygen treatment is prematurely permanently terminated at the physician’s written order. Specify why treatment was terminated. Report this cause of anomaly only once per infant.

g. If an eye not yet at Threshold is going to receive cryo or laser treatment of ROP, code g. Call the Study Chair, an ophthalmologist on the Executive Committee, or the Coordinating Center to provide details of the ophthalmic findings prior to surgery. If the call is not possible because of the timing of surgery, a call to explain the circumstances must be made as soon as possible following surgery. Report this cause of anomaly only once per eye.

h. Moved/lost to follow-up without explicit refusal/termination. Choose this only as a last resort, when convinced that no more follow-up is possible, but the parents have not explicitly refused follow-up (protocol anomaly 2b), and there is no more explicit way (such as a death form) whereby you can document the loss to follow-up.

3. Certification number and signature of Neonatologist or Ophthalmologist indicates form is completed and checked for accuracy. Ophthalmologist must sign if question 2.g is answered Yes.

4. Certification number and signature of Study Center Coordinator indicates form is completed and checked for accuracy.
TRANSFER FORM [07]

STOP-ROP ID: __________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ________________________

NAME CODE: __________

This form is used to document arrival of an infant transferred from one STOP-ROP Study Center to another STOP-ROP Study Center. The receiving SCC will submit the original to the Coordinating Center, copy to the sending SCC, and retain a copy for their files. When an infant is transferred from one hospital to another hospital within the same Study Center, **NO** transfer form is required.

1. TRANSFERRED FROM ONE STOP-ROP STUDY CENTER TO ANOTHER STOP-ROP STUDY CENTER

Call the Coordinating Center at 301/299-8655 to obtain the NEW IDENTIFIERS for the participant’s NEW STOP-ROP ID NUMBER. Then enter the numbers below.

NEW STOP-ROP ID NUMBER: __________

Center #  Hosp. Code  Patient #

NEW HOSPITAL ID NUMBER: ________________________

Obtain from Network Coordinating Center: (if applicable)

NEW NETWORK ID NUMBER: __________

Number  Center #

Signature of Study Center Coordinator

Date

Certification Number

STOP 07 V01, 01/12/94
INSTRUCTIONS FOR STOP 07 FORM

TRANSFER FORM

This form is used to document arrival of an infant transferred from one STOP-ROP Study Center to another STOP-ROP Study Center. It is **not** used to document the following:

- **Transfer of an infant from one hospital to another hospital within the same Study Center.** No form is required for this transfer; the STOP-ROP file and study equipment will accompany the infant at the time of transfer to the hospital with the STOP-ROP Study Center.

- **Permanent transfer of an infant from a STOP-ROP Study Center to a non STOP-ROP Study Center where no follow-up is possible; this requires completion of a Protocol Anomaly form (STOP 06), an Initial Discharge form (STOP 10) or Rehospitalization form (STOP 11).** Study equipment should not accompany the infant. At the completion of the transfer, the Study Center Coordinator should mail the data diskette to the Coordinating Center.

- **Temporary transfer of an infant to a non-STOP-ROP Study Center where follow-up of the infant is possible.** If weekly examinations cannot be performed, submit a Protocol Anomaly form (STOP 06). Study equipment should not accompany the infant.

The Study Center Coordinator who is initiating the transfer of an infant from one Study Center to another Study Center must call the Coordinating Center prior to transfer, in order to initiate the transfer process. The Study Center Coordinator who is receiving the transfer will complete this form with the new STOP-ROP identifiers. The sending Study Center Coordinator will mail the diskette to the Coordinating Center at the time of transfer. **No STOP-ROP equipment will accompany the infant to the new STOP-ROP Study Center; the STOP-ROP file should accompany the infant.**

When an infant is being transferred to another STOP-ROP Study Center, this is not considered an initial discharge. The transferring SCC must complete an **interim copy** of the Initial Discharge (STOP 10) form. Do not send this to the Coordinating Center. Instead, send the interim Initial Discharge form in the infant's STOP-ROP file to the receiving SCC. Later, when the receiving SCC initially discharges the infant, he or she should consider the material reported on the interim Initial Discharge form when completing the Final Initial Discharge (STOP 10) form.
GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

1. Transfer from one Study Center to another Study Center - If infant is transferred from one Study Center to another, all 7 digits of the STOP-ROP ID number will change. Call the Coordinating Center to request a new STOP-ROP ID number, enter this and the new hospital ID number in the appropriate spaces.

2. Certification number and signature of the Study Center Coordinator indicates form is completed and checked for accuracy.
**ADVERSE EXPERIENCE FORM [08]**

**STOP-ROP ID:**

<table>
<thead>
<tr>
<th>Center #</th>
<th>Hosp. Code</th>
<th>Patient #</th>
</tr>
</thead>
</table>

**HOSPITAL ID NUMBER:**

_____________________

**NAME CODE:**

_________ __________

---

**Complete this form whenever an adverse experience occurs. A separate report should be submitted to the Coordinating Center for each type of adverse event.**

---

1. Date first observed or first reported

2. Type of adverse experience

   If 06 is coded, answer question 3, otherwise skip to 4

   01) Excessive apnea and bradycardia episodes (triple the baseline in a 24 hour period and > 3 episodes) number of apnea/bradycardia episodes

   02) Documented hypoxia (pO₂ > 120 torr) while in the target range

   03) Documented hypoxia (pCO₂ < 45 torr) while in the target range

   04) Seizures (new onset)

   05) Necrotizing enterocolitis

   06) Pneumonia/sepsis with positive blood culture or requiring antibiotic treatment for more than five days

   99) Other serious events or events thought to be treatment-related (specify all such)

3. Respond to both the following questions if question 2 is coded 06: pneumonia/sepsis

   a) Is there evidence of sepsis? (1-No, 2-Definite, 3-Probable)

   b) Is there evidence of pulmonary disease?

      (1-No, 2-Definite pneumonia, 3-Probable pneumonia, 4-No pneumonia, but BPD exacerbation, 5-BPD exacerbation or pneumonia, cannot differentiate, 9-Other, [specify])

4. Was this type of adverse experience ever noted prior to STOP-ROP enrollment? (0-Unknown, 1-No, 2-Yes)

5. How was the adverse experience reported? (1-By clinician, 2-By parent(s), 3-By someone else)

6. Is there a relationship between this adverse experience and STOP-ROP treatment assignment? (1-Probably No, 2-Unable to judge, 3-Probably Yes, 4-Definitely Yes)

7. Is the adverse experience ongoing? (N-No, Y-Yes, if Yes skip to 9)

8. Date adverse experience resolved (or monitoring completed)

   M D Y

9. What was (is) the worst severity grade of this adverse experience?

   (1-Mild, no therapy needed, monitoring only

   2-Moderate, may require minimal or no medical intervention, except monitoring

   3-Severe, requires medical intervention

   4-Life-threatening, requires intensive medical intervention

   5-Death has occurred [complete STOP 12 form]

---

**Signature of Certified Neonatologist**

**Signature of Study Center Coordinator**

**Date of report**

---

**STOP 08 V02, 08/01/95**
INSTRUCTIONS FOR STOP 08 FORM

ADVERSE EXPERIENCE

This form is used to record an adverse experience observed in STOP-ROP participants. Deaths must be reported until the infant is 3 months corrected age. All other Adverse Experiences need be reported only up to treatment completion or discharge, whichever is last. However, if an infant is not discharged by 3 months corrected age, stop reporting any Adverse Experiences then. The neonatologist is responsible for completing the form. The Study Center Coordinator verifies that the form is completed.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

1. Date first observed or reported - This is the date first observed or first reported, e.g. the date of excessive apnea episodes, or the date of seizure onset.

2. Type of adverse experience - Enter the code that corresponds to the type of adverse experience observed by the clinician. For excessive apnea/bradycardia, report if the number of apnea/bradycardia events requiring stimulation in a 24-hour period is greater than 3 and also triple the baseline, where baseline is defined as the usual level during the previous week.

   Hypoxia or hyperoxia must be documented on an arterial blood gas, not a capillary blood gas sample. For all types of adverse experience other than 01) excessive apnea and bradycardia, and 99) other, if more than one experience is reported for the same date of first observance, a separate form must be completed for each event.

   Note: Complex events that lead to an adverse experience are best described in an addendum to this form.

3. A certified neonatologist is responsible for determining the responses to these questions.
For sepsis status, code 2 (Definite sepsis) includes, as examples, E.coli sepsis with 
NEC, and group B streptococcus pneumonia with positive blood cultures. 
Note: a urinary tract infection is not coded 2 (Definite Sepsis) unless it is 
accompanied by a positive blood culture.

For pulmonary status, if pneumonia, select 2 (Definite pneumonia) or 3 (Probable 
pneumonia). Generally, the "definite" categories are reserved for culture-proven 
disease.

At times, the pulmonary edema of BPD becomes acutely worse, oxygen 
requirements climb dramatically, and the neonatologist cannot differentiate between 
BPD exacerbation and pneumonia. Code 5 (BPD exacerbation or pneumonia, 
cannot differentiate) in this case. Do not use code 5 if a child who has BPD 
develops a definite pneumonia. Use code 2 (definite pneumonia) instead, even 
though the BPD makes the pneumonia worse. Code 9 (other) should be rare; one 
of the five choices should always be possible.

5. Clinician is defined as any member of the NICU/nursery staff.

6. Relationship - Enter the appropriate code based on the physician's assessment of 
the relationship between the STOP-ROP treatment assignment and the adverse 
experience.

7. Adverse experience ongoing - If Y is coded, do not send in an additional Adverse 
Experience form to document resolution of this event. The Coordinating Center will 
periodically distribute a query message to the SCC requesting an update of the 
status of the adverse experience. If death has occurred, code N.

8. Date adverse experience resolved or monitoring completed - Enter the date that the 
adverse experience was resolved or when monitoring of the experience was 
completed. For example, if pneumonia, enter the date that treatment or observation 
is no longer required.

9. If severity is 4 (life-threatening) or 5 (death), submit form by fax to the Coordinating 
Center within 24 hours, and mail original within 3 days. All other adverse 
experiences must be reported to the Coordinating Center by mail within a week.

10. Signature and certification number of the neonatologist indicates form is completed 
and checked for accuracy.

12. Signature and certification number of the Study Center Coordinator indicates form 
is completed and checked for accuracy.
INSTRUCTIONS FOR STOP 09 FORM

REVISED DENVER PRESCREENING DEVELOPMENTAL QUESTIONNAIRE

This form is used to assess secondary study outcomes in the infant at approximately 10-14 weeks post due date. Examinations which occur in this time frame are considered within the examination window. Example: for an infant born at 28 weeks gestation, 10-14 weeks post due date would be 22-26 weeks later (40 weeks is when the infant would have been born if he or she were full term).

The information needed to complete this form is obtained through direct communication with the parent or legal guardian. The form should be completed together with the parent or guardian by the SCC at the time of the 3-month Neonatal/Ophthalmic assessment. If it is impossible to complete the Neonatal/Ophthalmic portions of the 3-month examination, for instance if a family moved to a remote area where no study center existed, it is acceptable to complete this form over the telephone with the parent. The form should be mailed in advance to the parent to read and consider, and a telephone call should be scheduled at a time when the parent will not be distracted and has adequate time to discuss and complete the form together with the SCC. If the parent/guardian is unable to provide accurate answers, choose as respondent that individual who in your judgement is best able to provide accurate answers.

GUIDELINES

The following guidelines serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, please call the Coordinating Center.

This form is designed for general use and not specifically for STOP-ROP. Do not provide the name of the infant to the Coordinating Center; substitute the STOP-ROP ID and name code in the space provided for name. In the space provided for the name of the person completing R-PDQ, substitute the SCC’s signature and certification number. Where relation to child is requested, write the relationship of the person being interviewed, e.g. Mother. In the box labeled for office use only, insert today’s date and leave the other areas blank. This form may always be submitted with a STOP 04 or STOP 05 form, but in the event that it is separated it is important to have this basic identifying information recorded.

Begin with question #1 and continue to ask each question in turn until a total of 3 questions have been answered “no”. The no responses do not have to be consecutive.
It is unlikely, but possible, that you will have to turn over the page and continue on the back in order to attain your 3 cumulative “no” answers. If the infant has poor or extremely low vision, only negative responses to questions unrelated to vision should be counted toward the cumulative 3 no responses required prior to stopping. If the answer to a vision-related question is no because the child has poor or extremely low vision, do not circle no. Instead, write NA (not applicable) immediately to the left or below the Yes/No response for the question. The vision-related questions for which NA may be an appropriate answer are specifically identified and discussed in the instructions below. Do not count NA responses as no’s for the “3 no responses” stopping rule.

The instructions for each question on the form have been extensively field tested with parents and should be easy to follow. However, these are some “what if's” that may arise for our study population.

2. Stomach Lifts head:
   What if the infant cannot lie on stomach because of surgery or other problem on the abdomen or chest? Try to get an answer as to whether the head can be lifted above horizontal if the child is held in the face down position in the parent’s hands.

3. Regards Face:
   If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

4. Follows to Midline:
   If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

5. Responds to Bell:
   If the child is hearing impaired the answer is still "no".

6. Follows Past Midline:
   If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

7. Stomach, Head up 45 degrees:
   What if the infant can not lie on stomach because of surgery or other problem on the abdomen or chest? Try to get an answer as to whether the head can be lifted above horizontal if the child is held in the face down position in the parent’s hands.
12. Hands Together:
What if the child is unable to use one arm or hand and therefore only one (or none?) hand is working? Score this as "no" unless the child brings hand and foot together.

13. Follows 180 degrees:
If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

14. Grasps Rattle: [or pencil]
This question is handled satisfactorily with poor or extremely low vision normal infants.

19. Regards Raisin:
If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

20. Reaches for Object:
If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

23. Sits, looks for Yarn:
If the answer is no because the child has poor or extremely low vision, code NA rather than circling "no".

25. Sits, takes 2 cubes:
If the child has poor or extremely low vision, you may hand the cubes to him/her.

27. Rakes Raisin, Attains:
If the child has poor or extremely low vision, you may touch his/her hand to the raisin and observe.
INITIAL DISCHARGE FORM [10]

STOP-ROP ID: ____________

HOSPITAL ID NUMBER: ____________

NAME CODE: ____________

Complete this form at the earliest of: initial discharge to home, transfer to non STOP-ROP Study Center, death of the infant, or continuous hospitalization until 3 months corrected age. The Study Center Coordinator is responsible for completion of the form. The top copy of the form should be submitted to the Coordinating Center and the other two copies should be maintained in the infant and Study Center Coordinator files.

1. Date of earliest event in 1.a) ____________________________ M D Y
   a) Status of the infant (if codes 3 or 4, skip to question 3)
      1-Initial discharge to home
      2-Permanent transfer to a non STOP-ROP hospital,
      3-Death
      4-Remains hospitalized at 3 months corrected age) ____________________________

2. If discharge to home or permanent transfer to non STOP-ROP hospital, complete the following:
   a) Discharged home or to non STOP-ROP hospital on apnea monitor ____________________________ (N- No, Y-Yes)
   b) Discharged home or to non STOP-ROP hospital on oxygen ____________________________ (N- No, Y-Yes)

3. Was infant able to maintain oral feedings for three consecutive days? ____________________________ (N- No, Y-Yes)
   If YES, record the first date of the 3 consecutive days the infant was able to maintain feedings ____________________________ M D Y

Note that questions 4-10 should reflect the status of the infant only after randomization.

4. Number of days from randomization date ____________________________

5. Number of days in ICU with ventilator or CPAP ____________________________

6. Number of days in ICU with oxygen but no ventilator or CPAP ____________________________

7. Number of days in ward with a ventilator or CPAP ____________________________

8. Number of days in ICU without oxygen, ventilator or CPAP ____________________________

9. Number of days in ward with oxygen, but no ventilator or CPAP ____________________________

10. Number of days in ward without oxygen, ventilator or CPAP ____________________________

11. Was the entire hospitalization in a STOP-ROP institution? ____________________________ (N- No, Y-Yes)
ADVERSE EXPERIENCES

12. Has a new episode of any of the following occurred since completion of the last STOP-ROP weekly outcome form? ................................................................. (N-No, Y-Yes) ______

- Excessive apnea and bradycardia (number of episodes in a 24 hour period is triple the baseline and > 3)
- Documented hyperoxia (paO₂ >120 torr) while in the target range
- Documented hypoxia (paO₂ <45 torr) while in the target range
- Seizures (new onset)
- Necrotizing enterocolitis
- Pneumonia/sepsis with positive culture or requiring antibiotic treatment for more than five days
- Other serious events or events thought to be treatment-related

Reminder: If YES, complete an Adverse Experience (STOP 08) for each item.

Signature of Study Center Coordinator

Certification Number
INSTRUCTIONS FOR STOP 10 FORM

INITIAL DISCHARGE

Complete this form at the earliest of: initial discharge to home, transfer to non STOP-ROP Study Center, death of the infant, or continuous hospitalization until 3 months corrected age. A review of the infant’s medical record may be required to complete the form. The Study Center Coordinator will submit the original of the form and maintain one copy in the infant’s study file and another copy in the Study Center Coordinator’s file.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

When an infant is being discharged to another STOP-ROP Study Center, this is not considered an initial discharge. The discharging SCC must complete an interim copy of the Initial Discharge (STOP 10) form. Do not send this to the Coordinating Center. Instead, send the interim Initial Discharge form in the infant’s STOP-ROP file to the receiving SCC. Later, when the receiving SCC initially discharges the infant, he or she should consider the material reported on the interim Initial Discharge form when completing the Final Initial Discharge (STOP 10) form.

When completing this form, consider not only information accrued while the infant is at a STOP-ROP study center, but also information arising from temporary transfers up to the time of initial discharge. The goal is to obtain all information up to the time of initial discharge or death, whether it describes events in your institution or another institution. Permanent transfer to a non STOP-ROP facility requires submission of both an Initial Discharge (STOP 10) and a Protocol Anomaly (STOP 06) form.

1. For the purposes of this study, a "permanent transfer" is a transfer to a non STOP-ROP institution that, at the time of transfer, anticipates neither follow up, nor return to a STOP-ROP institution, even for a 3-month examination. (Reminder: this requires submission of a Protocol Anomaly (STOP 06) form.) All other transfers to non STOP-ROP institutions are defined as "temporary". That is, a "temporary" transfer is a transfer to a non STOP-ROP institution that allows some follow up, and/or that will culminate in return to a STOP-ROP institution, either at the 3-month examinations or earlier.
3. Maintaining oral feedings - Oral feedings are feedings taken from a bottle, cup, or at the breast. Oral feedings do not include NG, NJ, OG, OJ, or gastrostomy feedings. If the infant has not been able to maintain oral feedings for 3 consecutive days, enter N and skip to 4. If Y is coded, indicate the first of the 3 consecutive days at which the infant was able to maintain oral feedings.

4. Each hospital day starting from the day of randomization up to and including the date of initial discharge or death is to be counted as a day of hospitalization. The days of randomization and discharge are both counted as full days, even though they may actually be partial days. Below, each of these days will fall into one of six categories and these must add to this total.

5-10. Each hospital day is to be counted as one of six types of days. The total of the six types must add up to the total given in question 4. Any portion of a day that is in a higher type overrules a lower type for that day. For study purposes and data recording, ICU (NICU or PICU) will be defined as a nurse:patient ratio 1:1, 1:2, or 1:3. If the nurse:patient ratio is 1:4 or more, record as ward. Note that these definitions may differ from local conventions. The six types of day, listed in descending order, are:

   a) ICU with ventilator or CPAP
   b) ICU with oxygen but no ventilator or CPAP
   c) ward with ventilator or CPAP
   d) ICU without oxygen, ventilator, or CPAP
   e) ward with oxygen but no ventilator or CPAP
   f) ward without oxygen, ventilator, or CPAP

In tabular form, these are:

<table>
<thead>
<tr>
<th>type of day</th>
<th>ICU or ward</th>
<th>Oxygen</th>
<th>vent/CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>ICU</td>
<td>Y or N</td>
<td>Y</td>
</tr>
<tr>
<td>b</td>
<td>ICU</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>c</td>
<td>ward</td>
<td>Y or N</td>
<td>Y</td>
</tr>
<tr>
<td>d</td>
<td>ICU</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>e</td>
<td>ward</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>f</td>
<td>ward</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>
A short example: An infant is randomized on Thursday, January 6, at 10:00 pm, and is on CPAP in an ICU at that time. This is changed on Saturday, January 8 at 4:00 am to nasal cannula oxygen. Nasal cannula oxygen continues, sometimes all day, sometimes parts of days, until Saturday, January 22 at noon, when the child changes to room air and receives no more nasal cannula oxygen. He still has apnea, and is on a monitor at 1:3 nursing care status for two weeks until Saturday, February 5 at 8:00 am. He is then on convalescent status until he goes home at 10:30 am the next morning, Sunday, February 6.

The number of hospitalization days for this child is 32. The "day counts" are:

a) ICU with ventilator or CPAP - 3 days (1/6-1/8)
b) ICU with oxygen but no ventilator or CPAP - 14 days (1/9-1/22)
d) ICU without oxygen, ventilator, or CPAP - 14 days (1/23-2/5)
f) ward without oxygen, ventilator, or CPAP - 1 day (2/6)

11. If the entire hospitalization, from randomization to initial discharge, permanent transfer, or death, is at a STOP-ROP institution, code Y. Otherwise, code N.

12. If Weekly Outcome (STOP 03) forms are still being filed, code N. Otherwise, report any adverse experiences since completion of last Weekly Outcome form.

13. Signature and certification number of Study Center Coordinator verifies that the form is complete and checked for accuracy.

INFANTS RANDOMIZED AFTER INITIAL DISCHARGE

When an infant has been randomized after initial discharge:

1) Submit an Initial Discharge Form (STOP 10) when you submit the Baseline Form (STOP 01). The date of discharge specified in question 1 on the STOP 10 should precede the date of randomization specified in question 19 on the STOP 01. The answer to question 1a on the STOP 10 should be 1-initial discharge to home. Cost tracking questions 4-10 on the STOP 10 should be all zero. Question 12 should be answered No. Other questions on the STOP 10 should be answered using information from the infant’s medical record.

2) Subsequent hospitalizations should be documented with Rehospitalization Forms (STOP 11).
Perform interview with parent, if parent lives with the child. If the parent does not live with the child, perform interview with primary caretaker(s): legal guardian, adoptive mother or father, etc.

I would like to ask you some general questions about your personal history. You are free to refuse to answer any of the questions. Remember that this information is important to the study and will remain confidential.

1. Interview performed by (1 = personal interview, 2 = telephone call, 3 = other, specify ______________) __________

2. What is your relationship to the infant?
   (0 = not applicable
   1 = mother [bionl.]
   2 = father [bionl.]
   9 = other, specify ____________________________ ) ........... Caretaker 1 ______ Caretaker 2 ______

3. What is the highest level of education completed by the infant’s caretaker(s)?
   (0 = not applicable
   1 = less than 7 years
   2 = 7-9 years
   3 = 10 or more years without diploma
   4 = high school graduate or GED
   5 = some college/business/vocational
   6 = college degree
   7 = graduate work
   8 = refused to answer) ____________________________ Caretaker 1 ______ Caretaker 2 ______

4. What is the primary occupation of the infant’s caretaker(s)?
   Caretaker 1: Occupation ____________________________
   Caretaker 2: Occupation ____________________________

5. ____________________  Date of interview

Signature of Study Center Coordinator
INSTRUCTIONS FOR FORM 10A

PARENT/CARETAKER INTERVIEW

This form is completed by the Study Center Coordinator with the family at the time of initial discharge or the 3-month neonatal evaluation, whichever comes first. It can be done in person or over the phone. Ideally, the questions are asked of the infant's mother and father who live together with the infant; however, in our families, this is often not possible. We will need to calculate the Hollingshead Socioeconomic Score, therefore the questions should be answered by the adult(s) actually responsible for the infant; this may be a grandmother, aunt, adoptive parents, legal guardian, foster parents, etc. If working parents have day care or other infant care, the questions still apply to the parent(s). If there are two or more responsible adults in the home, take the data from the two most closely approximating "parents."

In rare circumstances, a Study Center Coordinator may determine that a family is so sensitive regarding the personal nature of these questions that asking them may jeopardize further follow-up of the infant. Because the Study Center Coordinator is often the best judge of a family's tolerance and sensitivity, in these cases the Study Center Coordinator may postpone completing this form until the 3-month neonatal examination even if initial discharge occurs first. If these circumstances apply, the Study Center Coordinator is required to notify the Coordinating Center at the time of initial discharge that form 10A is not being completed until the 3-month follow-up.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the data form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

2. If there is only one caretaker, code 0-not applicable for Caretaker 2.

3. Code highest level of education for caretaker(s). If there is only one caretaker, code Caretaker 2 as 0-not applicable or leave blank.

4. The question on occupation requires that you determine what the primary caretaker(s)'s work is, or usually is if temporarily unemployed. To avoid queries, it is important to be as specific as possible with respect to uncovering the respondent's specific occupation. If there is only one caretaker, code occupation for Caretaker 1 and leave Caretaker 2 blank.
For example, if the response is "engineer", ask what type (electrical, chemical, flight, industrial, sales). If the respondent is in the military, ask the rank. If the respondent works in construction, distinguish between painter, laborer, and inspector. If the respondent is in sales, distinguish between retail, wholesale, and manufacturing. Please distinguish between registered and practical nurses, and between clergymen who are professionally trained and clergymen who are not professionally trained. The Coordinating Center will determine the category to which the occupation belongs. If there is only one caretaker, leave Caretaker 2 blank.
REHOSPITALIZATION FORM [11]

STOP-ROP ID: ____________________________

Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: ________________

NAME CODE: ________________

Complete this form at discharge for each hospitalization excluding the initial hospitalization. Submit the top copy to the Coordinating Center, and maintain the other two copies in the infant and Study Center Coordinator files. The Study Center Coordinator is responsible for completion of this form.

1. Date of rehospitalization ____________________________ M  D  Y

2. Date of discharge to home, permanent transfer to non STOP-ROP hospital,
   death of the infant, or 3-month corrected age visit ____________________________ M  D  Y
   a) Status of the infant ____________________________ (1-Discharge to home, 2-Transfer to a non-STOP-ROP hospital,
   3-Death, 4-Rehospitalized at 3 months corrected age visit)

3. If discharge to home or permanent transfer to non STOP-ROP hospital, complete the following:
   a) Discharged home or to non STOP-ROP hospital on monitor ____________________________ (N-No, Y-Yes)
   b) Discharged home or to non STOP-ROP hospital on oxygen ____________________________ (N-No, Y-Yes)

4. Was infant able to maintain oral feedings for three consecutive days?   ____________________________ (N-No, Y-Yes, P-Previously answered)
   If YES, record the first date of the 3 consecutive days the infant was able
to maintain feedings. ____________________________ M  D  Y

Note that questions 5-11 should reflect the status of the infant only during this rehospitalization.

5. Number of days infant rehospitalized ____________________________

6. Number of days in ICU with ventilator or CPAP ____________________________

7. Number of days in ICU with oxygen but no ventilator or CPAP ____________________________

8. Number of days in ward with ventilator or CPAP ____________________________

9. Number of days in ICU without oxygen, ventilator or CPAP ____________________________

10. Number of days in ward with oxygen but no ventilator or CPAP ____________________________

11. Number of days in ward without oxygen, ventilator or CPAP ____________________________

12. What is the primary reason for this hospitalization? ____________________________
   (01-Pulmonary condition, 02-Surgical procedure, 03-Apnea, 04-Seizures, 05-Gastroenteritis, 06-Failure to thrive,
   07-ENT-related illness, 08-Child protective reason, 09-Non-pulmonary infection(s), 99-Other, specify ____________________________)

13. Indicate the number of visits to any doctor since the last hospitalization ____________________________

14. Was the entire rehospitalization in a STOP-ROP institution? ____________________________ (N-No, Y-Yes)

15. ____________________________ Certification Number

Signature of Study Center Coordinator

STOP 11 V01, 01/15/97
INSTRUCTIONS FOR STOP 11 FORM

REHOSPITALIZATION

This form is completed at the time of discharge for each hospitalization following the initial discharge to home. A review of the infant's medical record may be required to complete the form. The Study Center Coordinator will submit the original of the form and maintain one copy in the infant's study file and another copy in the Study Center Coordinator's file.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

2. For the purposes of this study, a "permanent transfer" is a transfer to a non STOP-ROP institution that does not allow any follow up, and that will not culminate in return to a STOP-ROP institution. (Reminder: this requires completion of a Protocol Anomaly (STOP 06) form.) All other transfers to non STOP-ROP institutions are defined as "temporary". That is, a "temporary" transfer is a transfer to a non STOP-ROP institution that allows some follow up, and/or that will culminate in return to a STOP-ROP institution, either at the 3-month examinations or earlier. If the infant dies during the rehospitalization, or remains hospitalized at the 3 month corrected age visit, skip question 3.

4. Maintaining oral feedings - Oral feedings are feedings taken from a bottle, cup, or at the breast. Oral feedings do not include NG, NJ, OG, OJ, or gastrostomy feedings. If the infant has not been able to maintain oral feedings for 3 consecutive days, enter N and skip to 5. If Y is coded, indicate the first of the 3 consecutive days at which the infant was able to maintain oral feedings. Enter P if the answer is Yes, and the question has been previously answered Yes on the Initial Discharge form (STOP 10) or a previous Rehospitalization form.

5. Each hospital day starting from the day of readmission is to be counted as a day of hospitalization. The day of discharge is also counted, even though it may be a partial day. Below, each of these days will fall into one of six categories and these must add to this total.
6-11. Each hospital day is to be counted as one of six types of days. The total of the six types must add up to the total given in question 5. Any portion of a day that is in a higher category overrides a lower category for that day. ICU is considered to be Pediatric Intensive Care, special BPD units, surgical or medical ICU, or similar situations that require more nursing than a regular pediatric ward.

**NOTE:** If your hospital does not have a PICU, but does have a special room/ward for chronic lung babies, determine level by this algorithm: if the nurse:patient ratio for the most part of the day is 1:1, 1:2 or 1:3, record as PICU. If the nurse:patient ratio is 1:4 or more, record as ward.

The six categories, listed in descending order, are:

a) ICU with ventilator or CPAP  
b) ICU with oxygen but no ventilator or CPAP  
c) ward with ventilator or CPAP  
d) ICU without oxygen, ventilator, or CPAP  
e) ward with oxygen but no ventilator or CPAP  
f) ward without oxygen, ventilator, or CPAP

In tabular form, these are:

<table>
<thead>
<tr>
<th>type of day</th>
<th>ICU or ward</th>
<th>Oxygen</th>
<th>vent/CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>ICU</td>
<td>Y or N</td>
<td>Y</td>
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<tr>
<td>b</td>
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<td>c</td>
<td>ward</td>
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<td>N</td>
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<tr>
<td>f</td>
<td>ward</td>
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A short example: An infant is rehospitalized on Thursday, January 6, at 10:00 pm, and is on CPAP in an ICU at that time. This is changed on Saturday, January 8 at 4:00 am to nasal cannula oxygen. Nasal cannula oxygen continues, sometimes all day, sometimes parts of days, until Saturday, January 22 at noon, when the child changes to room air and receives no more nasal cannula oxygen. He is then on ward care status until he goes home at 10:30 am the next morning, Sunday, January 23.
The number of rehospitalization days for this child is 18. The "day counts" are:

a) ICU with ventilator or CPAP - 3 days (1/6-1/8)
b) ICU with oxygen but no ventilator or CPAP - 14 days (1/9-1/22)
f) ward without oxygen, ventilator, or CPAP - 1 day (1/23)

10. These are ICU days without ventilator, CPAP, or oxygen. They will probably be few if any.

12. Primary reason for hospitalization -
   - Pulmonary condition (01) includes: RSV, pneumonia, BPD-related condition, or bronchiolitis
   - Surgical procedure (02) includes: hernia repair, orthopedic, cardiac, VP shunt, ophthalmic procedures, or other surgeries.
   - Non-pulmonary Infection (09) - use this code to record non-pulmonary infections (e.g., meningitis, cellulitis). Note that pulmonary infections (e.g., pneumonia, bronchiolitis) should be coded 01.

13. Record the total number of visits to any doctor since the last hospitalization, i.e., general pediatric or nurse practitioner visits, immunizations, consultations for surgery or ophthalmology, etc. Required study examinations (i.e. retinal or three-month examinations) should not be counted. If no visits were required, enter 0.

14. If the entire rehospitalization is at a STOP-ROP institution, code Y. Otherwise, code N.

15. Signature and certification number of Study Center Coordinator verifies that the form is complete and checked for accuracy.

INFANTS RANDOMIZED AFTER INITIAL DISCHARGE

When an infant has been randomized after initial discharge:

1) Submit an Initial Discharge Form (STOP 10) when you submit the Baseline Form (STOP 01). The date of discharge specified in question 1 on the STOP 10 should precede the date of randomization specified in question 19 on the STOP 01. The answer to question 1a on the STOP 10 should be 1-initial discharge to home. Cost tracking questions 4-10 on the STOP 10 should be all zero. Question 12 should be answered No. Other questions on the STOP 10 should be answered using information from the infant’s medical record.

2) Subsequent hospitalizations should be documented with Rehospitalization Forms (STOP 11).
DEATH FORM [12]

STOP-ROP ID:  ___________  ___________  ___________

HOSPITAL ID NUMBER: ____________________________

NAME CODE:  ___________  ___________  ___________

Complete when death occurs at or before 3 months corrected age. Fax copy of this form to the Coordinating Center at 301/299-3991 within 24 hours of notification, and mail the original to the Coordinating Center within 3 days. Submit copy of Discharge Summary when it becomes available. If parents have agreed to an autopsy, consent for an eye examination should be requested (see section 9.3.1 of the Manual of Procedures).

1. Date of death .................................................  ___________  ___________  ___________
   M  D  Y

2. Autopsy .................................................. (N-No, Y-Yes, U-Undecided or unknown) ___________

3. Status of primary cause of death ........... (F-Final, autopsy based; N-Final, not autopsy based; P-Provisional) ___________

4. Primary cause of death
   1-Cardio-vascular
   2-Respiratory (including sudden unexpected death in BPD infants)
   3-Accident
   4-Unknown
   5-Pneumonia/sepsis
   6-Sudden infant death syndrome without chronic lung disease
   9-Other, please specify ________________________________  ................................................. ___________

5. Date infant last received assigned oxygen treatment .................................................  ___________  ___________  ___________
   M  D  Y

6. Was death possibly associated with assigned oxygen treatment?  ................................................. (N-No, Y-Yes) ___________

7. Excluding the death, has a new episode of any of the following occurred since the last weekly exam? (N-No, Y-Yes) ___________
   Excessive apnea and bradycardia (number of episodes in a 24 hour period is triple the baseline and >3)
   Documented hypoxia (paO₂ >120 torr) while in the target range
   Documented hypoxia (paO₂ <45 torr) while in the target range
   Seizures (new onset)
   Necrotizing enterocolitis
   Pneumonia/sepsis with positive culture or requiring antibiotic treatment for more than five days
   Other serious events or events thought to be treatment-related

   Reminder: If answer to 6 or 7 is YES, complete an Adverse Experience (STOP 08) for each item.

   Reminder: If death occurs during initial hospitalization, complete Initial Discharge Form (STOP 10). If death occurs during a rehospitalization, complete Rehospitalization Form (STOP 11).

8. Did the death occur at a STOP-ROP institution?  ................................................. (N-No, Y-Yes) ___________

   Signature of Neonatologist _______________________________________________________________________

   Signature of Study Center Coordinator ___________________________________________________________________

STOP 12 VO1, 11/11/94
INSTRUCTIONS FOR STOP 12 FORM

DEATH

This form is used to record death of an enrolled infant at or before 3 months corrected age. The neonatologist is responsible for completion of the form. The Study Center Coordinator is responsible for verifying completion of this form.

GUIDELINES

The following guidelines are listed by question number and serve to supplement the instructions on the form, not replace them. Not all questions are represented with guidelines. If a problem is encountered that the instructions or guidelines do not address, consult the Manual of Procedures or call the Coordinating Center.

2. The issue of whether an autopsy has been or will be performed may be unknown or undecided because of the need to submit a Death form (STOP 12) within 24 hours of notification of an infant’s death. Code U for these cases. Unknown information may be resolved by contacting the office of Decedent Affairs or the Admissions office.

3. If an autopsy has been performed, the primary cause of death, reported in question 4, must be recorded F-Final, autopsy-based. If an autopsy has not been performed and never will be, primary cause of death must be recorded N-Final, not autopsy-based. If autopsy is undecided or unknown, primary cause of death should be recorded P-Provisional; the Coordinating Center will issue periodic queries for a final primary cause of death.

4. Primary cause of death - The primary cause of death is indicated on the death certificate, the autopsy report, or in the infant’s medical record. Death certificates commonly list cardiopulmonary arrest as the primary cause of death, but that is not usually the true cause of death. Ask for assistance from the involved physicians to make this determination. When the discharge summary is available, a copy must be submitted to the Coordinating Center with all infant identifiers obscured.

5. Last date infant received assigned oxygen treatment - This may be the same as the date of death, or it may occur prior to the infant’s death. If the infant is still on the study oxygen treatment assignment because both eyes have not reached endpoint, then the last date is the date of death.
6. Relation to assigned oxygen treatment - If Y is coded, an Adverse Experience form (STOP 08) must be submitted to the Coordinating Center within 24 hours.

7. If Y is coded, an Adverse Experience form (STOP 08) must be submitted to the Coordinating Center as discussed in the Manual of Procedures, section 4.11.2.

8. If death occurs at a STOP-ROP institution, code Y. Otherwise, code N.

9. Signature and certification number of neonatologist indicates form is completed and checked for accuracy.

10. Signature of Study Center Coordinator indicates form is completed and checked for accuracy.
**CRYO Outcomes Prediction for STOP-ROP Enrollees [13]**

**IDENTIFICATION:**

STOP-ROP ID# _______ | _______ | _______  
STOP-ROP name code: _______ | _______ | _______ 

**BASELINE CHARACTERISTICS:**

Birth Weight: _______ grams  
Check here if Birth Weight >1250 grams ______ (data sheet optional)

Birth place:  
1. Inborn  
2. Outborn

Multiple Birth:  
1. Single Birth  
2. Multiple Birth

**OPHTHALMOLOGY EXAMS:**

<table>
<thead>
<tr>
<th>RIGHT EYE</th>
<th>LEFT EYE</th>
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</thead>
</table>
| **Date of 1st eye exam:** _____ / _____ / _____  
Did vessels end in zone 1? (y or n)  
Date of 1st onset of ROP: _____ / _____ / _____  
Was ROP in zone 1? (y or n)  
Date of 1st onset of Prethreshold ROP: _____ / _____ / _____  
Was there Plus Disease? (y or n)  
This Eye (check one):  
1. Reached Threshold ROP by CRYO def.  
   On _____ / _____ / _____  
   Was ROP in zone 1? (y or n)  
   # of Hours of Stage 3?  
2. Was treated without reaching CRYO Threshold  
3. Regressed without reaching CRYO Threshold or receiving any ablative treatment  
4. Unknown - child died before ophthalmic endpoint  
5. Unknown - Follow-up Refused  
6. Unknown - Lost to Follow-up  
9. Other  |
| **Date of 1st eye exam:** _____ / _____ / _____  
Did vessels end in zone 1? (y or n)  
Date of 1st onset of ROP: _____ / _____ / _____  
Was ROP in zone 1? (y or n)  
Date of 1st onset of Prethreshold ROP: _____ / _____ / _____  
Was there Plus Disease? (y or n)  
This Eye (check one):  
1. Reached Threshold ROP by CRYO def.  
   On _____ / _____ / _____  
   Was ROP in zone 1? (y or n)  
   # of Hours of Stage 3?  
2. Was treated without reaching CRYO Threshold  
3. Regressed without reaching CRYO Threshold or receiving any ablative treatment  
4. Unknown - child died before ophthalmic endpoint  
5. Unknown - Follow-up Refused  
6. Unknown - Lost to Follow-up  
9. Other |

<table>
<thead>
<tr>
<th><strong>Threshold by STOP-ROP Definition</strong></th>
<th><strong>Threshold by CRYO-ROP Definition</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Zone 1:</strong> Any Stage 1+ or 2+ or Any Stage 3, with or without plus disease (2 quadrants).</td>
<td><strong>Zone 1:</strong> ≥ 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease</td>
</tr>
<tr>
<td><strong>Zone 2:</strong> ≥ 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease (2 quadrants).</td>
<td><strong>Zone 2:</strong> ≥ 5 Contiguous or ≥ 8 Composite clock hours of stage 3 with plus disease</td>
</tr>
</tbody>
</table>

SCC Signature __________________ Date __________ Certification #

STOP 13 Vol 1, 2/15/98
INSTRUCTIONS FOR STOP 13 FORM

CRYO OUTCOMES PREDICTION FOR STOP-ROP ENROLLEES

Baseline Characteristics

Birthweight

Infants who weigh >1250 grams are not intended to work in this program. You may optionally complete data sheets on infants >1250 grams. They will be analyzed separately. Please check the appropriate box if you are submitting an optional data sheet.

Birth Place

Inborn refers to a child who was born in the delivery suite or operating room at the same hospital where initial NICU care was given (in the first few days of life). A child who is inborn to the first hospital and transferred to another unit 3 or more days later is still Inborn. Delivery in the Emergency room, an ambulance, or in a community hospital where immediate transport to a NICU is required are all Outborn.

Ophthalmology Exams:

Vessels end in zone 1 means that at least one clock hour of vessels end in zone 1, even if other vessels end in zone 2 or 3.

ROP in zone 1 means at least one clock hour of disease located in zone 1.

Date of 1st onset of ROP should be the date when any stage of ROP is first observed even if the first observation of ROP was Threshold for that eye. If no ROP was ever observed for an eye, enter a date of xx/xx/xx. Also use this date to indicate Prethreshold was never reached.

Date of 1st onset of Prethreshold ROP should correspond to the dates recorded on the STOP:00 Patient Register for at least one eye (for some patients the companion eye may have reached prethreshold after the patient was randomized so this information is not on the Patient Register). If prethreshold is observed but not initially confirmed, record the earliest date of prethreshold observation.

Please note that CRYO and STOP definitions of Threshold ROP differ in Zone 1 - refer to the table on the dataform. Use the STOP-ROP standard definition for plus disease that requires a minimum involvement of 2 quadrants when determining CRYO threshold.

Dates of Onset:

To use the CRYO-Risk predictive models, we must collect data as it would have been collected in CRYO-ROP, not as it is currently collected in STOP-ROP. Unlike STOP-ROP, the CRYO-Risk form does not require confirmation of Prethreshold and Threshold ROP. A CRYO-Risk onset date is the date the condition is first observed, not the date it is confirmed. Similarly, the date of first eye examination is the date the infant first received an ophthalmic examination, which is not necessarily the date that STOP-ROP screening first began.
SECTION 3: MISCELLANEOUS REPORTS AND WORKSHEETS

Section 3 provides the user with a general description of and instructions for use of miscellaneous reports and worksheets. A sample of each report or worksheet is provided followed by instructions for its completion. The tab dividers are gray for this section to easily distinguish it from the main body of the handbook. Each report or worksheet has its own tab and a Table of Contents has been provided immediately following this introduction.

A STOP-ROP Order Form to obtain new forms and worksheets is provided in this section. In the event a question is not answered in this section, in the main body of this Handbook, or in the Manual of Procedures, call the Coordinating Center at (301) 299-8655.
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REPORTS AND WORKSHEETS

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3.2 Infant Examination Schedule
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3.6 Verification of Certification Report
3.7 Participant Information Worksheet
3.8 Site Visit Agenda
3.9 Release of Medical Records
3.10 Data Forms/Diskette Shipping Log
STOP-ROP RANDOMIZATION LOG

STRATUM A

One eye: Prethreshold ROP, any zone
Fellow eye: Worse than Prethreshold, any zone
OR
One eye: Prethreshold ROP zone 1
Fellow eye: Prethreshold ROP, any zone

<table>
<thead>
<tr>
<th>Seq.#</th>
<th>STOP-ROP ID Number</th>
<th>Name Code</th>
<th>Trt Assign C = Conv. or S = Suppl</th>
<th>Date of Randomization (M/D/Y)</th>
<th>Method of Randomization (1-Env.&amp; call 2-Env. no call)</th>
<th>NETWORK CENTERS</th>
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</table>
# STOP-ROP RANDOMIZATION LOG

**STRATUM A**

- One eye: Prethreshold ROP, any zone
- Fellow eye: Worse than Prethreshold, any zone
  
  **OR**
  
- One eye: Prethreshold ROP zone 1
- Fellow eye: Prethreshold ROP, any zone

### Study Center Code: ___

<table>
<thead>
<tr>
<th>Seq.#</th>
<th>STOP-ROP ID Number</th>
<th>Name Code</th>
<th>Trt Assign C = Conv. or S = Suppl</th>
<th>Date of Randomization (M/D/Y)</th>
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*STOP-ROP LOG V01, 11/15/93*
### STOP-ROP RANDOMIZATION LOG

**STRATUM B**

One eye: Prethreshold ROP, zone 2  
Fellow eye: Prethreshold ROP, zone 2  
OR  
One eye: Prethreshold ROP, any zone  
Fellow eye: less than Prethreshold ROP (includes no ROP)

<table>
<thead>
<tr>
<th>Seq.#</th>
<th>STOP-ROP ID Number</th>
<th>Name Code</th>
<th>Trt Assign C=Conv. or S=Suppl</th>
<th>Date of Randomization (M/D/Y)</th>
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<td>15</td>
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</tbody>
</table>
### STRATUM B

One eye: Prethreshold ROP, zone 2  
Fellow eye: Prethreshold ROP, zone 2

OR

One eye: Prethreshold ROP, any zone  
Fellow eye: less than Prethreshold ROP (includes no ROP)

<table>
<thead>
<tr>
<th>Seq.#</th>
<th>STOP-ROP ID Number</th>
<th>Name Code</th>
<th>Trt Assign C=Conv. or S=Suppl</th>
<th>Date of Randomization (M/D/Y)</th>
<th>Method of Randomization (1-Env.&amp; call, 2-Env. no call)</th>
<th>NETWORK CENTERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td></td>
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<td>30</td>
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</tr>
</tbody>
</table>

STOP-ROP LOG  V01, 11/15/93
RANDOMIZATION LOG

This log is used for all infants randomized in the STOP-ROP Study. Consult the Manual of Procedures, Section 6.5 for additional details regarding Randomization and Stratification.

GUIDELINES

This log is not a data form. All information is written by hand and must be updated every time a randomization occurs. When a participant is randomized, a permanent STOP-ROP identification is assigned. This consists of a 7-digit STOP-ROP ID #, and a participant name code.

For Network Study Centers, the 4-digit Network number and 2-digit Network Center number assigned by the Network Coordinating Center should also be recorded.

Procedure For Randomization

The randomization code is executed at the Coordinating Center, and sets of treatment assignments will be distributed to each Study Center in sealed envelopes. The envelopes will be sealed with strong glue to prevent possible unobtrusive opening and resealing. Each randomization set will consist of a series of sealed envelopes, sequentially numbered within stratum. On the outside of each envelope will be the stratification identification, sequence number, the 2-digit Study Center code and a list of questions. The SCC must answer "Y" to the questions listed on the outside of the envelope to proceed with randomization.

During the telephone call to the Coordinating Center to randomize an infant, the Coordinating Center will ask the Study Center Coordinator to open the envelope corresponding to the stratification code and the lowest sequence number within the stratum. Within the sealed envelope will be a folded, postcard size, two-part, tear-apart card imprinted on one half with the treatment arm designation and a space to complete the STOP-ROP ID #. The other half will be imprinted with the Coordinating Center’s address and postage. The SCC will record the date and time of randomization, hospital code, STOP-ROP ID #, and name and certification number of person enrolling the infant on each section of the tear-apart card, mail one card to the Coordinating Center and retain the other half in the infant’s study chart. The opened envelope used to randomize the infant should be mailed to the Coordinating Center at the completion of randomization.
An entry into the randomization log must be made following each randomization by the Study Center Coordinator. When the participant is randomized, the SCC must verify that the envelope from the correct stratum and the next sequence number is selected and that the participant’s 3-digit patient number assigned is the next sequential number from the last participant who has been randomized. The SCC will then record the 7-digit STOP-ROP Identification number on the appropriate sequence line of the Randomization Log corresponding to the proper stratum. The remaining information requested on the Log will then be completed.

When the Coordinating Center cannot be reached by telephone, randomization will be accomplished by means of the sealed envelopes alone. The Study Center Coordinator will follow the procedure as outlined above with the exception that upon opening the sealed envelope, the SCC will telephone the Coordinating Center at 301-299-8659 and provide the following information for the telephone answering machine:

- today’s date and time of call
- infant’s namecode and registration number
- eligibility information requested
- treatment assignment

Randomization logs must be available for inspection at scheduled STOP-ROP site visits.
**STOP-ROP**

Schedule of Post-randomization Examinations

Study Number 1234567  
Name Code ODENEL  
DOB (mm/dd/yy) 11/26/93  
Gestational age at birth (weeks, days) 26, 0  
Randomization date:time 02/09/94:1015

<table>
<thead>
<tr>
<th>Exam</th>
<th>Earliest mm/dd/yy:hhmm</th>
<th>Target mm/dd/yy:hhmm</th>
<th>Latest mm/dd/yy:hhmm</th>
<th>Performed mm/dd/yy:hh</th>
<th>Exam Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rsp Spt</td>
<td>02/09/94:1415</td>
<td>02/09/94:1815</td>
<td>02/09/94:2215</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rsp Spt</td>
<td>02/09/94:2215</td>
<td>02/10/94:0215</td>
<td>02/10/94:0615</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rsp Spt</td>
<td>02/10/94:0615</td>
<td>02/10/94:1015</td>
<td>02/10/94:1415</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Week 1  
Su 02/13/94  
We 02/16/94  
Sa 02/19/94

Week 2  
02/20/94  
02/23/94  
02/26/94

Week 3  
02/27/94  
03/02/94  
03/05/94

Week 4  
03/06/94  
03/09/94  
03/12/94

Week 5  
03/13/94  
03/16/94  
03/19/94

Week 6  
03/20/94  
03/23/94  
03/26/94

Week 7  
03/27/94  
03/30/94  
04/02/94

Week 8  
04/03/94  
04/06/94  
04/09/94

Week 9  
04/10/94  
04/13/94  
04/16/94

Week 10  
04/17/94  
04/20/94  
04/23/94

Jk 11  
04/24/94  
04/27/94  
04/30/94

Jk 12  
05/01/94  
05/04/94  
05/07/94

Initial hospital discharge

3-month  
Fr 05/13/94  
Fr 05/27/94  
Fr 06/10/94

*3-month exam may be performed later, if necessary

Use military clock (0-2400 hrs)

Exam codes:

- **M** - Missed exam before endpoint in both eyes
- **P** - Performed exam; at least one eye not at endpoint
- **R** - Reached endpoint in both eyes and completed at least two weeks of assigned oxygen treatment; no further weekly exams required

Note: except after an R code, or dates of M-code exams, LEAVE NO BLANKS

Endpoints:

Infant dies
Parents refuse further follow-up
Each eye has either threshold ROP or beyond, mature vessels, or vessels in zone 3 for the 3rd time or more (3-month exam is the next required exam)

Note: if one eye goes to threshold, necessitating treatment, and the fellow eye is Prethreshold, or less than Prethreshold, CONTINUE TREATMENT AND FOLLOW-UP
SCHEDULE OF POST-RANDOMIZATION EXAMINATIONS

This form is faxed from the Coordinating Center to the Study Center Coordinator immediately following randomization or notification of the Coordinating Center that a randomization has occurred. This form outlines the examination schedule for an infant who was just randomized and is used to record whenever examinations occur and to help schedule upcoming examinations. The Study Center Coordinator must verify the information for currentness and accuracy. (See Section 1.11 of this handbook to document any corrections made). Retain the form in the participant’s STOP-ROP file. **DO NOT SEND THIS FORM TO THE COORDINATING CENTER.**

GUIDELINES

This form should be consulted to help schedule future exams and should be updated following any examination until an endpoint has been reached.

Enter the date the examination was performed.

Enter the Exam Code as:

- **M** - Missed exam before endpoint in both eyes
- **P** - Performed exam; at least one eye not at endpoint
- **R** - Reached endpoint in both eyes: no further weekly exams required

**Note:** except after an R exam code, or dates of missed exams, **leave no blanks.**

STOP-ROP VO1 11/15/93
<table>
<thead>
<tr>
<th>Subject</th>
<th>Namecode</th>
<th>Form</th>
<th>Visit</th>
<th>Days Past</th>
<th>Why form is considered missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>9901001</td>
<td>HEPKAT</td>
<td>Randomization</td>
<td>6</td>
<td>6</td>
<td>Infant enrolled, but no Baseline (STOP 01) form submitted.</td>
</tr>
<tr>
<td>9901001</td>
<td>HEPKAT</td>
<td>Anomaly</td>
<td>16</td>
<td>16</td>
<td>Weekly exam indicates parents refuse further treatment/follow-up.</td>
</tr>
</tbody>
</table>
MISSING FORMS REPORT

The Coordinating Center generates a Missing Forms Report bi-monthly that serves to notify each Study Center of forms that are not in the master databases at the Coordinating Center. These reports are sent with the Missing Data Report. Missing forms listed on this report should be sent to the Coordinating Center before the next update.
Sample

STOP-ROP INVENTORY OF MISSING DATA/DATA QUERIES

Study Center = Boston Consortium (01)

<table>
<thead>
<tr>
<th>STOP-ROP ID #</th>
<th>Name</th>
<th>Form Name</th>
<th>Week</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0101001</td>
<td>SMIBAG</td>
<td>Weekly Exam (03)</td>
<td>02</td>
<td>02/02/94</td>
</tr>
<tr>
<td>0101005</td>
<td>DOGMAJ</td>
<td>Baseline\Elig\Rand (01)</td>
<td></td>
<td>03/02/94</td>
</tr>
<tr>
<td>0120112</td>
<td>PATJAM</td>
<td>Protocol Anomaly (06)</td>
<td></td>
<td>04/04/94</td>
</tr>
</tbody>
</table>
STOP-ROP MISSING DATA/DATA QUERIES REPORT
CENTER  99

The Data Evaluation System has found the following missing values or anomalies in
the STOP-ROP data sent to the Coordinating Center and key entered prior to 05/01/94.
This report displays the STOP-ROP Identification number, form, field and data for
which an anomaly has been found. Refer to the appropriate source material and make
any modifications to the hard copy of the form and the appropriate line on this form.
If the missing data or anomaly cannot be resolved, enter an explanation in the
comments section. Send this query to the Data Base Manager at the Coordinating Center.

STOP-ROP ID #  9901001
NAMECODE      HEPKAT
EXAM DATE     04/26/94

<table>
<thead>
<tr>
<th>FORM</th>
<th>FIELD</th>
<th>SUBMITTED DATA</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEEKLY</td>
<td>IS INFANT ON DIURETICS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a are either missing or incorrectly coded.

STOP-ROP VOL  5/10/94
MISSING DATA/DATA QUERIES

The Missing Data Reports are generated by the Coordinating Center and are made available to the Study Centers following an update. They list missing data and possible errors or inconsistencies in data sent to the Coordinating Center. In an effort to keep the database as accurate as possible, these anomalies and missing items need to be addressed by the Study Center Coordinator. Missing data items or anomalies should be resolved in writing. The Missing Data Report provides space for corrections or comments. Fill in the requested data or modification. Send a copy of the report along with a copy of the Query Inventory to the Database Administrator at the Coordinating Center as soon as possible. Place a check mark on the Query Inventory next to the queries that are being sent. The resolution to the Missing Data Report should be kept in the infant’s file.

Corrections documented in this manner do not relieve the Study Center Coordinator of the responsibility of making the modification to the hard copy of the form. All corrections or modifications made on the Missing Data Report should reflect the data on hard copy of the form. Corrections to the STOP-ROP Data Forms are made by placing a line through the incorrect item, recording the correct response, and dating and initialing the correction.

If data are missing and are unobtainable, the Database Administrator can make exceptions and suppress future queries for the item for which an exception is requested. Notify the Database Administrator of a possible reason for excepting the missing item or anomaly by filling in the comments field on the Missing Data Report with the reason the field is blank or contains data that initiated the query. Send a copy of the report back to the Database Administrator before the next update. Keep a copy of the request in the infant’s file. Note on the hard copy of the form the reason the data are unobtainable.
STOP-ROP ORDER FORM

Requested by: ____________________  Study Center #: ______________
Hospital Code #: ______________

Date requested: ________________  Date returned: ______________

<table>
<thead>
<tr>
<th>Forms (NCR)</th>
<th>Number requested</th>
<th>Number sent</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOP 00</td>
<td></td>
<td></td>
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<tr>
<td>STOP 01</td>
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<td></td>
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<td>STOP 02</td>
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<td>STOP 12</td>
<td></td>
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<tr>
<td>STOP 13</td>
<td></td>
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</tr>
</tbody>
</table>

Worksheets (NCR)

Data Forms/Diskette
Shipping Log

Worksheets (plain paper - use your original to make duplicate copies)

Randomization Log  
Order form  
Participant Information  
Medical records authorization  
Medical records release

STOP-ROP  
Order Form - 02/03/98
STOP-ROP SUPPLY ORDER FORM

Name of Study Center __________________________________________

Name of Study Center Coordinator ________________________________

Date of order _________________________________________________

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity requested</th>
<th>Quantity shipped **</th>
<th>Date shipped **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leaflet - English</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leaflet - Spanish</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytip probes (boxes of 10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytip replacement tapes (sheets of 5)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Adhesive disks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interconnect cables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labels for interconnect cables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case studies - neo/SCC</td>
<td></td>
<td></td>
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<tr>
<td>Case studies - ophthal.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Parent booklet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manual of Procedures *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data Management Handbook *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please fill in)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Based on availability

** Shaded area reserved for Coordinating Center. Your order will be filled within two weeks of receipt.

Please fax or mail this form to: STOP-ROP Coordinating Center
11325 Seven Locks Road, Suite 214
Potomac, MD 20854
Attn: Bernadette Jolles, Administrative Coordinator
Fax: 301/299-3991

STOP-ROP Supply Order Form
01/05/95
STOP-ROP VERIFICATION OF CERTIFICATION REPORT

<table>
<thead>
<tr>
<th>PERSON CERTIFIED</th>
<th>CERTIFICATION NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOP-ROP STUDY CENTER</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CERTIFICATION</th>
<th>DATE CERTIFIED</th>
<th>CERTIFIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPHTHALMOLOGIST:</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>NEONATOLOGIST:</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>STUDY CENTER COORDINATOR:</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>RANDOMIZATION:</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

STOP-ROP VO1 01/21/94
PARTICIPANT INFORMATION WORKSHEET

STOP-ROP ID: ________  ________  ________
Center #  Hosp. Code  Patient #

HOSPITAL ID NUMBER: __________________________

NAME CODE: __________________________

DATE FORM COMPLETED  ________  ________  ________  ________
OR UPDATED  M  D  Y

DATE OF BIRTH:  ________  ________  ________  ________

Circle one

Complete this form at time of randomization. Please review and update on a monthly basis.

Participant’s name: __________________________
First  Middle  Last

Home address: __________________________

Home telephone: (____) __________________________

City and state, or country of birth: __________________________

MOTHER’s business address and telephone  FATHER’s Business address and telephone

________________________

________________________

________________________

Mother’s last name: __________________________

Father’s last name: __________________________

Alternate Address: (Temporary residence for ≥3 months such as vacation home or relative’s home)

________________________

Alternate telephone: (____) __________________________

Business telephone: (____) __________________________

Dates: __________________________

Two people (not in participant’s household) who are likely to know the whereabouts of parents of participant:

1. Name: __________________________
First  Last
Address: __________________________

Home telephone: (____) __________________________
Business telephone: (____) __________________________
Relationship to parents: __________________________

2. Name: __________________________
First  Last
Address: __________________________

Home telephone: (____) __________________________
Business telephone: (____) __________________________
Relationship to parents: __________________________

STOP-ROP V01  11/15/93
PARTICIPANT INFORMATION

This form is used to record information that may be needed in the future to locate the participant’s parents or designated legal guardians. The Study Center Coordinator must check the information for currentness and accuracy, make any necessary additions or modifications and enter the date the information was checked or updated.

This information is collected at the time of randomization and is very important to the study, and should be updated monthly. **DO NOT SEND THIS FORM TO THE COordinating CENTER. RETAIN FORM IN THE INFANT'S STOP-ROP FILE.**

GUIDELINES

Enter the date that the form is completed or updated at the top of the form.

This form should be updated on a monthly basis.
STOP-ROP SITE VISIT

STUDY CENTER OPERATIONS - GENERAL INTERVIEW

STUDY CENTER ____________________________ DATE ___/___/___

HOSPITAL NAME ____________________________

INTRODUCTION TO STAFF

TOUR OF FACILITY (location of SCC office, NICU, etc.)

______________________________

______________________________

______________________________

STUDY ORGANIZATION

1. Review of filing system for correspondence and memos. Location, security, etc.

______________________________

2. Location of Manual of Procedures, DMH, Directory, list of key personnel for staff to contact (visibility and accessibility)

______________________________

3. Where and how will Manual of Procedures changes be incorporated? _______
Describe how changes are communicated to staff. ____________________________

______________________________

4. Location of Minutes of the Technical Group and Coordinator meetings?

______________________________

5. Review of data forms, oxygen monitoring and submission procedures.
Questions? ____________________________

______________________________

STOP-ROP Site Visit
General Interview
STOP-ROP PERSONNEL

1. Do you and your staff have adequate time to complete study-related work? ____
   If no, can we assist you to improve situation? ____________________________

2. Do you have adequate number of trained and certified personnel (minimum of 2
   certified ophthalmologists and 2 individuals [SCC + designee] for randomization
   procedures)? ____________________________

3. Are there regularly scheduled meetings between the PI and SCC? _________
   Others? ____________________________

4. How are nursing staff issues relating to STOP-ROP addressed? ______________

5. Where are certification numbers of personnel maintained? ________________

6. How are ophthalmologists masked to infant’s treatment assignment? _________

RECRUITMENT OF INFANTS

1. Who attends routine screening examinations? ____________________________

2. Who is responsible for scheduling follow-up exams? ____________________

3. Who is responsible for explaining the study to parents? _________________

4. What provisions are made to ensure infants do not miss follow-up examinations?
   _____________________________________________________________________

5. Is the leaflet provided to parents before infant reaches Prethreshold disease? ____
   Is it helpful? __________________________________________________________
6. Do you use the video to obtain informed consent? _____
Any problems? ____________________________________________
__________________________________________________________

7. Comments regarding IRB or informed consent? __________________________________________
__________________________________________________________

8. Are confirming examinations occurring within 24 hours? _____
Problems encountered: ______________________________________
__________________________________________________________

9. Use Patient Register to review infants excluded from the study. Any areas for improvement in recruitment of infants? __________________________________________
__________________________________________________________

10. Is recruitment of infants within the target submitted by the PI? _____
If not, what difficulties have you encountered? __________________________________________
__________________________________________________________

11. What provisions have you made to keep parents of infants enrolled in the study interested in STOP-ROP? (phone calls, cards, incentives, other) __________________________________________
__________________________________________________________

12. Any problems with infant attrition? __________________________________________
__________________________________________________________

HUMAN SUBJECT CONSIDERATIONS

1. Copy of Informed Consent in all audited charts __________________

2. Current IRB approval on file. Date of last review: __________________

3. Provisions made to obscure infant's name on log __________________
on discharge summary __________________________________________

STOP-ROP Site Visit
General Interview
STOP-ROP INFANT FILES

1. Where will these be maintained? ________________________________
   ____________________________________________________________________

2. Is there one folder/binder per patient? ______________________________
   ____________________________________________________________________

3. How are they filed? (e.g. by registration #, name code...) ______________
   ____________________________________________________________________

4. Are they secure and locked? _________________________________________
   ____________________________________________________________________

5. Review of ___ STOP-ROP charts with medical record validation of data submitted
   to the Coordinating Center

CONSORTIUM MEMBERS ONLY

Describe the following:

1. Location of all files ________________________________________________
   ____________________________________________________________________

2. Logistics of randomization (any problem ?) ____________________________
   ____________________________________________________________________

3. Transfer of equipment _______________________________________________
   ____________________________________________________________________

4. Dissemination of information __________________________________________
   ____________________________________________________________________
PROTOCOL ADHERENCE AREAS

1. Recruitment
2. Randomization logs
3. Data forms submission
4. Missing data reports
5. Missing forms reports
6. Patient Register (STOP 00)
7. Protocol Monitoring phone calls
8. Transfers
9. Participant worksheets

Areas identified for Coordinating Center to assist Study Center

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

General Notes
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
STOP-ROP SITE VISIT
EQUIPMENT CHECKLIST

STUDY CENTER ___________________________ DATE __/__/_

HOSPITAL NAME __________________________

I. STOP-ROP pulse oximeter and laptop computer

A. Location _________________________________________________________

B. Describe security of equipment when not in use ___________________________

C. Id numbers of pulse oximeters ____________________
   Id numbers of laptop computers ____________________

D. Cable lock(s) in place and secure ______________________________________

E. Location of equipment key (with charge nurse) ____________________________

F. Location of back-up key (narcotic cabinet) _________________________________

G. Is there evidence that equipment has been checked by biomedical department?
   ___________________________________________________________________

H. Verification of date and time in laptop YES ___ NO __

I. Are diskettes labeled and inserted in drive? YES ___ NO __

J. Describe type of outlet used for equipment (emergency use or not)
   ___________________________________________________________________

K. Battery pack functional _______________________________________________

L. Demonstration of how equipment is used during eye examinations (is masking maintained?)
   ___________________________________________________________________

M. Notes (any issues related to equipment/program)
   ___________________________________________________________________

STOP-ROP Site Visit
Equipment Check
II. Shipment of diskettes and data forms

1. Are shipment forms properly completed? YES ___ NO ___

2. Prepare Federal Express label and standardize STOP-ROP shipping lists correctly.
   a) Are STOP-ROP Id Numbers, name codes, number of diskettes and date of collection and mailing indicated on shipping label? YES ___ NO ___
   b) Are copies of forms shipping list retained in the STOP-ROP file? YES ___ NO ___
   c) Was the shipper correctly addressed? YES ___ NO ___

STOP-ROP Site Visit
Equipment Check
AUTHORIZATION FOR THE RELEASE OF MEDICAL RECORDS

DATE: __________________

TO: ____________________________
Name of Hospital or Physician

______________________________
Address

Dear Doctor/Medical Records Clerk:

My son/daughter is a patient at ______________________ participating in the Supplemental Therapeutic Oxygen for Prethreshold Retinopathy for Prematurity Study (STOP-ROP). I authorize you to forward to that study any of the following information requested regarding your treatment of my child.

- Discharge summary
- History and Physical Examination
- Laboratory test results
- Operative report
- Medications
- Other pertinent information

Please forward the information requested as promptly as possible.

Signature of Parent or Designated Legal Guardian ____________________________ Date of Signature ____________________________

Infant's Name (printed) ____________________________ Signature of Witness ____________________________

Date of Birth ____________________________

(Additional information) ____________________________

Please mail to: Study Center Coordinator
(Study Center name
address
City, State, zip)

STOP-ROP VOL 11/15/93
INSTRUCTIONS FOR AUTHORIZATION
FOR THE RELEASE OF MEDICAL RECORDS

This document is provided by the Coordinating Center as an example of a release of medical records. A current release is maintained in the participant's STOP-ROP file; currentness is verified at every follow-up visit.

GUIDELINES

This sample release may be edited to suit the needs of the individual Study Center.
SAMPLE COVER LETTER

Date

Doctor/Medical Records Clerk
Name of hospital
Street address
City, State Zip Code

RE: Patient’s Name

Dear Doctor/Medical Records Clerk:

Enclosed you will find a Release of Medical Records signed by the parent/legal guardian of patient ______________. I would greatly appreciate it if you would send me the discharge summary for this patient’s hospitalization from _______ to _________.

It is necessary for us to have a copy of this medical information because this patient is participating in a national study sponsored by the National Eye Institute, and we are required to document the hospitalization.

Please send the medical information to:

Study Center Coordinator
STOP-ROP
Clinical Center
Street Address
City, State Zip Code

Thank you very much for your assistance.

Sincerely,

Study Center Coordinator

Enclosure

Copy: STOP-ROP Principal Investigator

STOP-ROP VOL 1 11/15/93
INSTRUCTIONS FOR MEDICAL RECORDS RELEASE

COVER LETTER

This document is provided by the Coordinating Center as an example of a cover letter to accompany a signed authorization to release medical records.

GUIDELINES

This sample letter should be completed and signed by the Study Center Coordinator. It may be edited to suit the needs of the individual Study Center.
STOP-ROP DATA FORMS/DISKETTE SHIPPING LOG

Enclosed you will find the STOP-ROP Data Forms and/or diskettes for the patients listed below.

Study Center

<table>
<thead>
<tr>
<th>STOP-ROP ID Number</th>
<th>Name Code</th>
<th>Data Forms/Diskette</th>
<th>Date of Form/Date of Exam</th>
<th>Log Check</th>
<th>Keyed</th>
<th>Verify</th>
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</tbody>
</table>

* Shaded columns for use by Coordinating Center.

Name of person completing this form: ______________ Date of completion: ___________

Please mail to: The EMMES Corporation, 11325 Seven Locks Road, # 214, Potomac, MD 20854

STOP-ROP VO2 01/05/95
STOP-ROP DATA FORMS/DISKETTE SHIPPING LOG

The STOP-ROP Data Forms/Diskette Shipping Log is used to track STOP-ROP data forms and data diskettes submitted to the Coordinating Center. This log must accompany each shipment of forms and/or diskettes to the Coordinating Center.

GUIDELINES

1. Enter the name of the Study Center on the line provided.

2. Enter the 7-digit STOP-ROP ID Number and Name Code for each data form/diskette included in the shipment.

3. Enter the STOP-ROP data form numbers and dates for that individual. If more than one form is being sent for an infant, put each form number on a separate line and fill in the date that has been entered for question #1 of the form or the date of the exam, whichever is applicable for the form. For example, if several Weekly Outcome forms, each for the same infant, were sent in the same shipment of forms, each line entered for this infant's Weekly Outcome forms would have the corresponding date of examination entered in the date column. If a data diskette is being sent, enter “diskette” under the data form/diskette column.

4. The shipping log, data diskettes and original data forms (except STOP 00 which requires submission of the second copy) will be sent to the Coordinating Center. The Study Center Coordinator will maintain a copy of the Data Forms/Diskette Shipping Log in the STOP-ROP files. Copies of the data forms should be placed in the infant's STOP-ROP file.

5. The data diskettes should be shipped in a special cardboard mailer and should have a gummed paper label giving the STOP-ROP ID Number, Name Code, and start date. A protective label should be put on the outside of the mailing envelope denoting Caution: Floppy diskettes enclosed.

REMINDER: All diskettes sent to the Coordinating Center must be listed on a STOP-ROP Data Form/Diskette Shipping Log. For diskettes being mailed separately, fill out a Shipping Log and place it in the mailer along with the diskette.

STOP-ROP VO1 05/10/94