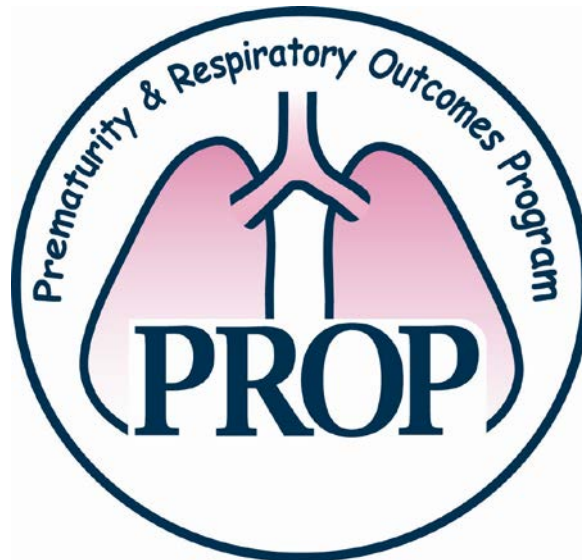


Prematurity and Respiratory Outcomes Program (PROP)

Core Database Manual of Procedures



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WEBSITE: <http://www.propstudy.org/>

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Protocol Summary

Title	Prematurity and Respiratory Outcomes Program (PROP) Core Database Study
Study Design	The PROP multicenter project establishes a core database of comprehensive clinical and outpatient data and respiratory assessments to address the primary aim. Clinical sites will collect data during hospitalization from birth to discharge such as maternal data, daily medication and respiratory support (oxygen/ventilation) data. A bundle of non-invasive respiratory assessments will be conducted at 36 and 40 weeks PMA, or discharge, whichever occurs first.
Study Duration	4 years
Study Centers	Five clinical centers (11 affiliated clinical sites) at UCSF, Washington University, Cincinnati, Vanderbilt, Rochester/Buffalo
Objectives	<ol style="list-style-type: none">1. To evaluate if a series of quantitative respiratory assessments performed prior to NICU discharge in extremely preterm infants will predict symptomatic respiratory disease and health care utilization during the first year of life more accurately than the current clinical or physiological diagnoses of BPD.2. To create a biospecimen repository for preterm infants, by collecting DNA from PROP study participants and their parents and by obtaining tracheal aspirate and urine samples from infants at pre-specified postnatal ages, that can be used to stratify patient populations based on molecular as well as clinical phenotypes.3. To collect detailed descriptive data on respiratory medication exposures in extremely preterm infants from birth through 1 year of age in order to understand the variability of current prescribing practice and its relationship to respiratory morbidity.4. To create a multi-center core database containing prospectively collected, standardized, clinical data and to test for associations between these clinical parameters and the novel, putative biomarkers with the goals of quantifying severity, refining diagnosis and prognosis, and identifying mechanisms of causation of respiratory disease in preterm infants.5. To assess pulmonary physiologic outcomes at 1 year of age by infant pulmonary function testing (iPFT) in a subset of infants to identify associations between standard measurements of lung function at 1 year and the quantitative and qualitative assessments of respiratory function and morbidity between 36 weeks PMA and 1 year of age.
Number of Participants	750
Inclusion Criteria	Gestational Age 23 0/7 – 28 6/7 weeks
ClinicalTrials.gov Identifier:	NCT01435187

1 Study Overview

1.1 Objectives

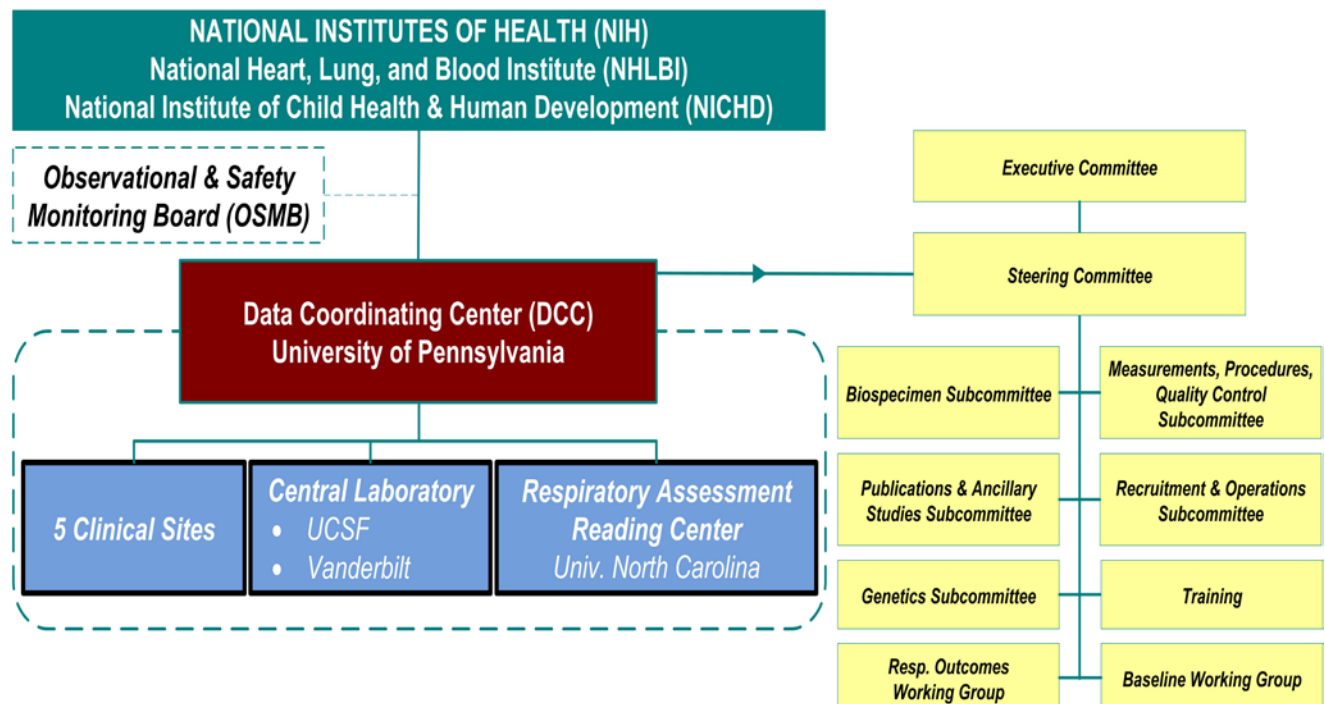
The primary aim of the PROP is to test the following hypothesis:

In survivors of extreme prematurity to 36 weeks PMA, respiratory morbidity, as described by respiratory health care utilization and respiratory symptoms between 0 and 1 year corrected age, will be predictable from biologic, physiologic and clinical data obtained during the initial hospitalization.

1.2 Description

The PROP multicenter project establishes a core database of comprehensive clinical and outpatient data and respiratory assessments to address the primary aim. Clinical sites will collect data during hospitalization from birth to discharge such as maternal data, daily medication and respiratory support (oxygen/ventilation) data. A bundle of non-invasive respiratory assessments will be conducted at 36 and 40 weeks PMA, or discharge, whichever occurs first. A comprehensive questionnaire will be administered to the primary caregiver at 3-month intervals during the first year of life to document potential risk factors for respiratory disease, respiratory symptoms, and health resource utilization including the use of respiratory medications. A focused, standardized expert physical exam will be performed at discharge and the one year visit. Infant Pulmonary Function Tests (iPFTs) will be conducted in a subgroup of PROP infants at the one year visit.

1.3 Study Organization



1.3.1 Sponsors

The National Heart, Lung and Blood Institute (NHLBI), and the National Institute of Child Health and Human Development (NICHD), of the National Institutes of Health (NIH) are the study sponsors.

1.3.2 Laboratory and Reading Centers

CENTRAL LABORATORY & READING CENTERS

Tracheal Aspirate (TA) Core Lab University of California, San Francisco San Francisco, CA	Philip L. Ballard MD, PhD
DNA and Urine Core Labs Center for Human Genetics Research (CHGR) Vanderbilt University, Nashville, TN	Judy Aschner, MD Marshall Summar, MD
RIP and Pulmonary Function Tests University of North Carolina Chapel Hill, NC	Stephanie Davis, MD

1.3.3 Data Coordinating Center

The University of Pennsylvania, School of Medicine, in Philadelphia, PA, serves as the administrative center for the PROP research network. The Center for Clinical Epidemiology and Biostatistics and the Clinical Research Computing Unit (CRCU) function as the Data Coordinating Center (DCC) for the study in providing comprehensive biostatistical support and research management, tools and technology for the study.

1.3.3.1 DCC Responsibilities

The DCC is responsible to:

- Coordinate the development of the study protocol, study forms and manual of procedures
- Develop the study statistical design
- Develop and maintain a web-based remote data capture system for the collection of study data and a web site for facilitating study communications
- Provide training and ongoing education to clinical site staff in study procedures, management, and data collection procedures
- Oversee quality control associated with the reporting and management of data (monitor data entry activities and error rates, data control, documentation of database changes)
- Prepare clinical site recruitment and retention reports and overall data quality reports.
- Monitor clinical site performance for protocol adherence and data integrity
- Prepare interim and final statistical reports

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- Track and monitor adverse events
- Track IRB approvals and expirations and provide other regulatory support as necessary
- Coordinate conference calls and study meetings.
- Provide logistical support for in-person meetings; prepare and distribute meeting materials, summaries, and follow-up on action items

1.3.4 Clinical Sites

Six clinical centers (11 affiliated clinical sites) are responsible for screening, enrolling and following PROP infants according to the protocol and established procedures. Clinical site staff includes the Principal Investigator (PI) Co-Investigator (Co-I), Research Coordinator/Study Manager, Nurse or Nurse Practitioner, Respiratory Therapist (RT), and Lab Technician. The roles of the research staff vary among sites and may include some or all of the study responsibilities. It is the responsibility of all members of the study team to adhere to the study protocol and Manual of Procedures (MOP). The participating clinical sites are:

Centers #	Affiliated Clinical Sites
01 Cincinnati	011 - Cincinnati University Hospital 012 - Cincinnati Children's Hospital 013 - Cincinnati Good Samaritan
02 Washington U	021 - Washington University
03 UCSF	031 - University of California, San Francisco 032 - Alta Bates Summit Medical Center/CHO 033 - University of Texas, Houston
04 Vanderbilt	041 - Monroe Carell Jr. Children's Hospital at Vanderbilt 042 - Jackson-Madison County General Hospital
05 Rochester and Buffalo	051 - University of Rochester 052 - University of Buffalo
06 Duke and Indiana	061 - Duke University 062 - Indiana University

1.3.4.1 Clinical Site Responsibilities

Clinical site investigators and staff will participate in planning and implementing all research activities and are responsible for all direct interactions with infants and families in enrolling and following study participants. The study will require significant effort at the clinical site in collecting data during hospitalization and the follow-up phase. Specific expertise and/or training will be required in the conduct of respiratory assessments and use of the web-based data management system. The Principal Investigator is responsible for the overall study conduct and all site related activities. Specifically, the clinical sites are responsible to:

The PI is responsible for the overall conduct of research activities at the clinical site which are to:

- Ensure that all site personnel assisting in the conduct of the study adhere to the study protocol and procedures
- Spend adequate time observing study procedures and to hold regular discussions with staff to resolve problems that may arise
- Review reported adverse events, determine level of severity
- Report to the Sponsor/DCC and IRB all changes in research activity and all unanticipated problems involving risk to human subjects
- Make no changes to the research protocol without obtaining prior Steering Committee and IRB approval except in circumstances to minimize immediate threats to the safety of human subjects
- Represent the clinical site at steering committee meetings and sub-committee meetings

The PI may delegate some or all of the following responsibilities to the Research Coordinator:

- Submit copy of IRB approval letter and approved informed consent to the DCC prior to study initiation. Also submit to the DCC, the IRB approval letter and revised informed consent documents for all protocol amendments that occur throughout the study.
- Maintain IRB correspondence and regulatory documentation
- Recruit potentially eligible participants and evaluate study infants for eligibility
- Obtain informed consent from the parent(s) before initiating research-related activities
- Instruct and educate participants regarding study follow-up contact
- Develop strategies to retain study participants
- Schedule tests and study visits and phone contacts for participants within timeframes required by the protocol
- Ensure the accuracy and completeness of data
- Resolve data queries in a timely manner
- Perform quality inspection on aspects of data collection that were completed by other study staff
- Maintain source documentation for each study participant
- Ensure the collection, storage and shipment of specimens
- Identify and document Adverse Events (AEs) and Serious Adverse Events (SAEs)

1.3.5 Communication

1.3.5.1 Distribution Lists and Email

Distribution lists will be used to communicate with clinical sites and to distribute study documents. The DCC will manage the access of study members to the list tool. If the

clinical site staff changes or requires different access to a particular list, a site staff member should contact the DCC to provide complete information about the access required for a particular individual. The following list includes the PROP lists that have been established to date:

Mailing List	Committee/Working Group
prop-bio@lists.upenn.edu	Biospecimen Committee
prop-blbpd@lists.upenn.edu	Baseline Working Group
prop-bpca@lists.upenn.edu	BPCA Working Group
prop-pi@lists.upenn.edu	Principal Investigators
prop-pulm@lists.upenn.edu	Pulmonologists
prop-resp@lists.upenn.edu	Outcome Working Group
prop-sc@lists.upenn.edu	Steering Committee
prop-rc@lists.upenn.edu	Research Coordinators
prop-pjm@lists.upenn.edu	DCC Project Managers

DCC personnel will also use email to send documents and current information to PROP study members. Email lists and individual addresses will be used to send information and documents to site staff. DCC staff members are easily accessible by email and will reply to questions and requests for information as soon as possible.

A contact list and comprehensive study directory will be developed and revised regularly to provide clinical site staff members with current email and phone contact information for all DCC, laboratory and clinical site personnel.

1.3.5.2 Web Landing Page

A web landing page will provide all PROP members with one interface from which to access study news, calendar, documents, case report forms, the data management system and tools for entering study data and all other relevant study information. The website will require a username and password in order to provide a secure environment from which to access study documents and reports.

The address of the web landing page is: <http://www.propstudy.org>
<http://rt5.cceb.upenn.edu/portal/page/portal/PROP%20Portal/PROP-Portal>

1.3.5.3 Helpdesk

The PROP DCC will operate a helpdesk to assist users in accessing the data management system. The DCC will staff the helpdesk Monday through Friday from 9 AM to 5 PM (Eastern). Assistance from the DCC helpdesk is focused on access to tools and technology to enter study data. The helpdesk contact information is listed below:

Phone: (215) 573-4623

Email: crcuhelp@mail.med.upenn.edu

Fax: (215) 573-6262

2 Launching the Study

2.1 Training

A comprehensive training session will be held before the start of the study. A minimum of two site staff members should attend the initial training session and subsequent sessions conducted over the course of the study. All members of the site staff should read the protocol, Case Report Forms (CRFs) and Manual of Procedures (MOP) in preparation for the start of the study.

As roles and responsibilities vary among sites, delegation of responsibility for the conduct of study procedures such as administration of informed consent, collecting and processing specimens, conducting the respiratory assessments and entering study data should be clearly defined and documented on the Staff Delegation of Responsibilities Log.

When a staff member leaves the study team, or a new staff member joins the study team, a new delegation log must be completed and sent to the DCC. The DCC should be notified anytime a staff member leaves the study so they can be removed from distribution lists and access to PROP tools.

One or two staff members should be designated as the Lead Trainer at each site. This person will be responsible for ensuring that PROP procedures are performed only by appropriately trained staff members. In addition, the Lead Trainer will oversee training of all staff members as well as new staff.

Two clinical site staff members should attend all data management system (DMS) training sessions. They in turn will serve as a resource for new users, as needed. All users of the DMS will be required to perform the required skills listed on the Data Management Certification Checklist (DMCERT).

The DCC will provide all training materials and checklists for documentation of training. In addition, the DCC will provide webinar training and make training materials available to clinical site staff members via the website. Each clinical site is responsible to maintain training files for each staff member of the PROP study and be able to provide these materials for review by the DCC or during a site monitoring visit.

2.2 Regulatory Documentation

1. The clinical site is responsible to submit all protocol related material to its IRB, provide the DCC with copies and retain copies for their own regulatory binder. All relevant IRB communication should be included.
2. All site personnel should be listed on the delegation of responsibility log and their role on the study must be specified. The log must be revised when study personnel resign and when new staff members join the study.
3. Regulatory binder documents should be available for review upon request by the sponsor or local institution.

2.3 Obtaining Informed Consent

Each clinical center is responsible to ensure that informed consent is obtained according to the guidelines of its local Institutional Review Board (IRB). The DCC has developed a Template Consent Form which has been reviewed and approved by the Steering Committee and the OSMB. Each site should use the template consent language as the basis for preparing its' consent form as per local IRB guidelines. The DCC must approve all local consents to ensure their consistency with the template language as well as ICH guidelines before being submitted to their IRB. Each site must also forward a copy of their local consent to the DCC when it receives IRB approval. The informed consent form must be obtained (signed and dated by the participant) before collecting study data. Specifically, the following must be accomplished during the informed consent process:

1. The parents/legal guardian must be informed that participation in the study is voluntary and that refusal to participate will involve no penalty or loss of benefits.
2. The parent/legal guardian must be informed that the study involves research.
3. The parent/legal guardian must be informed of any alternative procedures.
4. The parent/legal guardian must be informed of any reasonable foreseeable risks.
5. The parent/legal guardian must be informed of any benefits from the research.
6. An outline of safeguards to protect participant's confidentiality must be included, as well as an indication of which parties are allowed to review the data.
7. The parent/legal guardian's right to withdraw without penalty. This should be balanced with a discussion of the effect withdrawals have on the study, and the responsibility a participant has, within limits, to continue in the study if they decide to enroll.
8. The participant/parent/legal guardian must be informed of his/her right to have questions answered at any time. The RC should allow the potential participant time to consider the study obligations and discuss the study with his/her family members before signing the consent form.
9. The informed consent form must be signed in the presence of the PI or the RC, prior to collection of any study-related data or specimens.

2.3.1 Consent Process

An infant is screened to confirm his/her eligibility by reviewing the inclusion and exclusion criteria from the NICU medical record. If there is a lack of clarity in determining if an infant's family should be approached about enrolling in PROP, the person obtaining consent should discuss the infant's participation in PROP with the NICU physician. If eligible, the RC will provide the parent or legal guardian with a copy of the Informed Consent Form and ask the parent/legal guardian to read the form. After a discussion with the parent/legal guardian, the consent form must be signed and dated.

The informed consent form should be reviewed in a comfortable setting where the parent/legal guardian is able to make a free choice without pressure. Ample time should be given to allow the parent/legal guardian to thoroughly read, process the information, and ask questions. If the family wishes to take the Informed Consent home before reaching a

decision, they may do so. At the subsequent visit, the RC and/or principal investigator should answer any questions raised by the family. The importance of continued follow-up should be stressed and balanced with a discussion of the effect of participant withdrawal on the study.

The Informed Consent Form must be signed and personally dated by the parent/legal guardian, and by the person obtaining consent. A parent/legal guardian should not be asked to sign the consent statement if s/he has any doubts about enrolling their child or if the clinical staff believes s/he does not understand what participation involves. Under no circumstance is any study information to be collected or study procedures performed for the specific purpose of the trial before the participant's parent or legal guardian has signed the informed consent form.

The RC will maintain the original consent document in the participant's confidential file with other confidential documentation, and provide a copy of the signed and dated informed consent(s) to the parent/legal guardian who should be urged to retain the document for future reference. A second copy of all informed consent(s) should be made as a back up and stored together in a separate "study-confidential file". In addition, the informed consent process must be documented on a progress note or similar form as designated by your institution, signed/dated and maintained in the participant's file.

To ensure confidentiality, the RC will not send copies of the informed consent form(s) signed by the parent/legal guardian to the DCC.

2.3.2 HIPAA

Parents must sign a Health Insurance Portability and Accountability Act (HIPAA) Authorization in addition to the PROP Consent Form. The HIPAA Authorization may or may not be incorporated into the PROP consent depending on the policy of the clinical site. However, if the HIPAA language is incorporated into the Informed Consent Form, it must be submitted to the IRB for prior approval. This form describes both the kinds of health information collected in the study and also all of the disclosures of health information that will be made. The form must also list parties to whom disclosures of personal health information will be made.

2.3.3 Confidentiality

Extensive efforts will be made to ensure and maintain confidentiality of all information collected, except as may be required by law. All individually identifiable health information must be maintained in a secure area at all times and must not appear on CRFs. Consent form(s) must be maintained in a separate folder from original CRFs. If source documentation must be made available for data audits, copies of the source documents should be forwarded to the DCC with only Participant ID (PID) number visible and personal information obscured.

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The DCC staff has access to the PID number for data management purposes. All communication between the DCC staff and the clinical site staff regarding participant data occurs via the PID number only.

3 Case Report Form Guide

Enrolling infants in PROP is achieved by identifying eligible babies, obtaining parental consent, and following the infants from birth to discharge up to one year corrected age. Case Report Forms (CRFs) accompany every step of the trial, and this section is intended to assist in the collection and submission of CRF data.

Core Database Case Report Forms (CRFs)		
CRF Name	CRF Form Code	Notes
Screening for Eligibility and Consent	ELIG	Completed within 7 days of infant's birth.
Maternal Baseline Data	MABASE	Completed before mother's discharge from the hospital.
Baby's Baseline Data	BABASE	Completed within 7 days of infant's birth.
Specimen Collection	SPEC	Completed for each type of specimen collected during hospitalization.
Daily Growth and Nutrition/ Daily Medication Data	GNMDAY	Completed daily from the day of birth to EDC or discharge, whichever comes first.
Daily Respiratory Data	RESDAY	CRF To be completed daily from the day of birth to EDC or discharge, whichever comes first. Respiratory data will be collected on a <u>weekly</u> basis from infants who remain hospitalized after their EDC date.
Brain Imaging Data	BRAIN	Completed during Week 1 and Week 4 and PRN after each brain imaging between 34 and 36 weeks Post Menstrual Age.
Comorbidities of Prematurity	COMORB	Completed at Week 36, Week 40 PMA or discharge, whichever occurs first.
Additional Medication Log	ADDMED	Record any medication not listed in the Daily Medication Log that was administered to the infant during hospitalization.
Adverse Event Log	AE	Completed if any adverse events were associated with respiratory tests performed for the PROP study.
Discharge Form	DISC	Completed at infant's discharge from hospital.
Record of Death	DEATH	Completed as soon as possible after infant's death.
Study Status Form	SSTATUS	Completed if the infant's participation in the study ends early.
Follow-up Interview Form	FUP	Completed by parent interview at corrected age months 3, 6, 9, and 12. Available in Spanish.

Core Database Case Report Forms (CRFs)		
CRF Name	CRF Form Code	Notes
Standard Visit Form	STV	A brief form completed at corrected age months 3, 6, 9, and 12 to indicate the follow-up visit status.
Infant Gastro Espophageal Reflux Questionnaire	IGERQ	Completed by parent interview at corrected age months 6 and 12. Available in Spanish.
Respiratory Medication Worksheet	RESMED	The RESMED form is used during the parent interview to collect information about respiratory medications used during the follow-up phase.
Medication Log	MEDLOG	The MEDLOG lists the medications that the baby was administered in between the follow up visits.
Follow		

3.1 General Instructions

3.1.1 Collecting Data

PROP data is obtained through source documents, interviews, laboratory tests and targeted evaluations. The infant's caregiver and family should be reassured that confidentiality is maintained on all collected data, throughout the course of the study. The infant's primary caregiver/primary respondent should be urged to use their "best estimate" rather than leaving a question unanswered. However, exercise caution that you do not paraphrase or answer questions on the caregiver's behalf. The data collected should adhere to the following general rules:

1. Print legibly and clearly on all study documents – Case Report Forms (CRFs), Source Documents, Lab Forms, etc.
2. Always use a ballpoint pen with black or blue ink. Do NOT use pencil or multi-colored ink (green, red, etc).
3. Dates must match any source or supportive chart, lab, or evaluative documentation. The approved format for collecting dates is Month / Day / Year. If only partial dates are available, write in the known data and supply "01" for the missing information. For example, if a participant answers "June of 2009", but cannot recall the exact day, enter 06 / 01 / 2009.
4. Times are collected in military (24-Hour) clock format. The CRFs will also specify which collection method is being utilized. If only a partial time is available, write in the known data and supply "01" for the unknown units of time. For example, if a participant answers "a little after 4PM", but cannot remember the exact amount of minutes, enter 16:01 (24-Hour) clock.
5. Completely fill in study information at the top right corner of each CRF.
6. Provide signature and date as required on forms.
7. Do not use erasers or correction fluid.

8. If an error is made, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be clearly initialed and dated. The correct response may be circled for clarification, if necessary.
9. Avoid using abbreviations when collecting and entering data.
10. Be clear, concise, and to the point when completing CRFs, writing comments, or providing additional / supportive information.
11. Do not write comments in the margins or on the reverse side of the CRFs.
12. Keep in mind, that all information must be entered into the database to be considered study data. We are not collecting paper Case Report forms.
13. Questions should not be left unanswered. If a participant chooses to leave a question blank, write "ND per participant's choice", date and initial next to the blank question.
14. When data queries are issued for missing data fields, one can respond appropriately by referencing the CRFs.
15. Even though medical / chart information may contradict participants' response, do not alter participant responses on the participant completed CRFs.
16. Site staff will review all CRFs for inconsistencies and missing information before the participant leaves the area, and will attempt to collect any missing data.
17. The **CRF FORM CODE** is located in a box in the bottom right corner of the CRF pages; this is an abbreviation of the form name and is used in structuring the form layout within Oracle™ Clinical Remote Data Capture (RDC).
18. Each CRF is dated and identified with a version number, located in the bottom left corner. This number is important should a CRF become revised at a later date. Note the version number and date of each form, should it change for any reason you will be notified.

3.1.2 Identifying and Acquiring Case Report Forms (CRFs)

Case Report Forms (CRFs) can be obtained directly from website by accessing the Study Documents section of the PROP website. CRFs are available as Adobe Portable Document Files (pdf) in visit packets or as single forms. If paper is being used to collect data, site staff are responsible to print CRF packets from the website.

NOTE: It is not recommended that Site Staff print complete CRF visit packets for each participant at the time of enrollment (e.g. full set of CRFs from Baseline through Discharge). Rather, the staff should print only a few CRFs in advance of the infant's hospitalization. This method will:

- Ensure that all CRF packets printed represent the current version of the approved CRFs.
- Reduce wasted paper by potentially replacing newer versions of forms with older versions.
- The DCC will notify the Clinical Centers of CRF revisions which include changes to old CRFs and the introduction of new CRFs. The DCC will instruct the staff how to incorporate CRF changes into the study and how updates will impact the Data Management System (DMS).
- The website will also store CRFs and Administrative forms. **NOTE:** Administrative forms are not entered into the database.

3.1.2.1 Administrative Forms

- Administrative forms are designed to manage different aspects of study administration - Contact, etc. and are not data collection points but are useful in the day-to-day operations of the study.
- Administrative forms are not entered into the database.
- Some administrative forms contain private and confidential participant information – such as name, address, contact numbers, etc – and must be locked in a secure location. Forms that contain **Protected Health Information (PHI)** should **never be submitted to the DCC.**

3.1.2.2 Data Entry CRFs

Data Entry CRFs represent those forms that are completed by Site Staff and / or the parent, and are entered into RDC. These forms are used to gather valuable Primary and Secondary Endpoint data, safety data, and efficacy data. It is important to ensure that all questions are answered in their entirety before entry into RDC.

3.1.3 Entering and Submitting CRF Data

- ◆ *Only site staff who have been trained are permitted to enter data in the online database.*

All individuals who access the database must be documented and certified by the DCC. The site must inform the DCC when users leave the study so that access to the system can be terminated. The user who submits the data should ensure that all data are complete, accurate and supported by local source documents.

Begin the data entry process by logging onto the system with your unique username and password. Choose a CRF from the CRF Menu. Data are saved after you click the “Save Complete” button. For complete details on data entry, see Oracle Clinical Remote Data Capture (RDC) Onsite User’s Manual.

NOTE: It is not necessary to collect data on paper. ALL information must be entered into the database to be considered study data.

3.1.3.1 Source Documents

Source documents, as defined by the GCP guideline 1.52 are “Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).”

3.1.4 System Access and Security

- ◆ *Username and Password will be issued to users by the DCC.*

After training is completed, the DCC will issue a personal username and password to each individual at your clinical centre who is authorized to handle PROP data. **DO NOT SHARE YOUR PERSONAL USERNAME AND PASSWORD WITH ANYONE.** Your username and password will identify you on the system and will track your activity. The database records that you submit will be electronically stamped with your username and the date and time of the submission.

- ◆ *When you have finished working in the database, logout using the LOGOUT button on the menu.*

NEVER exit the system by closing the browser window without logging out first! For complete details on system requirements and technical support, please refer to the Oracle Clinical Remote Data Capture User Manual.

3.2 Site List and Patient Identification Numbers (PIDs)

3.2.1 Center Identification:

Center #	Site #	Site ID#	Name
01 Cincinnati	1	University	011 Cincinnati University Hospital
	2	Children's	012 Cincinnati Children's Hospital
	3	Good Samaritan	013 Cincinnati Good Samaritan
02 Washington U	1	Washington U	021 Washington University
03 UCSF	1	UCSF	031 University of California, San Francisco
	2	AB/CHO	032 Alta Bates Summit Medical Center/CHO
	3	UT Houston	033 University of Texas, Houston
04 Vanderbilt	1	MCJCHV	041 Monroe Carell Jr. Children's Hospital at Vanderbilt
	2	Jackson	042 Jackson-Madison County General Hospital
05 Rochester and Buffalo	1	Rochester	051 University of Rochester
	2	Buffalo	052 University of Buffalo
06 Duke & Indiana	1	Duke	061 Duke University Medical Center
	2	Indiana	062 Indiana University Health

3.2.2 Patient Identification Numbers (PIDs)

Each individual participating in the study must have a patient identification number (PID) which will serve as his/her unique identifier.

- ◆ *These unique patient identifiers are constructed to contain the SITE ID# (2-digit center number, followed by a 1-digit site or satellite number) and sequential 4-digit identification number.*

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For example, **Patient Position 012001** would refer to Center **01** - Cincinnati, site/satellite **2** - Cincinnati Children’s Hospital and patient number ‘0001’. RDC users are able to insert patients by selecting one of the available patient positions linked to a given site.

- ◆ *A PID Log will be provided to each site with assigned Patient Identification (PID) Numbers specific to the site. The corresponding PIDs will also be available to each site in the Remote Data Capture (RDC) interface.*

3.2.3 Data Collection

- ◆ *Screening for Eligibility and Consent [ELIG] form must be completed for all screened infants.*
- ◆ *Once the infant is enrolled into the PROP study, Maternal Baseline [MABASE] and Baby Baseline [BABASE] forms should be completed.*
- ◆ *Daily Growth and Nutrition/Daily Medication Log [GNMDAY] and the Daily Respiratory Data [RESDAY] must be completed for every day of the infant’s hospitalization dating back to the baby’s Date of Birth.*

The data must be completed using the infant’s medical record as a source document. In the event that the baby is transferred from another hospital, all efforts should be made to obtain the data needed to complete these forms.

Table 1: CRFs by Visit Schedule

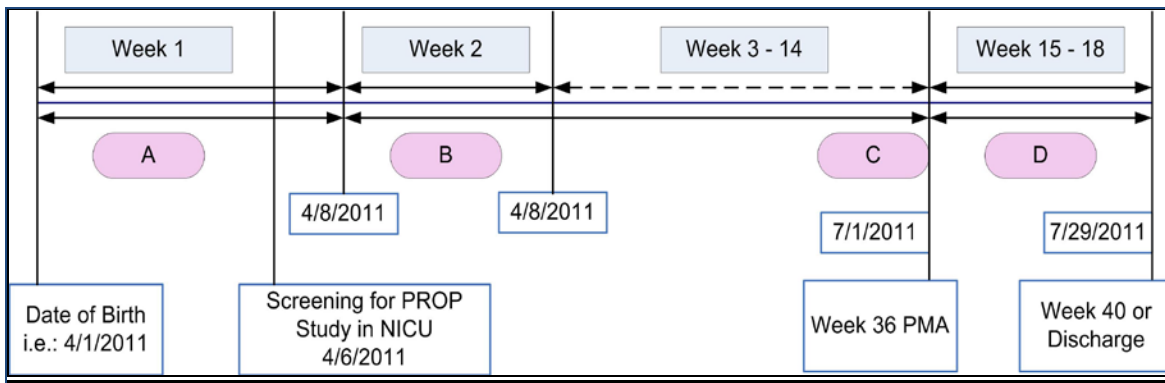
Baseline	Week 1 Week 18	PRN	Discharge
<i>NOTES: CRFs to be completed within 7 days of infant’s birth.</i>	<i>NOTES: CRFs to be completed daily.</i>	<i>NOTES: CRFs to be completed as needed.</i>	<i>NOTES: CRFs to be completed at discharge.</i>
[ELIG] Screening for Eligibility and Consent [MABASE] Maternal Baseline Data [BABASE] Baby’s Baseline Data	[GNMDAY] Daily Growth and Nutrition/Medication Log [RESDAY] Daily Respiratory Data	[BRAIN] Brain Imaging Data [SPEC] Specimen Collection Form [ADDMED] Additional Medication Log [DEATH] Record of Death [SSTATUS] Study Status Form	[COMORB] Comorbidities of Prematurity [DISC] Discharge Form [PE] Physical Exam [CONTACT] (administrative form)

3.2.4 Visit Schedule Example

Please see below for a sample CRF Completion Schedule (Figure 1):

- BASELINE** Complete **Baseline Forms: Screening for Eligibility and Consent Form [ELIG], Maternal Baseline [MABASE] and Baby Baseline [BABASE]**. These forms are completed only once during the study.
- A: WEEK 1** **Daily Growth and Nutrition/Daily Medication Log [GNMDAY] and Daily Respiratory Data [RESDAY]** must be completed daily, dating back to the baby's date of birth.
- In example timeline below, these forms should be completed for April 1, 2, 3, 4, 5, and 6th in the database.
- April 1= Week 1 Day 1= complete forms GNMDAY1 and RESDAY1
 - April 2= Week 1 Day 2= complete forms GNMDAY2 and RESDAY2
 - April 3= Week 1 Day 3= complete forms GNMDAY3 and RESDAY3
 - April 4= Week 1 Day 4= complete forms GNMDAY4 and RESDAY4
 - April 5= Week 1 Day 5= complete forms GNMDAY5 and RESDAY5
 - April 6= Week 1 Day 6= complete forms GNMDAY6 and RESDAY6
 - April 7= Week 1 Day 7= complete forms GNMDAY7 and RESDAY7
- Also to be completed in Week 1 is the **Specimen Collection Form [SPEC]** for saliva, urine and tracheal aspirate (if applicable). **Brain Imaging Data [BRAIN]** may be completed PRN.
- No matter what the gestational age of the baby is, daily forms should be completed for ALL babies beginning at Week 1.
- B: WEEK 2** In the database, forms have been provided to account for enrollment of the earliest infant at Week 23, 0/7 days PMA up to Week 40 PMA. Not all babies are expected or required to have all CRFs completed for all weeks.
- From example timeline, Week 2 will start with April 8th
- April 8= Week 2 Day 1= complete forms GNMDAY1 and RESDAY1 etc.
 - If baby was born at 23 weeks 0/7 days on April 1, 2011:
 - Each visit will be completed from Week 1 to Week 18 if baby is still hospitalized
 - Week 18 = Week 40 PMA
- C: WEEK 36** Assess and perform non-invasive respiratory tests: RIP, RAC and HCT, as appropriate.
- D: WEEK 40** If still hospitalized, assess and perform respiratory tests again if necessary. At discharge, complete the Comorbidity [COMORB] and Discharge [DISC] forms.
- If still hospitalized, after Week 40, Respiratory data must be completed on a weekly basis
 - Click on "Post 40" to complete the respiratory data pages.

Figure 1



4 Screening and Enrollment

The primary aim of the PROP study is to: identify biomarkers (biochemical, physiological and genetic) and clinical variables that are associated with and thus potentially predictive of pulmonary status in preterm infants up to 1 year corrected age.

With enrollment, certain aspects of the baby’s hospitalization will be monitored daily for the PROP study, including a daily nutrition and medication log and respiratory data up until Week 40 or Discharge. Respiratory data will be collected on a weekly basis if infant is still hospitalized after Week 40.

Sample Introduction Script:

“I would like to talk to you about a study called PROP that is being done here at [name of institution.] It is focused on breathing and lung health in premature babies, during their hospital stay and the first year of life. The screening process for the PROP Study will include premature babies born between 23 and 28 gestational age, which is why we are meeting with you today. If you are able to talk with me for a few minutes, I’d like to discuss the study with you. *As with all information we collect, the answers to these questions will be kept confidential.*” (In addition to the interview with primary caregiver, please record data using source documents such as the infant’s medical record or nursing log, whenever possible.)

4.1 Eligibility Criteria

When a preterm infant whose baby’s postnatal age is less than or equal to 7 days and is between 23 and 28 6/7 weeks gestational age is admitted to the NICU, the infant should be assessed for eligibility for the PROP study. The ELIG form should be completed on **all** infants who are evaluated. The data from this form will be entered into the Data Management System. A report generated from the ELIG form will quantify the number of infants screened, eligible/ineligible and consented/not consented.

It is possible for an infant to be enrolled in a **single site study** as well as in the core database, depending on the study criteria. This should be documented on the ELIG form, indicating the infant’s

status in question #1. If an infant is NOT enrolled in PROP, the date of birth field (question #2) will not be required in the data management system.

4.1.1 Inclusion Criteria

- Gestational Age (GA) between 23 weeks and 0/7 days and 28 weeks and 6/7 days
- Infants who are less than or equal to 7 days old

4.1.2 Exclusion Criteria

Infants who meet any of the following conditions will be excluded from the PROP cohort:

- The infant is not considered to be viable
(decision made not to provide life-saving therapies)
- Congenital heart disease
(not including PDA and hemodynamically insignificant VSD or ASD)
- Structural abnormalities of the upper airway, lungs or chest wall
- Other congenital malformations or syndromes that adversely affect life expectancy or cardio-pulmonary development
- Family is unlikely to be available for long-term follow-up

Infants may not be available for long-term follow up because their parents are not legal residents in the country, or because they live very far from the nearest PROP center, or because the child is likely to become a ward of the court. If you are uncertain about the possibility of loss to follow-up, and if there are no other exclusions present, ask the parents directly about the feasibility of performing the follow-up assessments and discuss the situation with the investigator.

4.1.3 Enrollment

An infant is enrolled in the study when she/he meets both inclusion criteria, none of the exclusion criteria and whose parent(s) consent to the study as indicated on the ELIG form. The consent section of the ELIG form should be completed for all babies who are eligible for the PROP core database.

Study data are obtained by the clinical site coordinator/manager on review of the mother's and baby's medical charts. Retrospective data should be collected on infant's who are enrolled after the first day of life. For example: if an infant is enrolled in PROP on day 5 of life, the coordinator should collect clinical data on days 1 – 4 from the medical chart and enter it into the data management system. If the infant has been transferred from an external hospital, this data may not be available, but if it is available it should be collected.

The ELIG form contains important data which are needed to generate reports and data collection schedules and should be entered into the Data Management System (DMS) as soon as possible after completion.

4.1.4 Using Scheduling Reports

The Scheduling Reports tab on the DMS section of the website contains 6 reports that provide very useful information to assist the site in identifying specific timeframes for collecting data, anticipating windows for conducting tests and contacting families.

Today is 05/15/2012

Available Reports for PROP:

Enter your Oracle Clinical Sys (re
Report Date (re
Subject ID (re

- Respiratory Assessments Report
- Visit Schedule through Follow Up Report
- Babies Approach 36 Weeks Report
- Babies Approach 40 Weeks Report
- Babies with Events in Next Week Report
- Composite Follow-up Visit Report
- Respiratory Assessments Report

4.1.5 Visit Schedule through Follow-up Report

This report provides complete information for a specific PID about the approximate date for specimen collection, data collection and tests. Data from the ELIG form (date of birth and gestational age) and the discharge form are required to run this report. It provides a complete follow-up schedule through one-year corrected age. This is a useful report to give to parents so that they can see the planned follow-up scheduled after discharge.

4.1.5.1 Babies Approaching 36 Weeks Report

This report includes infants who are between 34 weeks 0 days and 36 weeks 6 days in gestational age. Only those infants who are enrolled and assigned to the PROP Core Database are included in this report. An infant is not included in this report if a STUDY STOP form, or a DISCHARGE form, or a DEATH form has been entered.

4.1.5.2 Babies Approaching 40 Weeks Report

This report includes infants who are between 37 weeks 0 days and 40 weeks 6 days in gestational age. Only those infants who are enrolled and assigned to the PROP Core Database are included in this report. An infant is not included in this report if a STUDY STOP form, or a DISCHARGE form, or a DEATH form has been entered.

4.1.5.3 Babies with Events in the Next Week Report

This report identifies infants who are post 40 weeks 0 days and who will reach a corrected age of 13 weeks, 26 weeks, 39 weeks and 52 weeks within the next 7 days of the report date. In addition, infants who have not been discharged from the hospital will include events that would occur at 7, 14, 21... days post 40 weeks. Only those infants

that are enrolled and assigned to the PROP Core Database are included in this report. An infant is not included in this report if a STUDY STOP form or a DEATH form has been found for the subject.

4.1.5.4 Composite Follow-up Visit Report

This report includes all infants who are reaching 3 Months, 6 Months, 9 Months or 12 Months corrected age. Babies with a Study Stop form or Death form are excluded from this report. Infants who have completed the Standard Visit form (STV) for the visit are excluded from this report.

4.1.5.5 Respiratory Assessments Report

This report provides a summary of the respiratory tests (RAC, RIP and HCT) that have been conducted to date for all infants at the site to identify tests that have been performed.

All of the reports are dependent on data entry of the related forms.

4.2 Data Collection During Hospitalization

4.2.1 Paperless?

Data can be collected directly from the institution NICU clinical data system into the electronic Oracle Remote Data Capture (RDC) system “going paperless” using the electronic CRFs as a guide to data entry. Data may also be collected on paper CRFs and entered into the electronic Oracle Remote Data Capture (RDC) system. Each method has different risks and benefits. Entering data without using paper CRFs is often faster than writing on CRFs but it can result in errors that are difficult to resolve.

Collecting a high volume of daily data can result in errors, often in date fields, which can cause erroneous calculations and reports. To ensure accuracy while collecting data it is helpful to have a schedule for collecting and entering data, ideally performed by a small number of designated staff members. A process should also be developed for correcting data that generate discrepancies or resolving queries generated by the DCC.

4.2.2 Daily Data Collection

1. GNMDAY Form

Growth, nutrition, and medication data are collected on a daily basis during initial hospitalization through 40 weeks PMA. This data collection instrument is *discontinued* after 40 weeks 6/7 days PMA.

2. RESDAY Form

Respiratory data is collected on a daily basis from initial hospitalization through 40 weeks 6/7 days PMA. When the infant reaches 40 weeks PMA, respiratory data will be collected on a *weekly* basis during the period of continued hospitalization until the baby

reaches 3 months corrected age. At 3 months corrected age, data will no longer be collected via the RESDAY form. A Follow-up Interview [FUP] should be completed, indicating that the infant is still hospitalized.

4.3 Collecting Data from External Hospital

When an infant is transferred to a non-PROP hospital, it may be possible to continue to collect data about her/his respiratory status and medications. If the transfer hospital is part of the institutional network (covered entity) you are permitted to access and record this information by the signed informed consent document. Ideally, you should continue to collect daily respiratory and medication data. However, if the transfer hospital is not part of the hospital consortium agreement, you will need explicit permission to collect and submit this data to the PROP database. A current signed, release of information form from the transfer hospital is required in this situation. Depending on availability, it may be possible to continue to collect daily respiratory and medication data though such a request may exceed the capability of the transfer hospital. In this situation, you should strive to collect respiratory and medication data until the time of discharge on a *weekly* basis.

PROP tests, specimens or assessments may not be conducted in hospitals outside of the covered entity.

4.3.1 36 Weeks PMA

When an infant approaches 36 weeks (± 1 week) PMA or discharge, whichever occurs first, he/she should be assessed for eligibility to conduct non-invasive respiratory assessments (NIRA). There are two classes of NIRAs: challenges studies and observational studies. Challenge NIRAs assess respiratory function in response to a change in FiO₂, whereas observational NIRAs analyze respiratory data acquired during feeding or sleep. The Room Air Challenge (RAC) and Hypoxic Challenge Test (HCT) are challenge tests; the Respiratory Inductive Plethysmography (RIP) test is an observational NIRA. The NIRA manual and Frequently Asked Questions (FAQ) document contain complete information about the eligibility and conduct of these tests. Infants that cannot have NIRA tests at during the 36 week time frame because of instability or the level of respiratory support should be assessed again at 40 weeks PMA for eligibility for NIRA tests, if still hospitalized.

4.4 Using 'As Needed' Forms

'As Needed' Forms include the following: Additional Medication Log, Record of Death, Study Status, Brain Imaging and Specimen collection. These forms are located in a separate visit from other data collection forms and can be entered at any point of the study. They are currently found in the PRN visit.

5 Remote Data Capture (RDC) Interface:

[ELIG] Screening for Eligibility and Consent – Screen 1

This section describes the Screening for Eligibility and Consent. All babies screened for the PROP multicenter study should be entered on this form.

SCREENING FOR ELIGIBILITY AND CONSENT	
1. Indicate the baby's data set (check all that apply):	<input type="checkbox"/> PROP Core Database <input type="checkbox"/> Single-Center Data Set
2. What is the baby's date of birth?	_____ Month Day Year
3. What is the baby's time of birth?	_____ 24 hour clock
4. Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female
5. Infant Ethnicity (reported by parent)	<input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino
6. Infant Race (reported by parent- check all that apply)	<input type="checkbox"/> North American Indian/ Native Alaskan <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> Native Hawaiian/ Other Pacific Islander <input type="checkbox"/> White/ Caucasian <input type="checkbox"/> Other: _____
Record all babies who fulfill the single center inclusion criteria and/or both of the PROP Inclusion Criteria below.	
Inclusion Criteria:	
7. Is the baby's Gestational Age (GA) between 23 and 0/7 days and 28 weeks and 6/7 days?	<input type="checkbox"/> No <input type="checkbox"/> Yes
7a. Indicate the number of completed weeks and the number of completed days:	___ Weeks ___ Day
7b. What method was used to determine the Gestational Age of the baby?	<input type="checkbox"/> Early dating ultrasound (<20 weeks) <input type="checkbox"/> Certain LMP date (if early dating ultrasound is not available) <input type="checkbox"/> Best clinical estimate (if certain LMP date is not available)
8. Is the baby's postnatal age less than or equal to 7 days?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Exclusion Criteria:	
9. Is the baby considered not to be viable (decision not to administer effective therapies)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
10. Does the baby have congenital heart disease (not including PDA and hemodynamically insignificant VSD or ASD)?	<input type="checkbox"/> No <input type="checkbox"/> Yes

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[ELIG] Screening for Eligibility and Consent – Screen 1

- Q 1:** **Indicate the infant’s data set (check all that apply):**
Please select one or both options.
*(Note that validation checks will be implemented only for PROP Multi-site Core Database and not the Single –Center Database.)
- Q 2:** **What is the baby’s date of birth?**
Please enter to the child’s birth date in “mm/dd/yyyy” format.
- Q 3:** **What is the baby’s time of birth?**
Please enter to the child’s time of birth using military time or 24 hour clock [hours: minutes: seconds]. Acceptable ranges include 00:00:00 [12:00 am] to 23:59:00 [11:59 pm].
- Q 4:** **Gender**
Record the participant's gender by checking the appropriate box, 1-Male, 2-Female.
- Q 5:** **Infant Ethnicity (reported by parent)**
Record the participant's ethnicity by checking the appropriate box, “1-Hispanic or Latino”, 2-Not Hispanic or Latino”.
This field must always be completed for reporting purposes.
- Q 6:** **Infant Race (reported by parent- check all that apply)**
Check the appropriate response(s) for each race that applies to the participant. If ‘Other’ is checked, please be as specific as possible. Information from this question is crucial for reporting demographic information.
- Q 7:** **Is the baby’s Gestational Age (GA) between 23 weeks and 0/7 days and 28 weeks and 6/7 days?**
Please respond by checking the appropriate box, “0-No” or “1-Yes” based on gestational age recorded in medical records.
- Q 7a:** **Indicate the number of completed weeks and completed days:**
Please provide gestational age in weeks and days. Please note: in order to be enrolled in the PROP Multisite Core Database, the infant must be between 23 weeks and 0/7 days to 28 weeks and 6/7 days.
- Q 7b:** **What method was used to determine the Gestational Age of the baby?**
Select one response that best describes the method used to determine the Gestational Age of the baby.
- Q 8:** **Is the baby’s postnatal age less than or equal to 7 Days?**
Please respond using date of birth recorded in medical records and in above question.
- Q 9:** **Is the baby considered not to be viable (decision not to administer effective therapies)?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. Please note, this is part of the exclusion criteria. If “1-Yes” is checked, participant is not eligible to be enrolled in the PROP study.
- Q 10:** **Does the baby have congenital heart disease?**
Please do not include PDA and hemodynamically insignificant VSD or ASD and respond by checking the appropriate box, “0-No” or “1-Yes”. Please note, this is part of the exclusion criteria. If “1-Yes” is checked, participant is not eligible to be enrolled in the PROP study.

[ELIG] Screening for Eligibility and Consent – Screen 2

SCREENING FOR ELIGIBILITY AND CONSENT

11. Does the baby have any structural abnormalities of the upper airway or lungs? No Yes

12. Does the baby have any other congenital malformations or syndromes that adversely affect life expectancy or development? No Yes

13. Is the baby unlikely to be available for long term follow-up? No Yes

Eligibility:

14. Does the baby meet both of the inclusion criteria and none of the exclusion criteria and is therefore eligible for the Core Database? No Yes

Complete the Consent Section only for babies who are eligible for the PROP Multi-site Core Database.

Consent

15. Were the parents of the baby approached about the study? No Yes

15a. If No, select the primary response that best explains why the parents were not approached:

- Research staff was not available
- Parents were not available
- Screening oversight
- On request of responsible physician
- Other, specify: _____

15b. If Yes, was parental consent obtained? No Yes

15c. If Question 15b is No, select the primary response that best explains why consent was not obtained:

- Parents object to participation in research studies
- Baby was enrolled in another research study
- Parents objected to long term follow-up
- Other, specify: _____

16. Was parental consent obtained for DNA sample collections? No Yes

16a. If Yes, indicate which samples were given consent: (check all that apply)

- Infant
- Mother
- Father

Enrollment

17. Was the baby enrolled into the study? No Yes

17a. If Yes, enter Date of Enrollment _____

The date of enrollment is the date on which the parent is notified that the baby has been enrolled, after documentation of parental consent and re-confirmation of the baby's eligibility for the multicenter PROP study. Month Day Year

[ELIG] Screening for Eligibility and Consent – Screen 2

- Q 11: Does the baby have any structural abnormalities of the upper airway or lungs?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. Please note, this is part of the exclusion criteria. If “1-Yes” is checked, participant is not eligible to be enrolled in the PROP study.
- Q 12: Does the baby have any other congenital malformations or syndromes that adversely affect life expectancy or development?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. Please note, this is part of the exclusion criteria. If “1-Yes” is checked, participant is not eligible to be enrolled in the PROP study.
- Q 13: Is the baby unlikely to be available for long-term follow-up?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. Please note, this is part of the exclusion criteria. If “1-Yes” is checked, participant is not eligible to be enrolled in the PROP study. In order to determine whether a family will be available for long-term follow-up, ask the following questions before considering the infant for enrollment:
- Are the parents legal residents in your country?
 - How far is the family residence from the nearest PROP centre?
 - Is the child likely to become a ward of the court?
- Q 14: Does the baby meet both of the inclusion criteria and none of the exclusion criteria and is therefore eligible for the Core Database?**
Based on responses above, record if baby is eligible to participate in the study. If ineligible, the patient icon and certain fields will appear yellow once the form is saved as complete. The yellow icon will indicate an ineligible baby.
- Next set of questions refer to Consent and should be answered for those infants who are eligible for the PROP Multi-site Core Database only.**
- Q 15: Were the parents of the baby approached about the study?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. If “No”, please complete question 15a. If “Yes”, skip #15a and answer question 15b.
- Q 15a: If No, select the primary response that best explains why the parents were not approached:**
Please select the best response. If “Other” is checked, be as specific as possible.
- Q 15b: If Yes, was parental consent obtained?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. If question 15b is “No”, answer question 15c. If response to question 15b is “Yes”, skip to Question 16.
Confirm that the parents were approached about the PROP study. If they were not approached, provide the reason why.
- Q 15c: If Question 15 b is No, select the primary response that best explains why consent was not obtained:**
Please select the best response. If “Other” is checked, be as specific as possible.
- Q 16: Was parental consent obtained?**
Please respond by checking the appropriate box, “0-No” or “1-Yes”. If “Yes”, please complete question 16a.
- Q16a:** If yes, indicate which samples were obtained. Check all that apply.
- Q17: Was the baby enrolled into the study?**
If “Yes”, enter date of enrollment under question 17a.

[MABASE] Maternal Baseline Data – Screen 1

MATERNAL BASELINE DATA

Maternal Demographic Data:

1. What is the mother's date of birth? _____
Month Day Year

2. What is the mother's ethnicity? Hispanic or Latino
 Not Hispanic or Latino

3. What is the mother's race (check all that apply)? North American Indian/ Native Alaskan
 Asian
 Black/ African American
 Native Hawaiian/ Other Pacific Islander
 White/ Caucasian
 Other _____

4. What is the mother's highest level of education? Less than 7th grade
 7th - 9th grade
 10-12th grade
 High school degree
 Partial college
 College degree
 Graduate degree
 Unknown

5. What is the family arrangement? Single parent family
 Two parent family
 Unknown

Paternal Demographic Data:

6. Was demographic data about the **biological father** obtained? No Yes

If Yes, please complete questions #7-9, regarding the **biological father**.

7. What is the father's ethnicity? Hispanic or Latino
 Not Hispanic or Latino

8. What is the father's race (check all that apply)? North American Indian/ Native Alaskan
 Asian
 Black/ African American
 Native Hawaiian/ Other Pacific Islander
 White/ Caucasian
 Other: _____

9. What is the father's highest level of education? Less than 7th grade
 7th - 9th grade
 10-12th grade
 High school degree
 Partial college
 College degree
 Graduate degree
 Unknown

[MABASE] Maternal Baseline Data – Screen 1

This section refers to maternal data and includes maternal birth date, ethnicity, family and partnership arrangements, education level, occupational status as well as maternal management, labor and delivery details. Some of these details may require maternal interview and should be collected as soon as possible after the mother has recovered from delivery. These items can be difficult to collect once the mother has been discharged from the hospital.

Introduction Script:

Good Morning/Afternoon- Ms. <Mother's name>. For the PROP study, we need to collect information pertaining to the biological parents of the infant. First, we'll collect your demographic data and if possible, paternal information as well. It is important that we obtain information about the BIOLOGICAL parents only. Please be as honest as possible and if information is unknown, please notify the interviewer.

Q 1: What is the mother's date of birth?

Please enter to the mother's birth date in "mm/dd/yyyy" format.

Q 2: What is the mother's ethnicity?

Record the participant's ethnicity by checking the appropriate box, "1-Hispanic or Latino", 2-Not Hispanic or Latino". Choose only ONE response. If the mother states that her ethnic background is mixed, ask the mother to choose which ethnic origin she considers to have had more importance to her. Indicate this single choice as her Ethnicity. This field must always be completed for reporting purposes.

Q 3: What is the mother's race?

Check the appropriate response(s) for each race that applies to the participant. If 'Other' is checked, please be as specific as possible. Information from this question is crucial for reporting demographic information.

Q 4: What is the mother's highest level of education?

Indicate the highest level of education obtained up to time of delivery.

Q 5: What is the family arrangement?

Specify whether family arrangement is single or two-parent family. If the second parent does not live with the family in the same residence but is significantly involved, choose a two-parent family.

Q 6: Was demographic data about the biological father obtained?

Indicate if any demographic data was obtained from either the primary caregiver or biological father. Please respond by checking the appropriate box, "0-No" or "1-Yes".

Q 7: What is the father's ethnicity?

Record the participant's ethnicity by checking the appropriate box, "1-Hispanic or Latino", 2-Not Hispanic or Latino". Choose only ONE response. If the father states that his ethnic background is mixed, ask the father to choose which ethnic origin he considers to have had more importance to him. Indicate this single choice as his Ethnicity. This field must always be completed for reporting purposes.

Q 8: What is the father's race?

Check the appropriate response(s) for each race that applies to the participant. If 'Other' is checked, please be as specific as possible. Information from this question is crucial for reporting demographic information.

Q 9: What is the father's highest level of education?

Indicate the highest level of education achieved.

[MABASE] Maternal Baseline Data – Screen 2

MATERNAL BASELINE DATA		
Pregnancy History:		
10. Did the mother have diabetes during pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
10a. If Yes, did she receive insulin for her diabetes?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
11. Did the mother have hypertension during pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
11a. If yes, did she receive medication to treat her hypertension?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
12. Did the mother have asthma during her pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
12a. If yes, did she take medication regularly to control her asthma?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
13. Did the mother take any medications to prolong pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
13a. If Yes , check all that apply:	<input type="checkbox"/> Progesterone <input type="checkbox"/> Cyclooxygenase inhibitors (Indocin) <input type="checkbox"/> Oral betamemetics <input type="checkbox"/> Calcium Channel Blockers <input type="checkbox"/> Oxytocin receptor antagonist <input type="checkbox"/> Magnesium Sulfate <input type="checkbox"/> Other _____	
14. Was a maternal or neonatal toxicology screen performed at the time of birth?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
14a. If Yes , indicate the results:	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive
14b. If Positive , indicate the substances (check all that apply)	<input type="checkbox"/> Amphetamines <input type="checkbox"/> Cocaine <input type="checkbox"/> Opiates <input type="checkbox"/> Barbiturates <input type="checkbox"/> Benzodiazepines <input type="checkbox"/> Phencyclidine (PCP) <input type="checkbox"/> Tetrahydrocannabinol (THC) <input type="checkbox"/> Ethanol <input type="checkbox"/> Methadone <input type="checkbox"/> Other: _____	
15. Did the mother smoke tobacco products during pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
15a. Did anyone else smoke tobacco regularly in the mother's home during her pregnancy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
16. Indicate the mother's height and weight at the time of delivery:	Height _____ cm	<input type="checkbox"/> Unknown
	Weight _____ kg	<input type="checkbox"/> Unknown

PROP Manual of Procedures (MOP)

[MABASE] Maternal Baseline Data – Screen 2

Introduction Script:

We will now discuss the pregnancy history- please keep in mind that we are collecting data for this pregnancy only.

Q 10-10a: Did the mother have diabetes during pregnancy?

Indicate if the mother had diabetes and if she received insulin at anytime during pregnancy. If response to Question 10 is 'No', please skip question 10a.

Q 11-11a: Did the mother have hypertension during pregnancy?

Indicate if the mother had hypertension and if she received medication at anytime during pregnancy. If response to Question 11 is 'No', please skip question 11a.

Q 12-12a: Did the mother have asthma during pregnancy?

Indicate if the mother had asthma and if she received medication at anytime during pregnancy. If response to Question 12 is 'No', please skip question 12a.

Q 13: Did the mother take any medications to prolong pregnancy?

Indicate if the mother was taking medication at anytime during pregnancy..

Q 14: Was a maternal or neonatal toxicology screen performed at the time of birth?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Q 14a: If Yes, indicate the results?

If response to question 14 is No, skip question 14a.

Q 14b: If Positive, indicate the substances (check all that apply):

If response to question 14a is 'Positive', indicate all substances that were screened for at the time of birth.

Q 15: Did the mother smoke tobacco products during pregnancy?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Q 15a: Did anyone else smoke tobacco regularly in the mother's home during her pregnancy?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Q 16: Indicate the mother's height and weight at the time of delivery

If Unknown, check box.

[MABASE] Maternal Baseline Data – Screen 3

MATERNAL BASELINE DATA	
Labor and Delivery Data:	
17. Was there placental abruption?	<input type="checkbox"/> No <input type="checkbox"/> Yes
18. Was the membrane rupture >18 hours before delivery?	<input type="checkbox"/> No <input type="checkbox"/> Yes
18a. If Question 18 is Yes, did the membrane rupture more than 7 days before delivery?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
19. Was there any clinical chorioamnionitis?	<input type="checkbox"/> No <input type="checkbox"/> Yes
19a. If Yes , was placental pathology obtained?	<input type="checkbox"/> No <input type="checkbox"/> Yes
19b. If Question 19a is Yes , was there histologic evidence of chorioamnionitis?	<input type="checkbox"/> No <input type="checkbox"/> Yes
20. Were antibiotics given?	<input type="checkbox"/> No <input type="checkbox"/> Yes
20a. If Yes , why were antibiotics given? (check all that apply)	<input type="checkbox"/> Chorioamnionitis <input type="checkbox"/> Group B Streptococcus (GBS) prophylaxis <input type="checkbox"/> Preterm labor <input type="checkbox"/> Other _____
21. Were antenatal corticosteroids given?	<input type="checkbox"/> No <input type="checkbox"/> Yes
21a. If Yes , total number of completed courses:	<input type="checkbox"/> None <input type="checkbox"/> One course <input type="checkbox"/> Two courses <input type="checkbox"/> Three courses <input type="checkbox"/> Four courses <input type="checkbox"/> Five courses
21b. Number of incomplete courses:	<input type="checkbox"/> None <input type="checkbox"/> One or more courses
22. Was magnesium sulfate given for any reasons other than tocolysis?	<input type="checkbox"/> No <input type="checkbox"/> Yes
22a. If Yes , check the primary indication:	<input type="checkbox"/> Preeclampsia/ eclampsia <input type="checkbox"/> Prevention of Cerebral Palsy
23. Was the onset of labor spontaneous?	<input type="checkbox"/> No <input type="checkbox"/> Yes
24. What was the mode of delivery?	<input type="checkbox"/> Vaginal Vertex <input type="checkbox"/> Vaginal Breech <input type="checkbox"/> Caesarian Section

PROP Manual of Procedures (MOP)

[MABASE] Maternal Baseline Data – Screen 3

Introduction Script:

We will now discuss the labor and delivery process. Please let interviewer know if a response is unknown.

Q 18: Was there placental abruption?

Indicate if placental abruption was present. Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 19: Did the membrane rupture > 18 hours before delivery?

Indicate if the membranes ruptured more than 18 hours before delivery. Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 19a: If Question 19 is Yes, did the membrane rupture more than 7 days before delivery?

Please respond by checking the appropriate box, “0-No”, “1-Yes” or “88-Unknown”. If response to question 19 is No, please skip question 19a.

Q 20: Was there any clinical chorioamnionitis?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If response is No, skip question 20a and 20b.

Q 20a: If Yes, was placental pathology obtained?

Complete question if response to question 20 is Yes. Please respond by checking the appropriate box, “0-No” or “1-Yes”. If response is No, skip question 20b.

Q 20b: If Question 20a is Yes, was there histologic evidence of chorioamnionitis?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 21: Were antibiotics given?

Indicate if antibiotics were given. Please respond by checking the appropriate box, “0-No” or “1-Yes”. If response is No, skip question 21a.

Q 21a: If Yes, why were antibiotics given?

Check all that apply.

Q 22: Were antenatal corticosteroids given?

Indicate if antenatal steroids were given. Please respond by checking the appropriate box, “0-No” or “1-Yes”. If response is No, skip questions 22a and 22b.

Q 22a-22b: If Yes, total number of completed courses:

Indicate the total number of completed courses in addition to the number of incomplete courses in question 22b.

Q 23: Was magnesium sulfate given for any reasons other than tocolysis?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If no, skip question 23a.

Q 23a: If Yes, check the primary indication

Select only one response.

Q 24: Was the onset of labor spontaneous?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 25: What was the mode of delivery?

Select the best primary response.

[BABASE] Baby's Baseline Data

BABY'S BASELINE DATA	
1. What is the baby's gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female
2. What is the baby's birth weight?	_____ gms
3. What is the baby's head circumference?	_____ cm
4. What was the baby's birth location?	<input type="checkbox"/> Born inside the study center <input type="checkbox"/> Born outside the study center
5. What was the baby's expected date of birth (EDC)?	_____ Month Day Year
6. Was this a multiple birth?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If Yes, answer questions 6a and 6b.	
6a. Indicate the baby's birth order	____ Number of ____ Number
6b. Record the PID(s) of siblings enrolled in the PROP Multicenter core database:	____ PID 1 ____ PID 2
7. Were umbilical cord blood gas analyses performed?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If Yes, record the result(s) of the umbilical cord blood gas analysis:	
7a. Sample pH: _____ Base Deficit: _____	
Type of sample: <input type="checkbox"/> Venous <input type="checkbox"/> Arterial <input type="checkbox"/> Uncertain	
7b. Sample pH: _____ Base Deficit: _____	
Type of sample: <input type="checkbox"/> Venous <input type="checkbox"/> Arterial <input type="checkbox"/> Uncertain	
8. What was the APGAR Score? _____ [0-10] at 1 minute _____ [0-10] at 5 minutes	
9. Were any stabilization procedures provided at birth?	<input type="checkbox"/> No <input type="checkbox"/> Yes
9a. If Yes, check all that apply:	
<input type="checkbox"/> Supplemental Oxygen	
<input type="checkbox"/> CPAP	
<input type="checkbox"/> Non-invasive positive pressure ventilation with flow inflating or self inflating bag	
<input type="checkbox"/> T-Piece resuscitator	
<input type="checkbox"/> Intubation	
<input type="checkbox"/> Chest Compression	
<input type="checkbox"/> Cardiac Drugs (Epinephrine)	
<input type="checkbox"/> Surfactant Administration	
10. What was the first temperature recorded at the first NICU admission? _____ degrees C	
10a. Indicate how the temperature was obtained:	<input type="checkbox"/> Core temperature (e.g. rectal), or <input type="checkbox"/> Peripheral/ skin temperature (e.g. axillary)
11. Was Prophylactic Indomethacin given within the first 24-hours of life?	<input type="checkbox"/> No <input type="checkbox"/> Yes

PROP Manual of Procedures (MOP)

[BABASE] Baby's Baseline Data

Introduction Script:

This form focuses on the infant's data from birth to NICU admission. It contains characteristics of the infant at birth, including gender, and birth weight.

- Q 1: What is the baby's gender?**
Record the infant's gender.
- Q 2: What is the baby's birth weight?**
Record the infant's birthweight in grams.
- Q 3: What is the baby's head circumference?**
Record the infant's head circumference in centimeters.
- Q 4: What was the baby's birth location?**
Select the best response.
- Q 5: What was the baby's expected date of birth (EDC)?**
Provide the infant's expected date of birth.
- Q 6: Was this a multiple birth?**
Please respond by checking the appropriate box, "0-No" or "1-Yes".
- Q 6a: If Yes, indicate the baby's birth order:**
If baby was one of a multiple birth, provide the birth order. The denominator should be the total number delivered, regardless of survival.
- Q 6a: Record the PID(s) of siblings enrolled in the PROP Multicenter Core database.**
Enter up to two PIDs.
- Q 7: Were umbilical cord blood gas analyses performed?**
Please respond by checking the appropriate box, "0-No" or "1-Yes". If Yes, complete questions 7a-7b.
- Q 7a-7b: Provide umbilical cord pH and Base Deficit values and indicate type of sample.**
- Q 8: What was the APGAR Score?**
Provide the APGAR [0-10] at 1 minute and 5 minutes.
- Q 9-9a: Were any stabilization procedures provided at birth?**
Please respond by checking the appropriate box, "0-No" or "1-Yes." If Yes, complete questions 9a, checking all that apply.
- Q 10: What was the first temperature recorded at the first NICU admission?**
Provide first temperature recorded.
- Q 10a: Indicate how the temperature was obtained**
Select best response.
- Q 11: Was Prophylactic Indomethacin given within the first 24-hours of life?**
Please respond by checking the appropriate box, "0-No" or "1-Yes." Indomethacin for prophylaxis includes indomethacin administered to prevent PDA or IVH; this question is concerned only with prophylactic indomethacin.

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 1

Daily Growth and Nutrition / Daily Medication Data			
Daily Growth and Nutrition Data			
For question 1 and 2: If more than one measurement is taken on the same day, enter the first value obtained.			
1. What was the baby's body weight?	_____ gms	<input type="checkbox"/> Not done	
2. What is the baby's head circumference	_____ cm	<input type="checkbox"/> Not done	
3. How much milk did the baby receive today?		<input type="checkbox"/> None <input type="checkbox"/> Partial Feed <input type="checkbox"/> Full Feed (no parenteral nutrition on this day)	
3a. If Partial or Full indicate the type of milk provided:		<input type="checkbox"/> Human milk <input type="checkbox"/> Formula <input type="checkbox"/> Both	
Daily Medication Data			
4. Were any drugs given today?		<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes, indicate which of the following drugs were given today:			
5. Methylxanthine drugs		<input type="checkbox"/> No	<input type="checkbox"/> Yes
5a. If Yes, choose one:			
<input type="checkbox"/> Caffeine Citrate	Dose _____ mg	Given every _____ hour(s)	Route: <input type="checkbox"/> PO <input type="checkbox"/> IV
<input type="checkbox"/> Aminophylline	Dose _____ mg	Given every _____ hour(s)	
<input type="checkbox"/> Theophylline	Dose _____ mg	Given every _____ hour(s)	
<input type="checkbox"/> Other (record on the Additional Medication Log)			
* If your site calculates the dose of Anhydrous Caffeine Base rather than Caffeine Citrate, multiply the Caffeine Base dose by 2.			
6. Systemic Corticosteroid drugs:		<input type="checkbox"/> No	<input type="checkbox"/> Yes
6a. If Yes, choose one:			
<input type="checkbox"/> Hydrocortisone	Dose _____ mg	Given every _____ hour(s)	Route: <input type="checkbox"/> PO <input type="checkbox"/> IV
<input type="checkbox"/> Dexamethasone	Dose: _____ mg	Given every _____ hour(s)	Route: <input type="checkbox"/> PO <input type="checkbox"/> IV
<input type="checkbox"/> Prednisone/Prednisolone	Dose: _____ mg	Given every _____ hour(s)	
<input type="checkbox"/> Methylprednisolone	Dose: _____ mg	Given every _____ hour(s)	
<input type="checkbox"/> Other (record on the Additional Medication Log)			

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 1

The next set of questions should be completed daily from birth to Week 40 Post Menstrual Age (PMA) or discharge, whichever occurs first. It will describe use of respiratory supports, duration and amount of exposure to supplemental oxygen and nitric oxide, growth parameters and feeding status. It is vital to the PROP study that these questions are completed and we thank you in advance for your cooperation. As always, please use medical records and appropriate source documents to record data.

Please note for questions 1 and 2, if multiple measurements are taken,
please record only the first value obtained.

Q 1: What was the baby's body weight?

Record the baby's body weight in grams. This should be recorded as often as available and at least once per week.

Q 2: What was the baby's head circumference?

Record infant's head circumference in centimeters. This should be recorded as often as available and at least once per week.

Q 3: How much milk did the baby receive today?

Indicate None, Partial Feeds or Full feeds (no parenteral nutrition given)

Q 3a: indicate the type of milk provided:

If PARTIAL or FULL milk feed, indicate if it was human milk, formula or both.

Q 4: Were any drugs given today?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

If Yes, indicate which drugs were given today.

Q 5-5a: Methylxanthine drugs:

Please respond by checking the appropriate box, "0-No" or "1-Yes". If Yes, please specify which medication (choose one) and provide dose, frequency and route if applicable. If there is another medication not listed, please record the medication in the Additional Medication Log (ADDMED).

Q 6-6a: Systemic Corticosteroid drugs

Please respond by checking the appropriate box, "0-No" or "1-Yes". If Yes, please specify which medications and provide dose, frequency and route if applicable. Please note: these medications are PO or IV, not Inhaled. For Inhaled Steroids, please see question #7. If there is another medication not listed, please record the medication in the Additional Medication Log (ADDMED).

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 2

NOTE: If utilizing a combination therapy drug, record the individual components in their respective drug categories. For example Symbicort (Budesonide and Formoterol) would be recorded as Budesonide - Inhaled Steroid and Formoterol - Inhaled Bronchodilator.

7. Inhaled Steroid drugs

No Yes

7a. If Yes, check all that apply:

- | | | |
|--|--|---------------------------|
| <input type="checkbox"/> Budesonide (Nebulized or MDI) | Dose: _____ <input type="checkbox"/> mcg <input type="checkbox"/> mg | Given every _____ hour(s) |
| <input type="checkbox"/> Beclomethasone | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Ciclesonide | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Flunisolide | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Fluticasone | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Mometasone | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Triamcinolone | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Dexamethasone | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Other (record on the Additional Medication Log) | | |

If route of administration is Metered Dose Inhalator (MDI), calculate dose by multiplying the number of puffs by strength per puff.

8. Inhaled Bronchodilator drugs

No Yes

8a. If Yes, check all that apply:

- | | | |
|--|--|---------------------------|
| <input type="checkbox"/> Albuterol | Dose: _____ <input type="checkbox"/> mcg <input type="checkbox"/> mg | Given every _____ hour(s) |
| <input type="checkbox"/> Levalbuterol | Dose: _____ <input type="checkbox"/> mcg <input type="checkbox"/> mg | Given every _____ hour(s) |
| <input type="checkbox"/> Ipratropium bromide | Dose: _____ <input type="checkbox"/> mcg <input type="checkbox"/> mg | Given every _____ hour(s) |
| <input type="checkbox"/> Formoterol | Dose: _____ mcg | Given every _____ hour(s) |
| <input type="checkbox"/> Racemic epinephrine | Dose: _____ mg | Given every _____ hour(s) |
| <input type="checkbox"/> Other (record on the Additional Medication Log) | | |

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 2

If utilizing a combination therapy drug, record the individual components in their respective drug categories. For example Symbicort (budesonide and formoterol) would be recorded as budesonide – Inhaled Steroid and formoterol – Inhaled Bronchodilator.

Q 7- 7a: Inhaled Steroid Drugs:

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications and provide dose, frequency and route if applicable. If there is another medication not listed, please record the medication in the Additional Medication Log (ADDMED).

Q 8-8a: Inhaled bronchodilator drugs:

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications and provide dose, dose units, frequency and route if applicable. If there is another medication not listed, please record the medication in the Additional Medication Log (ADDMED).

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 3

NOTE: If utilizing a combination therapy drug, record the individual components in their respective drug categories. For example Aldactazide (Spironolactone and Hydrochlorothiazide) would be recorded as Spironolactone and Hydrochlorothiazide.

9. Diuretic drugs No Yes

9a. If Yes, check all that apply:

- | | | | |
|--|----------------|---------------------------|---|
| <input type="checkbox"/> Furosemide | Dose: _____ mg | Given every _____ hour(s) | Route: <input type="checkbox"/> PO
<input type="checkbox"/> IV |
| <input type="checkbox"/> Bumetanide | Dose: _____ mg | Given every _____ hour(s) | Route: <input type="checkbox"/> PO
<input type="checkbox"/> IV |
| <input type="checkbox"/> Chlorothiazide | Dose: _____ mg | Given every _____ hour(s) | Route: <input type="checkbox"/> PO
<input type="checkbox"/> IV |
| <input type="checkbox"/> Hydrochlorothiazide | Dose: _____ mg | Given every _____ hour(s) | |
| <input type="checkbox"/> Spironolactone | Dose: _____ mg | Given every _____ hour(s) | |
| <input type="checkbox"/> Metolazone | Dose: _____ mg | Given every _____ hour(s) | |
| <input type="checkbox"/> Other (record on the Additional Medication Log) | | | |

10. Cardiovascular drugs: No Yes

10a. If Yes, check all that apply:

- | | |
|---|---|
| <input type="checkbox"/> Epinephrine infusion | <input type="checkbox"/> Vasopressin |
| <input type="checkbox"/> Dopamine infusion | <input type="checkbox"/> Norepinephrine |
| <input type="checkbox"/> Dobutamine infusion | |

11. Other Cardio/Respiratory drugs: No Yes

11a. If Yes, check all that apply:

- | | |
|--|--|
| <input type="checkbox"/> Vitamin A IM or Oral
(for prevention of BPD) | <input type="checkbox"/> Other pulmonary vasodilators for treatment
of pulmonary hypertension other than Nitric Oxide |
| <input type="checkbox"/> Surfactant | <input type="checkbox"/> Mucolytic |
| <input type="checkbox"/> Sildenafil | <input type="checkbox"/> Dornase Alfa |
| <input type="checkbox"/> Milrinone | |

12. Neuro-Muscular Blocking Agent No Yes

13. Antimicrobial drugs and other agents to prevent infections: No Yes

13a. If Yes, check all that apply:

- Antibacterial
- Antifungal
- Antiviral
- Palivizumab
- Probiotic

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 3

Q 9- 9a: Diuretic Drugs

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications and provide dose, frequency and route if applicable. If there is another medication not listed, please record the medication in the Additional Medication Log (ADDMED).

Q 10-10a: Cardiovascular drugs

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

Q 11-11a: Other Cardio/respiratory drugs:

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

Q 12: Neuro-muscular blocking agent

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 13-13a: Antimicrobial drugs and other agents to prevent infections

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 4

14. Anxiolytic, Anticonvulsant, and Narcotic Analgesic drugs:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
14a. If Yes, check all that apply:		
<input type="checkbox"/> Benzodiazepines		
<input type="checkbox"/> Phenobarbital		
<input type="checkbox"/> Phenytoin		
<input type="checkbox"/> Levetiracetam		
<input type="checkbox"/> Morphine		
<input type="checkbox"/> Fentanyl		
<input type="checkbox"/> Methadone		
15. Anti-Gastroesophageal Reflex drugs:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
15a. If Yes, check all that apply:		
<input type="checkbox"/> Proton Pump Inhibitors		
<input type="checkbox"/> H2 Receptor Antagonists		
<input type="checkbox"/> Motility agents		
<input type="checkbox"/> Other		
16. Use of blood products and Hematologic Supplements:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
16a. If Yes, check all that apply:		
<input type="checkbox"/> Erythropoietin		
<input type="checkbox"/> Red Blood Cell Transfusion		
<input type="checkbox"/> Platelets		
<input type="checkbox"/> Iron Supplements		
17. Oral Vitamins and Electrolyte Supplements:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
17a. If Yes, check all that apply:		
<input type="checkbox"/> Vitamin D		
<input type="checkbox"/> Vitamin E		
<input type="checkbox"/> Multivitamin		
<input type="checkbox"/> Potassium Supplement		
<input type="checkbox"/> Sodium Supplement		

[GNMDAY] Daily Growth & Nutrition/Daily Medication Data – Screen 4

Q 14-14a: Anxiolytic, Anticonvulsant and Narcotic Analgesic drugs

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

Q 15-15a: Anti-Gastroesophageal Reflux Drugs

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

Q 16-16a: Use of blood products and Hematologic Supplements

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

Q 17-17a: Oral Vitamins and electrolyte Supplements

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If Yes, please specify which medications were administered.

[RESDAY] Daily respiratory Data

Daily Respiratory Data	
1. Did the baby receive any supplemental oxygen today?	<input type="checkbox"/> No <input type="checkbox"/> Yes
1a. If Yes, how long was supplemental oxygen used for?	<input type="checkbox"/> 12 hours or less <input type="checkbox"/> More than 12 hours
1b. What was the concentration of supplemental oxygen at 1200 (Noon) today?	_____ %
2. Did the baby receive any other respiratory support today?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If Questions 1 or 2 are Yes, answer questions 3 - 6.	
3. Was Positive Airway Pressure with Endotracheal Tube used today?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3a. If Yes, select ventilation mode and record the associated values at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available	
<input type="checkbox"/> Conventional Mechanical Ventilation (CMV):	
Mean Airway Pressure (MAP): _____	cmH2O
Positive End Expiratory Pressure (PEEP): _____	cmH2O
<input type="checkbox"/> High Frequency Oscillation	
MAP: _____	cm H2O
<input type="checkbox"/> High Frequency Jet Ventilation	
MAP _____	cm H2O
4. Was Respiratory support without Endotracheal Tube used today:	<input type="checkbox"/> No <input type="checkbox"/> Yes
4a. If Yes, select ventilation mode and record the associated values at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available	
<input type="checkbox"/> Nasal Intermittent Mandatory Ventilation (NIMV):	
MAP: _____	cm H2O
PEEP: _____	cm H2O
<input type="checkbox"/> Continuous Positive Airway Pressure (CPAP):	
CPAP _____	cm H2O
<input type="checkbox"/> Nasal Cannula with flow rate	
Nasal Cannula flow: _____	Lpm
5. Was inhaled nitric oxide given today?	<input type="checkbox"/> No <input type="checkbox"/> Yes
5a. If Yes, record the concentration at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available	_____ ppm
6. Was the baby reintubated today?	<input type="checkbox"/> No <input type="checkbox"/> Yes
6a. If Yes, indicate the primary reason why the baby was reintubated:	
<input type="checkbox"/> Increasing respiratory distress	
<input type="checkbox"/> Stridor	
<input type="checkbox"/> Apnea and Bradycardia	
<input type="checkbox"/> Suspected infection	
<input type="checkbox"/> For diagnostic or therapeutic procedures, including surgery	
<input type="checkbox"/> Unplanned extubation(s), indicate the number of occurrences this day: _____	
<input type="checkbox"/> Other specify _____	

[RESDAY] Daily Respiratory Data

The next set of questions should be completed daily from birth to Week 40 Post Menstrual Age (PMA) or discharge, whichever occurs first. Respiratory data will be collected on a weekly basis from infants who remain hospitalized beyond 40 weeks PMA. Respiratory data collected opst 40 weeks PMA are to be entered in visits labeled as: HOSP M1, HOSP M2, HOSP M3.

It is vital to the PROP study that these questions are completed and we thank you in advance for your cooperation. As always, please use medical records and appropriate source documents to record data.

Question 1: Did the baby receive any supplemental oxygen today?

Includes supplemental oxygen given via any method. Please respond by checking the appropriate box, "0-No" or "1-Yes". If Yes, complete question 1a and 1b.

Question 1a: How long was supplemental oxygen used for?

Indicate if the infant received oxygen for 12 hours or less or greater than 12 hours.

Question 1b: What was the concentration of supplemental oxygen at 1200 today?

Provide the % concentration of supplemental oxygen.

Question 2: Did the baby receive any other respiratory support today?

Please respond by checking the appropriate box, "0-No" or "1-Yes."

If responses to Questions #1 or #2 are "Yes", please answer questions #3-6.

Question 3: Was Positive Airway Pressure with Endotracheal Tube used today?

Please respond by checking the appropriate box, "0-No" or "1-Yes," includes any type of positive airway pressure administered via an endotracheal tube. This includes Pressure-Support CPAP via an Endotracheal Tube.

Question 3a: Select ventilation mode

If response to Question 3 was "yes", select the ventilation mode and record the associated values at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available. Mean Airway Pressure (MAP) and Positive End Expiratory Pressure (PEEP) are recorded in cmH₂O.

Question 4: Was Respiratory Support without Endotracheal Tube used today?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Question 4a: Select ventilation mode

If response to Question 4 was "yes", select the ventilation mode and record the associated values at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available. Mean Airway Pressure (MAP) and Positive End Expiratory Pressure (PEEP) are recorded in cmH₂O.

Question 5: Was Inhaled Nitric Oxide given today?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Question 5a: record concentration

If response to Question 5 was "yes", select the ventilation mode and record the associated values at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available.

Question 6: Was the baby reintubated today?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Question 6a: Indicate the primary reason the baby was reintubated

If response to Question 6 was Yes, indicate the primary reason baby was intubated (select only one).

If this was an unplanned extubation, indicate the number of occurrences for the day.

If there is another reason, not listed, please be as specific as possible.

[BRAIN] Brain Imaging Data

BRAIN IMAGING DATA

NOTE: Please indicate date of brain imaging exam in date field above.

1. Was brain imaging performed? No Yes
- 1a. If Yes, indicate which time: Within 7 days +/- 1 week after baby's birth
 Within 30 days +/- 1 week after baby's birth
 Between 34 Weeks and 40 Weeks Post-Menstrual Age
2. What imaging technique was used? Head Ultrasound (HUS)
 Magnetic Resonance Imaging (MRI)
3. What were the results of the brain imaging, either the Worst HUS or MRI for this imaging?
Check ALL that apply.
- Normal
 - Subependymal hemorrhage (Grade 1 hemorrhage)
 - IVH without ventricular dilation (Grade 2 hemorrhage)
 - IVH distending at least one lateral ventricle (Grade 3 hemorrhage)
 - Intraparenchymal echodense lesion (Grade 4 hemorrhage)
 - Cystic Periventricular Leucomalacia (PVL)
 - Porencephalic cyst
 - Ventriculomegaly (with or without resolving IVH)
 - Cortical Atrophy
 - Cerebellar Hemorrhage
 - Other, specify *: _____

* Do NOT report normal variants. Examples of normal variants include: Cavum septi pellucidum, congenital cysts, isolated choroid plexus cysts.

[BRAIN] Brain Imaging Data

The Brain Imaging Data is to be completed at within 7 days +/- 1 week after baby birth, within 30 days +/- 1 week after baby birth, and between 34- 40 weeks PMA to document ischemic changes. Also, please indicate the date of the brain imaging exam in the date field located in the top right corner of the database form.

Q 1: Was brain imaging performed?

Please respond by checking the appropriate box, "0-No" or "1-Yes".

Q 1a: Indicate at which time

If response to question #1 is Yes, please indicate which time period the imaging was taken.

Q 2: What imaging technique was used

Indicate which imaging technique was used: Head Ultrasound or Magnetic Resonance Imaging

Q 3: What were the results of the brain imaging?

Record the results of the brain imaging from either the WORST HUS or MRI. Check all that apply. If "Normal" is checked, no other responses should be recorded. If Other is checked, please be as specific as possible. Normal variants are not to be included, for example: *Cavum septi pellucidum, connatal cysts, and isolated choroid plexus cysts.*

6 PRN Visit: As Needed Forms

[ADDMED] Additional Medication Log

ADDITIONAL MEDICATION LOG
Record any "other" medication administered to the infant during hospitalization.

Medication Sequence Number	Drug Code	Drug Name
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

[ADDMED] Additional Medication Log

This form is to be used to record any “Other” medications that may have been administered to the infant during hospitalization, specifically those in the following drug classes:

Methylxanthine drugs, Systemic Corticosteroids, Inhaled Steroids, Inhaled Bronchodilators and Diuretics.

Please refer back to the Daily Growth and Nutrition/Daily Medication Log (GNMDAY) to ensure that all medications are recorded.

[SPEC] Specimen Collection Form

SPECIMEN COLLECTION FORM	
1. Collection Date	_____ [mm/dd/yyyy]
2. Collection Time (if applicable)	_____ [24 hour clock]
3. Type of Specimen	<input type="checkbox"/> Infant Tracheal Aspirate <input type="checkbox"/> Infant Urine <input type="checkbox"/> Infant Saliva for DNA <input type="checkbox"/> Mother Saliva for DNA <input type="checkbox"/> Father Saliva for DNA
4. Laboratory Accession Number (from TA or UR vial label) Site #/ Sample Type*/ Sample #	_____ e.g. 011TA1234
4a. Enter Tracheal Aspirate CL Lab Accession Number Site #/ Sample Type*/ Sample #	_____ e.g. 011CL1234
5. Number of Aliquots (for Tracheal Aspirate Supernatant and Urine)	_____
5a. Date Tracheal Aspirate or Urine Specimen Frozen	_____ [mm/dd/yyyy]
5b. Time Tracheal Aspirate or Urine Specimen Frozen	_____ [24 hour clock]
6. Date sample shipped to Core Lab:	_____ [mm/dd/yyyy]
<p>* Sample Type: TA= Tracheal Aspirate Supernatant; send to UCSF Tracheal Aspirate Core Lab CL= Tracheal Aspirate Cell Pellet; send to UCSF Tracheal Aspirate Core Lab UR= Urine; send to Vanderbilt Urine Core Lab DN= DNA (Saliva); send to Vanderbilt DNA Core Lab</p>	

PROP Manual of Procedures (MOP)

[SPEC] Specimen Collection Form

This form is to be completed along with any specimens collected for the PROP Study.

1. Tracheal aspirate (TA) and urine collections (4 each per infant) are made at the collection times noted in the SOP for each using collection kits provided by the UCSF Core.
2. The collection kits for both TA and urine will contain 5 bar-coded 1-ml tubes. As part of processing of each sample, 0.25 ml is aliquoted into tubes 1-4 and any remaining volume of TA supernatant or urine into tube #5. If the center is performing studies on either TA or urine, tube #5 and, if needed, tube #4 are retained at the site. The aliquoting requires that the laboratories/personnel at each site have a pipetter, tips and someone with pipetting experience. Aliquoting at the time of storage eliminates one thaw-freeze cycle, which may be important for stability of some biomarkers. The samples are then frozen and shipped in batches to UCSF (TA) and Vanderbilt (urine) for biorepository storage as described in the current SOPs.
3. After collection of each sample, the Biorepository Collection Form is completed, entering PID, date and time of collection, type of sample, sample accession number (obtained from the bar-coded tubes), date/time of freezing sample, and date of shipping to the Biorepository lab. The accession number has 3 components: XXX (site ID)/XX (type of sample)/ XXXX (sequential sample accession number for that site).

Q 1: Collection Date

Enter specimen collection date in the following format: mm/dd/yyyy

Q 2: Collection Time

Enter collection time if applicable, 24 hour clock

Q 3: Type of Specimen

Select only one type of specimen per form.

Q 4: Laboratory Accession Number:

Number will consist of 3 components: XXX (site ID)/XX (type of sample)/ XXXX (sequential sample accession number for that site).

Type of Sample codes are: TA (Tracheal Aspirate Supernatant), CL (Tracheal Aspirate Cell Pellet), UR (Urine).

Q 5: Number of aliquots

Aliquot Number will only be available for Urine and Tracheal Aspirate.

Q 5a-5b: Date and Time Specimen Frozen

Data will only be available for Urine and Tracheal Aspirate.

Q 6: Date sample shipped to Core Lab

Enter specimen ship date in the following format: mm/dd/yyyy. Forms may be saved as incomplete once the specimens are batched and shipped.

Note: Multiples and Paternal Specimens: In the case of multiple births, submit the SPEC form for the maternal and/or paternal specimens for 1 PID, using the PID for twin A. It is not necessary to associate the paternal samples with all of the infants as this will be linked via the PID numbers entered on the BABASE form.

[DEATH] Record of Death

CRF Blank

PROP **Prematurity and Respiratory Outcomes Program** PID: 12004
Date: _____

RECORD OF DEATH

1. What was the baby's date of death? _____
Month Day Year

2. What was the baby's primary cause of death?
(Specify cause of death from the death certificate) _____

3. Was an autopsy performed? No Yes Unknown

4. If **Yes**, what were the findings: _____

* If a death certificate is not available, please contact the primary care physician for a description of the events leading to death.

▲

[DEATH] Record of Death

This form is to be completed as soon as possible following the infant's death.

Due to the infants' fragile state of health, it has been determined that any loss, will be "replaced" by a new baby/recruit to a particular stratum. The early deaths will be used in the assessment of total mortality as a secondary outcome.

Q 1: What is the baby's Date of Death?

Provide the date of death in the following format: MM/DD/YYYY

Q 2: What was the baby's primary cause of death?

Specify the cause of death from the death certificate. If in case, a death certificate is not available, please contact the primary care physician for a description of the events leading to death and provide a response in the space provided.

Q 3: Was an autopsy performed?

Please respond by checking the appropriate box, "0-No" or "1-Yes" or "Unknown."

Q 4: What were the findings?

If the response to Question #3 is Yes, please be as specific and concise as possible.

If an autopsy report or death/discharge summary report is NOT available, provide a narrative description of the events leading to death.

[SSTATUS] Study Status Form

		CRF Blank <input type="checkbox"/>
PROP	Prematurity and Respiratory Outcomes Program	PID: 12004 _____
		Date: _____
STUDY STATUS		
NOTE: This form must be completed when the infant's participation in the study ends early.		
1. Date of last contact?	_____	
	Month Day Year	
2. Indicate the primary reason participation stopped:	<input type="checkbox"/> Unable to contact parents/caregivers	
	<input type="checkbox"/> Parents/Caregivers refuse further participation	
	<input type="checkbox"/> Other, specify:	

PROP Manual of Procedures (MOP)

[SSTATUS] Study Status Form

This form is to be completed once the infant's participation in the study ends early.

Q 1: Date of last Contact?

Provide the date of last contact in the following format: MM/DD/YYYY

Q 2: Indicate the primary reason participation stopped:

Select the most accurate reason participation stopped.

If "Other" is checked, please be as specific and concise as possible.

7 Discharge Visit

[COMORB] Comorbidities of Prematurity – Screen 1

COMORBIDITIES OF PREMATUREITY		
AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST		
Cardio-Pulmonary		
1. Did the baby have any of the following types of air leaks?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes , indicate the type(s) of air leak by answering questions 1a-1d:		
1a. Pneumothorax:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes , complete 1a1 and 1a2		
1a1. Was a chest tube placed?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
1a2. Has there been evidence of a bronchopleural fistula?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
1b. Pulmonary Interstitial Emphysema (PIE):	<input type="checkbox"/> No	<input type="checkbox"/> Yes
1c. Pneumomediastinum:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
1d. Pneumopericardium:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
2. Did the baby have any pulmonary hemorrhages?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes , complete 2a and 2b.		
2a. Did these hemorrhages require transfusion of blood products?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
2b. Did these hemorrhages require increased concentrations of supplemental oxygen and/or ventilator support?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
3. Did the baby have a clinical diagnosis of Patent Ductus Arteriosus (PDA)?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
3a. Was the PDA confirmed by Echocardiogram?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
Indicate if any of the following treatments were used to treat the suspected or confirmed PDA:		
3b. Indomethacin (do not report any prophylactic Indomethacin given within the first 24-hours of life):	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes , indicate the first date of each distinct course of Indomethacin:		
_____	_____	_____
Month Day Year	Month Day Year	Month Day Year
First Course	Second Course	Third Course
3c. Ibuprofen:	<input type="checkbox"/> No	<input type="checkbox"/> Yes
If Yes , indicate the first date of each distinct course of Ibuprofen:		
_____	_____	_____
Month Day Year	Month Day Year	Month Day Year
First Course	Second Course	Third Course

[COMORB] Comorbidities of Prematurity – Screen 1

This form is to be completed once over the course of the study at Week 36, Week 40 or Discharge, whichever occurs first.

Q 1: Did the baby have any of the following types of air leaks?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, please answer questions 1a-1d.

Q 1a: Pneumothorax

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, please answer questions 1a1-1a2.

Q1b-1d: Indicate the types of air leaks

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 2: Did the baby have any pulmonary hemorrhages?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, please answer questions 2a-2b.

Q 2a-2b: Indicate if transfusion of blood products or increased concentrations of supplemental oxygen/ventilator support was required

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If red blood cells were required in response to a pulmonary hemorrhage, ensure that “Red Blood Cell Transfusion” is checked on the appropriate day(s) on the Daily Growth and Nutrition/Daily Medication Log.

Q 3: Did the baby have a clinical diagnosis of Patent Ductus Arteriosis (PDA)?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Complete Questions 3a-3d if any of the treatment were used to treat the PDA (suspected or confirmed)

Q 3a: Was the PDA confirmed by echocardiogram?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

Q 3b: Indicate if Indomethacin was used to treat the suspected or confirmed PDA

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, provide dates of each distinct course administered.

Q 3c: Indicate if Ibuprofen was used to treat the suspected or confirmed PDA

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, provide dates of each distinct course administered.

[COMORB] Comorbidities of Prematurity – Screen 2

COMORBIDITIES OF PREMATUREITY			
AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST			
3d. Surgical Ligation:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
If Yes , date of surgery:	_____		
	Month Day Year		
4. Was a diagnosis of pulmonary hypertension made by a pediatric cardiologist?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
4a. If Yes , was this diagnosis based on (Check all tht apply)			
<input type="checkbox"/> Echocardiogram	_____		
	Month Day Year		
	Date of diagnosis		
<input type="checkbox"/> Cardiac catheterization	_____		
	Month Day Year		
	Diagnosis date		
5. Was airway endoscopy performed by an ENT surgeon or pediatric pulmonologist?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
5a. If Yes , indicate the clinical findings (check all that apply):			
<input type="checkbox"/> No abnormality noted			
<input type="checkbox"/> Tracheomalacia	_____	_____	
	Month Day Year	Month Day Year	
	1st Procedure	2nd Procedure	
<input type="checkbox"/> Laryngomalacia	_____	_____	
	Month Day Year	Month Day Year	
	1st procedure	2nd procedure	
<input type="checkbox"/> Subglottic stenosis	_____	_____	
	Month Day Year	Month Day Year	
	1st procedure	2nd procedure	
<input type="checkbox"/> Vocal Cord Paralysis (unilateral)	_____	_____	
	Month Day Year	Month Day Year	
	1st procedure	2nd procedure	
<input type="checkbox"/> Vocal Cord Paralysis (bilateral)	_____	_____	
	Month Day Year	Month Day Year	
	1st procedure	2nd procedure	
<input type="checkbox"/> Other, specify:	_____	_____	
	Month Day Year	Month Day Year	
	1st procedure	2nd procedure	
6. Did the baby have a tracheotomy?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
6a. If Yes , indicate the procedure date:	_____		

[COMORB] Comorbidities of Prematurity – Screen 2

Q 3d: Surgical Ligation

Please respond by checking the appropriate box, “0-No” or “1-Yes”.
If yes, provide dates of each distinct course administered.

Q 4: Was a diagnosis of pulmonary hypertension made by a pediatric cardiologist?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, answer question 4a.

Q 4a: What was the diagnosis based on?

Check either echocardiogram or cardiac catheterization and provide date of diagnosis in MM/DD/YYYY format.

Q 5: Was airway endoscopy performed by an ENT surgeon or pediatric pulmonologist?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, answer question 5a.

Q 5a: Indicate clinical findings

Check all findings and provide dates of procedures.

Q 6: Did the baby have a tracheotomy?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, answer question 6a

Q 6a: Indicate procedure date:

Provide date of tracheotomy.

[COMORB] Comorbidities of Prematurity – Screen 3

COMORBIDITIES OF PREMATUREITY
AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER COMES FIRST

7. Was Ventilator- Associated Pneumonia (VAP) suspected in this baby? No Yes

If **Yes**, to 7, answer 7a-7c.

7a. Did the baby have worsening gas exchange (e.g. O2 desaturations, Increased oxygen requirements, or increased ventilator demand)? No Yes

7b. Did the baby have any of the following associated conditions (check all that apply)?

- Temperature instability with no other recognized cause
- Leukopenia (<4,000 WBC/mm³)
- Leukocytosis (>=15,000 WBC/mm³) and left shift (>= 10% band forms)
- New onset of purulent sputum
- Change in character of sputum
- Increased respiratory secretions
- Increased suctioning requirements
- Apnea
- Tachypnea
- Nasal flaring with retraction of chest wall or grunting
- Wheezing
- Rales
- Rhonchi
- Cough
- Bradycardia (<100 beats per minute)
- Tachycardia (>170 beats per minute)
- None of the above

7c. Did the baby have serial chest radiographs with any of the following (check all that apply)?

- New infiltrate
- Progressive and persistent infiltrate
- Consolidation
- Cavitation
- Pneumatoceles
- None of the above

[COMORB] Comorbidities of Prematurity – Screen 3

Q 7: Was Ventilator-Associated Pneumonia (VAP) suspected in this baby?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If yes, answer question 7a-7c

Q 7a: Did the baby have worsening gas exchange

Please respond by checking the appropriate box, “0-No” or “1-Yes”. Examples include: O₂ Desaturations, increased oxygen requirements, or increased ventilator demand.

Q 7b: Did the baby have any of the following associated conditions?

Check all that apply.

Q 7c: Did the baby have serial chest radiographs?

Check all that apply.

[COMORB] Comorbidities of Prematurity – Screen 4

COMORBIDITIES OF PREMATUREITY AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST			
Infection			
8. Did the baby have any blood culture-proven sepsis	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
8a. If Yes , indicate the type(s) of Sepsis:			
<input type="checkbox"/> Bacterial	Number of distinct episodes: _____		
<input type="checkbox"/> Fungal	Number of distinct episodes: _____		
<input type="checkbox"/> Viral	Number of distinct episodes: _____		
8b. Presumed, but not culture-proven Sepsis?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
If Yes , number of distinct episodes _____			
9. Did the baby have any culture-proven Meningitis?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
9a. If Yes , indicate the type(s) of Meningitis:			
<input type="checkbox"/> Bacterial	Number of distinct episodes: _____		
<input type="checkbox"/> Fungal	Number of distinct episodes: _____		
<input type="checkbox"/> Viral	Number of distinct episodes: _____		
9b. Presumed, but not culture-proven Meningitis?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
If Yes , number of distinct episodes _____			
10. Did the baby have upper respiratory tract infection of confirmed viral etiology?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
10a. If Yes , indicate the confirmed viral etiologies (check all that apply):			
<input type="checkbox"/> Influenza	_____	_____	
	1st Diagnosis	2nd Diagnosis	
<input type="checkbox"/> Parainfluenzae	_____	_____	
	1st Diagnosis	2nd Diagnosis	
<input type="checkbox"/> Rhinovirus	_____	_____	
	1st Diagnosis	2nd Diagnosis	
<input type="checkbox"/> Respiratory Syncytial virus	_____	_____	
	1st Diagnosis	2nd Diagnosis	
<input type="checkbox"/> Other, specify	_____	_____	
	1st Diagnosis	2nd Diagnosis	

[COMORB] Comorbidities of Prematurity – Screen 4

We will now collect data on types of infections that the baby may have encountered during hospitalization.

Q 8: Did the baby have any blood culture proven sepsis?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. Record all culture proven infections in the blood, whether they are bacterial, fungal or viral. If “Yes”, answer question 8a. If response is “No”, skip to question 8b.

Q 8a: Type

Check all that apply and provide number of distinct episodes.

Q 8b: Presumed but not culture proven sepsis?

Please respond by checking the appropriate box, “0-No” or “1-Yes” and provide number of distinct episodes.

Q 9: Did the baby have any culture proven Meningitis?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. Record all culture proven infections in the CSF, whether they are bacterial, fungal or viral. If “Yes”, answer question 9a. If response is “No”, skip to question 9b.

Q 9a: Type

Check all that apply and provide number of distinct episodes.

Q 9b: Presumed but not culture proven Meningitis?

Please respond by checking the appropriate box, “0-No” or “1-Yes” and provide number of distinct episodes. This should be based on suggestive CSF counts, protein and glucose concentrations.

Q 10: Did the baby have Upper Respiratory Tract Infection of confirmed viral etiology?

Please respond by checking the appropriate box, “0-No” or “1-Yes”. If response is Yes, answer question 10a.

Q 10a: Indicate the viral etiologies

Check all that apply and provide date of distinct diagnosis in MM/DD/YYYY format.

[COMORB] Comorbidities of Prematurity – Screen 5

COMORBIDITIES OF PREMATUREITY
AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER OCCURS FIRST

11. Did the baby have any other infections? No Yes

11a. If **Yes**, indicate the infections (check all that apply):

<input type="checkbox"/> Urinary Tract Infection	_____	_____
	1st Diagnosis	2nd Diagnosis
<input type="checkbox"/> Cellulitis	_____	_____
	1st Diagnosis	2nd Diagnosis
<input type="checkbox"/> Osteomyelitis	_____	_____
	1st Diagnosis	2nd Diagnosis
<input type="checkbox"/> Cytomegalovirus (CMV)	_____	_____
	1st Diagnosis	2nd Diagnosis
<input type="checkbox"/> Surgical Wound Infection	_____	_____
	1st Diagnosis	2nd Diagnosis
<input type="checkbox"/> Other, specify	_____	_____
	1st Diagnosis	2nd Diagnosis

[COMORB] Comorbidities of Prematurity – Screen 5

Q 11: Did the baby have any other infections?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, answer question 11a.

Q 11a: Indicate the infections

Check all that apply and provide date of distinct diagnosis in MM/DD/YYYY format.

[COMORB] Comorbidities of Prematurity – Screen 6

COMORBIDITIES OF PREMATUREITY			
AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST			
Gastro Intestinal			
12. Did the baby have Necrotizing Enterocolitis (NEC) Bell stage 2 or 3?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
12a. If Yes , date of first medical diagnosis:	_____		
	Month Day Year		
12b. Were there any bowel perforations?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
12c. Did the baby have surgery for NEC?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
If Yes , indicate the surgical procedure(s) performed (check all that apply) and provide the date(s) of surgery:			
<input type="checkbox"/> Peritoneal Drain	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	
<input type="checkbox"/> Laparotomy	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	
<input type="checkbox"/> Bowel Resection	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	
<input type="checkbox"/> Repair of adhesion/ Strictures	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	
13. Did the baby have any Isolated Bowel Perforations not considered to be associated with NEC?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
13a. If Yes , date of first medical diagnosis:	_____		
	Month Day Year		
13b. Did the baby receive any surgery for Isolated Bowel Perforations not considered to be associated with NEC?	<input type="checkbox"/> No	<input type="checkbox"/> Yes	
If Yes , indicate the surgical procedure(s) performed (check all that apply) and provide the date(s) of surgery:			
<input type="checkbox"/> Peritoneal Drain	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	
<input type="checkbox"/> Laparotomy	_____	_____	
	Month Day Year	Month Day Year	
	1st Surgery	2nd Surgery	

[COMORB] Comorbidities of Prematurity – Screen 6

We will now collect data on GastroIntestinal events that the baby may have encountered during hospitalization.

Q 12: Did the baby have Necrotizing Enterocolitis (NEC) Bell stage 2 or 3?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, answer question 12a- 12c.

Q 12a: Date

Provide date of first medical diagnosis in MM/DD/YYYY format.

Q 12b: Were there any bowel perforations?

Please respond by checking the appropriate box, “0-No” or “1-Yes.”

Q 12c: Did the baby have surgery for NEC?

Please respond by checking the appropriate box, “0-No” or “1-Yes.”

If “Yes”, check all applicable surgical procedures and provide date in MM/DD/YYYY format.

Q 13: Did the baby have any Isolated Bowel Perforations not considered to be associated with NEC?

Please respond by checking the appropriate box, “0-No” or “1-Yes”.

If response is Yes, answer question 13a- 13b.

Q 13a: Date

Provide date of first medical diagnosis in MM/DD/YYYY format.

Q 13b: Did the baby have surgery for Isolated Bowel Perforations not considered to be associated with NEC?

Please respond by checking the appropriate box, “0-No” or “1-Yes. If “Yes”, check all applicable surgical procedures and provide date in MM/DD/YYYY format.

[COMORB] Comorbidities of Prematurity – Screen 7

COMORBIDITIES OF PREMATURITY
AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER OCCURS FIRST

Ophthalmologic

14. Were any Retinopathy of Prematurity (ROP) examinations performed prior to discharge from the PROP study center? No Yes

15. Was this baby diagnosed with ROP? No Yes

If **Yes**, answer the following questions:

15a. What was the worst stage ever reported in any zone? _____ Left eye (1-5)
_____ Right eye (1-5)

15b. Did the baby undergo laser or cryo-surgery?

Left eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of procedure	_____
				Month Day Year
Right eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of procedure	_____
				Month Day Year

15c. Did the baby undergo Bevacizumab (Avastin) treatment?

Left eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of Procedure	_____
				Month Day Year
Right eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of Procedure	_____
				Month Day Year

15d. Did the baby undergo vitrectomy?

Left eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of Procedure	_____
				Month Day Year
Right eye:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Date of Procedure	_____
				Month Day Year

[COMORB] Comorbidities of Prematurity – Screen 7

We will now collect data on Ophthalmologic events that the baby may have encountered during hospitalization.

- Q 14: Were any Retinopathy of Prematurity (ROP) examinations performed prior to discharge?**
Please respond by checking the appropriate box, “0-No” or “1-Yes.
- Q 15: Was this baby diagnosed with ROP?**
Please respond by checking the appropriate box, “0-No” or “1-Yes.
If response is “Yes”, answer questions 15a-15d.
- Q 15a: What was the worst stage ever reported in any zone?**
On a scale from 1-5, record worst stage ever reported on any exam in both the left eye and the right eye.
- Q 15b: Did the baby undergo laser or cryo-surgery?**
Please respond by checking the appropriate box, “0-No” or “1-Yes for both left and right eyes. If “Yes”, provide date of procedure in MM/DD/YYYY format.
- Q 15c: Did the baby undergo Bevacizumab treatment?**
Please respond by checking the appropriate box, “0-No” or “1-Yes for both left and right eyes. If “Yes”, provide date of procedure in MM/DD/YYYY format.
- Q 15d: Did the baby undergo vitrectomy?**
Please respond by checking the appropriate box, “0-No” or “1-Yes for both left and right eyes. If “Yes”, provide date of procedure in MM/DD/YYYY format.

[COMORB] Comorbidities of Prematurity – Screen 8

Date: _____	
COMORBIDITIES OF PREMATUREITY AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST	
Neurologic	
16. Did the baby receive a ventricular shunt?	<input type="checkbox"/> No <input type="checkbox"/> Yes
16a. If Yes , provide the date of first shunt placement:	_____ Month Day Year
Other Surgeries (excluding PDA ligation, surgery for NEC or Bowel Perforation, all surgeries for ROP, ventriculoperitoneal shunt placement, and tracheotomy)	
1. Type of Surgery: _____	Date of Surgery: _____ Month Day Year
2. Type of Surgery: _____	Date of Surgery: _____ Month Day Year
3. Type of Surgery: _____	Date of Surgery: _____ Month Day Year
4. Type of Surgery: _____	Date of Surgery: _____ Month Day Year
5. Type of Surgery: _____	Date of Surgery: _____ Month Day Year

[COMORB] Comorbidities of Prematurity – Screen 8

We will now collect data on Neurologic events that the baby may have encountered during hospitalization. Also, please record any other surgeries performed on the baby that has not been recorded previously on this form.

Q 16: Did the baby receive a ventricular shunt?

Please respond by checking the appropriate box, “0-No” or “1-Yes. If yes, answer question 16a.

Q 16a: Provide date

Provide date of procedure in MM/DD/YYYY format.

Other surgeries:

Specify any other surgeries not captured previously on the Comorbidities forms and provide dates of the surgeries.

[DISC] Discharge Form – Screen 1

DISCHARGE FORM	
1. What was the baby's discharge date?	_____ Month Day Year
2. Where was the baby discharged to?	<input type="checkbox"/> Home <input type="checkbox"/> Transfer to another hospital <input type="checkbox"/> Baby died at study center* <input type="checkbox"/> Other, Specify: _____
NOTE: If the child dies at the study center, record date of discharge as date of death and complete a Death Form. All remaining information on this form should reflect information collected up to the time of death.	
3. Was this baby enrolled in Tolsurf? 3a. If Yes , provide study specific Partipant ID	<input type="checkbox"/> No <input type="checkbox"/> Yes _____
4. Was this baby enrolled in the NRN Hydrocortisone for Extubation Trial? 4a. If Yes , provide study specific Partipant ID	<input type="checkbox"/> No <input type="checkbox"/> Yes _____
5. Was this baby enrolled in the NRN Generic database? 5a. If Yes , provide study specific Partipant ID	<input type="checkbox"/> No <input type="checkbox"/> Yes _____
6. Was this baby enrolled in any other randomized clinical treatment trials? 6a. If Yes , provide clinical trial name(s):	<input type="checkbox"/> No <input type="checkbox"/> Yes _____
7. Was this baby enrolled in any other long term follow-up studies? 7a. If Yes , provide study name(s):	<input type="checkbox"/> No <input type="checkbox"/> Yes _____
8. How many people normally live in your home including your baby (for at least 6 months of the year)? (Please select one)	<input type="checkbox"/> 2-3 <input type="checkbox"/> 4-6 <input type="checkbox"/> 7-10 <input type="checkbox"/> >10
8a. How many other children under 5 years old live in <baby's name>'s home?	_____ children
8b. How many children between ages 5-12 years old live in <baby's name>'s home?	_____ children
9. Is baby exposed to dogs, cats, or other furry animals at home?	<input type="checkbox"/> No <input type="checkbox"/> Yes

PROP Manual of Procedures (MOP)

[DISC] Discharge Form – Screen 1

This form is to be completed upon infant's discharge from the hospital.

Initiating the interview:

Every effort should be made to interview the primary caregiver (primary respondent) who will complete the initial interview and all subsequent interviews.

If the mother resides in the same household as the child, the mother is the primary caregiver. If each caregiver has exactly 50% custody, record as the primary caregiver, the person who comes in for the screening. This person should be able to answer all interview questions, if possible.

For all subsequent interviews, the interviewer will need to ask for the primary caregiver. In the event that the primary caregiver is not available, arrangements should be made to contact the primary caregiver when they will be free to complete the interview. If the primary respondent cannot be reached, after that a secondary respondent, who is familiar with the infant and his or her respiratory health, can be identified to complete the interview.

All interviews should be conducted privately in a room or office. Parents or guardians expressing concerns regarding their child's breathing should be advised to discuss them with their pediatrician.

Q 1: What was the baby's discharge date?

Provide date in MM/DD/YYYY format.

Q 2: Where was the baby discharged to?

Select best response. If baby died, please record date of death as the date of discharge and complete the Record of Death Form.

Q 3: Was this baby enrolled in TOLSURF?

Please respond by checking the appropriate box, "0-No" or "1-Yes. If yes, answer question 3a.

Q 3a: If yes, provide study specific Participant ID.

Q 4: Was this baby enrolled in the NRN (Neonatal Research Network) Hydrocortisone for Extubation trial?

Please respond by checking the appropriate box, "0-No" or "1-Yes. If yes, answer question 4a.

Q 4a: If yes, provide study specific Participant ID.

Q 5: Was this baby enrolled in the NRN generic Database?

Please respond by checking the appropriate box, "0-No" or "1-Yes. If yes, answer question 5a.

Q 5a: If yes, provide study specific Participant ID.

Q 6: Was this baby enrolled in any other randomized clinical treatment trials?

Please respond by checking the appropriate box, "0-No" or "1-Yes. If yes, answer question 5a.

Q 6a: If yes, provide clinical trial name(s)

Q 7: Was this baby enrolled in any other long term follow up studies?

Please respond by checking the appropriate box, "0-No" or "1-Yes. If yes, answer question 7a.

Q 7a: Provide names

Provide study names.

Q 8: How many people normally live in your home including your baby?

Indicate the number of people who reside in the home for at least 6 months of the year.

Question 8a: **NOT** including your baby, indicate how many children under 5 yrs old live in baby's home

Question 8b: **NOT** including your baby, indicate how many children between 5-12 yrs old live in baby's home

Q 9: Is baby exposed to dogs, cats or other furry animals at home?

Please respond by checking the appropriate box, "0-No", "1-Yes.

[DISC] Discharge Form – Screen 2

DISCHARGE FORM

10. Will your baby receive any care outside of the home in the next year? No Yes Unknown

11. Which one of the following five statements best describes smoking in <baby's name>'s home?

- Smoking is allowed anywhere in the home
- Smoking is limited to part of the house where <baby's name> rarely goes
- Smoking is not allowed inside the home at all

12. Which one of the following five statements best describes smoking in the car?

- Child rarely travels by car.
- There is no smoking inside the car.
- Smoking occurs in the car only when <baby's name> is not inside.
- Smoking is sometimes allowed in the car.
- Smoking is usually or always allowed in the car.

13. Please tell us what breathing and allergy problems run in the family (Check all that apply)

Symptoms	None/ Not Applicable	Biological Siblings (any)	Biological Parents (one or both)
a. Asthma/Recurrent lung infections	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Allergies/ Hayfever	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Eczema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. How will <baby's name>'s health care be paid for primarily: (Select only one) No Insurance (self pay) Private Insurance Medicaid/ Public Insurance

PROP Manual of Procedures (MOP)

[DISC] Discharge Form – Screen 2

This form is to be completed upon infant's discharge from the hospital.

- Q 10: Will your baby received any care outside of the home in the next year?**
Please respond by checking the appropriate box, "No", "Yes" or "Unknown".
- Q 11: Which one of the following three statements best describes smoking in <baby's name>'s home?**
Indicate the best response.
- Q 12: Which one of the following five statements best describes smoking in the car?**
Indicate the best response.
- Q 13: Please tell us what breathing and allergy problems run in the family**
Check all that apply or None/Not Applicable.
- Q 14: How will <baby's name>'s health care be paid for primarily**
Select only one response.

PROP Manual of Procedures (MOP)

[PE] Physical Exam

NOTE: The Physical Exam is to be performed at 36 weeks to 40 weeks or Discharge whichever occurs first and again at 1 year corrected age (M12 Follow Up).

1. What is the baby's body weight? _____ gms (Complete at W36, W40 or DC)
 _____ kg (Complete at M12 Follow Up)
2. What is the baby's length? _____ cm
3. What is the baby's Chest Circumference? _____ cm
4. Respiratory Rate _____ Breaths per minute
5. Infant status during Physical Exam

<input type="checkbox"/> ₀ Quiet Sleep	<input type="checkbox"/> ₁ Active Sleep
<input type="checkbox"/> ₂ Awake, Quiet	<input type="checkbox"/> ₃ Awake, Active
<input type="checkbox"/> ₉₉ Other, specify _____	
6. SpO2 in Room Air _____ % ₉₉ NA
 If 'NA' is checked, answer questions 6a and 6b.
 6a. What was the concentration of supplemental oxygen at time of exam? _____ %
 6b. Select ventilation mode and record the associated values for respiratory support:

<input type="checkbox"/> Positive Pressure Ventilation: MAP: _____ cmH ₂ O PEEP: _____ cmH ₂ O	<input type="checkbox"/> Continuous Positive Airway Pressure (CPAP): CPAP: _____ cmH ₂ O
<input type="checkbox"/> Nasal Cannula with flow rate: Nasal Cannula Flow: _____ Lpm	

Focused Pulmonary Exam Parameters

7. Retractions			
a. Suprasternal	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
b. Intercostal	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
c. Subcostal	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
8. Thoraco-abdominal Movement			
	<input type="checkbox"/> ₀ Synchronous	<input type="checkbox"/> ₁ Asynchronous	
9. Accessory Muscle Use			
a. Head Bobbing	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
b. Nasal flaring	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
c. Expiratory Abdominal Muscle Use	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
10. Wheezy/ Noisy Breathing			
a. Monophonic	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present without chest compression	<input type="checkbox"/> ₂ Present, with chest compression*
b. Polyphonic	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present without chest compression	<input type="checkbox"/> ₂ Present, with chest compression*
11. Crackles			
	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Localized	<input type="checkbox"/> ₂ Diffuse
12. Stridor			
	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	
13. Point of Maximal Impulse (PMI)			
	<input type="checkbox"/> ₀ Left Chest	<input type="checkbox"/> ₁ Subxiphoid	
14. Digital Clubbing			
	<input type="checkbox"/> ₀ Absent	<input type="checkbox"/> ₁ Present	

15. Examiner's Initials _____

*Chest compression is performed at the Month 12 Follow Up exam only.

PROP Manual of Procedures (MOP)

[PE] Physical Exam Form

This form is to be completed at 34 weeks to 41 weeks or 1 week prior to Discharge whichever occurs first and again at 1 year corrected age (M12 Follow up). Please refer to the NIRA MOP for additional instructions.

- Q 1: What is the baby's body weight?**
At W36, W40 or discharge, record the weight in gms. Weight should be measured in kg at the M12 Follow up visit.
- Q 2: What is the baby's length?**
Record length in cm. Please refer to NIRA MOP for further details.
- Q 3: What is the baby's Chest Circumference?**
Record circumference in cm. Please refer to NIRA MOP for further details.
- Q 4: Respiratory rate**
Record number of breaths per minute.
- Q 5: Infant status during Physical Exam**
Indicate the best response. If 'Other' is checked, please specify.
- Q 6: SpO2 in Room Air:**
Record percent oxygen saturation. If Not Applicable, check NA. If NA is checked, answer questions 6a and 6b.
- Q 6a: What was the concentration of supplemental oxygen at the time of exam?**
Provide percent concentration.
- Q 6b: Select ventilation mode and record the associated values for respiratory support**
Indicate the best response and provide associated values.
- Q 7- 14: Focused Pulmonary Exam Parameters**
Select best response for each area listed.
Chest compression is performed at the Month 12 Follow Up exam only.
- Q 15: Examiner's Initials**
Enter the examiner's initials.

8 NIRA Visit

This visit includes the respiratory assessments performed on the baby as well as the Adverse Event form to capture all AEs related to the study procedures. Please also refer to the NIRA MOP for specific questions.

[NIRA] Non Invasive Respiratory Assessments- Screen 1

Non Invasive Respiratory Assessments

NOTE: Please indicate date of assessment in date field

BASELINE DATA

1. Were RIP bands placed on the baby? No Yes

1a. If 'No', please check primary reason infant missed test

Baby was ineligible

Baby was eligible but discharged

Staff Oversight/ Staff not available to perform test

Other, specify: _____

2. Date PO feeds started? _____
mm/dd/yyyy

3. What was the baby's most recent body weight? _____ gms

4. Baseline Heart Rate: _____ Beats per minute

5. Respiratory Status: No Respiratory Support
 Nasal Cannula \leq 1 LPM

5a. If 'Nasal Cannula' is checked, provide oxygen flow: _____ LPM _____ %

6. Nasogastric Tube (NGT) placement at the start of the test In Out

OXYGENATION WHILE FEEDING [OWF]

7. Was the Oxygenation While Feeding [OWF] test performed? No Yes

7a. If 'No', please check primary reason infant missed test

Baby was ineligible

Baby was eligible but discharged

Staff oversight/ Staff not available to perform test

Site does not perform OWF

Other, specify: _____

Please Note: If your site does not perform OWF, skip to question #11.

8. Caloric density: _____ cal/oz

9. Start Volume in bottle _____ mL

10. End Volume in bottle _____ mL

Event Codes

P = Feeding Position	B = Begin Feeding	I = Interruption of feeding
R = Resumed Feeding	E = End of Feed or Bronchdilator	D = Disconnect
Q = Infant in Quiet Sleep	A = Infant Awake or Active Sleep	

[NIRA] Non Invasive Respiratory Assessments- Screen 1

- Q 1:** **Were RIP bands placed on the baby?**
Please respond by checking the appropriate box, "0-No", "1-Yes. If No, answer question 1a.
- Q 1a:** **Please check primary reason infant missed test**
Select best response. If "Other" is checked, provide reason.
- Q 2:** **Date PO Feeds Started.**
Enter date in mm/dd/yyyy format.
- Q 3:** **What was the baby's most recent body weight?**
Enter weight in grams
- Q 4:** **Baseline heart rate**
- Q 5:** **Respiratory Status:**
Select best response. If Nasal Cannula is checked provide oxygen flow
- Q 6:** **Nasogastric Tube placement at the start of the test**
Indicate if NGT was in or out. The test can be performed regardless of NGT placement, however it is preferred that the NGT is out.
- OWF:** **If your site does not perform OWF, skip to question #11. Please remember to enter all applicable event codes during the assessment.**
- Q 7:** **Was OWF test performed**
Please respond by checking the appropriate box, "0-No", "1-Yes. If No, answer question 7a- provide primary reason infant missed the test. .
- Q 8:** **Provide caloric density of the feed**
- Q 9-10:** **Provide start and end volume of the bottle.**

[NIRA] Non Invasive Respiratory Assessments- Screen 2

Non Invasive Respiratory Assessments

RESPIRATORY INDUCTIVE PLETHYSMOGRAPHY [RIP] and OXYGENATION WHILE SLEEPING [OWS]

11. Was the baby's last feed >30 minutes ago? No Yes

12. Was the baby in quiet sleep state at the start of the test? No Yes

13. Was the Respiratory Inductive Plethysmography [RIP] test performed? No Yes

13a. If 'No', please check primary reason infant missed test

- Baby was ineligible
- Baby was eligible but discharged
- Staff Oversight/ Staff not available to perform test
- Baby not in quiet sleep
- Other, specify: _____

14. Was the Oxygenation While Sleeping [OWS] test performed? No Yes

14a. If 'No', please check primary reason infant missed test

- Baby was ineligible
- Baby was eligible but discharged
- Staff Oversight/ Staff not available to perform test
- Baby not in quiet sleep
- Other, specify: _____

BRONCHODILATOR [BD] ADMINISTRATION

15. Was Bronchodilator administered to the baby? No Yes

15a. If 'No', please check primary reason infant missed test

- Baby was ineligible
- Baby was eligible but discharged
- Staff Oversight/ Staff not available to perform test
- Other, specify: _____

16. Was entire bronchodilator dose given? No Yes

17. Treatment Response Heart Rate: _____ BPM

POST - BRONCHODILATOR RIP DATA

18. Was bronchodilator administration terminated early? No Yes

18a. If 'Yes', check primary reason for early termination:

- Infant woke up
- Hypoxemia
- Respiratory Distress
- Heart Rate exceeded 10% above Baseline
- Other, specify: _____

Please Note: If any Adverse Events occurred during the assessments, record the details in the Adverse Event Log (AE).

[NIRA] Non Invasive Respiratory Assessments- Screen 2

- Q 11: Was the baby's last feed > 30 minutes ago?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 12: Was the baby in quiet sleep at the start of the test?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
The quiet sleep definition can be found in the NIRA MOP as well as the FAQs.
- Q 13: Was the RIP test performed?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 13a: If no, please check primary reason infant missed test**
- Q 14: Was the OWS test performed?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 14a: If no, please check primary reason infant missed test**
- Q 15: Was Bronchodilator administered to the baby?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 15a: If no, please check primary reason infant missed test**
- Q 16: Was entire bronchodilator dose given?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 17: Treatment Response Heart Rate:**
Record Heart Rate in BPM.
- Q 18: Was BD administration terminated early?**
Please respond by checking the appropriate box, "0-No", "1-Yes.
- Q 18a: If Yes, check primary reason for early termination**
Specify reason if "Other" is checked.