PROP

Data Entry

Annotated CRFs

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

SCREENING FOR ELIGIBILITY AND CONSENT

1. Indicate the baby's data set (check all that apply):
   - ☐ PROP Core Database SRDATASET1
   - ☐ Single-Center Data Set SRDATASET2
2. What is the baby's date of birth? DOB
   Month Day Year
3. What is the baby's time of birth? STSTTM
   24 hour clock
4. Gender SEX.M ☐ Male ☐ Female SEX.F
5. Infant Ethnicity (reported by parent)
   - ETHNIC.1 ☐ Hispanic or Latino
   - ETHNIC.2 ☐ Not Hispanic or Latino
6. Infant Race (reported by parent- check all that apply)
   - RACENAT ☐ North American Indian/ Native Alaskan
   - RACEAS ☐ Asian
   - RACEAA ☐ Black/African American
   - RACENH ☐ Native Hawaiian/ Other Pacific Islander
   - RACECAU ☐ White/ Caucasian
   - RACEOTH ☐ Other: _____ QCOTHERS

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? SRGESTAGE.0 ☐ No SRGESTAGE.1 ☐ Yes
   - 7a. Indicate the number of completed weeks and the number of completed days: SRWEEKS ___ Weeks ___ Day SRDAYS
   - 7b. What method was used to determine the Gestational Age of the baby?
     - IEMETHOD.1 ☐ Early dating ultrasound (<20 weeks)
     - IEMETHOD.2 ☐ Certain LMP date (if early dating ultrasound is not available)
     - IEMETHOD.3 ☐ Best clinical estimate (if certain LMP date is not available)
8. Is the baby's postnatal age less than or equal to 7 days? IEPOSTNAT.0 ☐ No ☐ Yes IEPOSTNAT.1

Exclusion Criteria:

9. Is the baby considered not to be viable (decision not to administer effective therapies)? IEVIABLE.0 ☐ No IEVIABLE.1 ☐ Yes
10. Does the baby have congenital heart disease (not including PDA and hemodynamically insignificant VSD or ASD)? IECONGDZ.0 ☐ No IECONGDZ.1 ☐ Yes

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

SCREENING FOR ELIGIBILITY AND CONSENT

11. Does the baby have any structural abnormalities of the upper airway or lungs? IELUNGS.0 ☐ No IELUNGS.1 ☐ Yes

12. Does the baby have any other congenital malformations or syndromes that adversely affect life expectancy or development? IECONGMAL.0 ☐ No IECONGMAL.1 ☐ Yes

13. Is the baby unlikely to be available for long term follow- up? IELONGTERM.0 ☐ No IELONGTERM.1 ☐ 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? IEORRES.N ☐ No IEORRES.Y ☐ 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? SRCONSENT.0 ☐ No SRCONSENT.1 ☐ Yes

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

- SRAPPROACH.1 ☐ Research staff was not available
- SRAPPROACH.2 ☐ Parents were not available
- SRAPPROACH.3 ☐ Screening oversight
- SRAPPROACH.4 ☐ On request of responsible physician
- SRAPPROACH.98 ☐ Other, specify: _____ SROTHER

15b. If Yes, was parental consent obtained? ☐ No ☐ Yes IECONSENT.0 IECONSENT.1

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

- SRNOCON.1 ☐ Parents object to participation in research studies
- SRNOCON.2 ☐ Baby was enrolled in another research study
- SRNOCON.3 ☐ Parents objected to long term follow-up
- SRNOCON.98 ☐ Other, specify: _____ SVPROTS

16. Was parental consent obtained for DNA sample collections? LBBLSAMP.0 ☐ No LBBLSAMP.1 ☐ Yes

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

- ☐ Infant LBICON
- ☐ Mother LBMCON
- ☐ Father LBFCON

Enrollment

17. Was the baby enrolled into the study? IEMET.0 ☐ No ☐ Yes IEMET.1

17a. If **Yes,** enter Date of Enrollment SRENRDTC _____ Month Day Year

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

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

MATERNAL BASELINE DATA

Maternal Demographic Data:

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

2. What is the mother's ethnicity?
   - ☐ Hispanic or Latino ETHNIC.1
   - ☐ Not Hispanic or Latino ETHNIC.2

3. What is the mother's race (check all that apply)?
   - ☐ RACENAT North American Indian/ Native Alaskan
   - ☐ RACEAS Asian
   - ☐ RACEAA Black/ African American
   - ☐ RACENH Native Hawaiian/ Other Pacific Islander
   - ☐ RACECAU White/ Caucasian
   - ☐ RACEOTH Other QCOTHERS

4. What is the mother's highest level of education?
   - ☐ SREDU.1 Less than 7th grade
   - ☐ SREDU.2 7th - 9th grade
   - ☐ SREDU.3 10-12th grade
   - ☐ SREDU.4 High school degree
   - ☐ SREDU.5 Partial college
   - ☐ SREDU.6 College degree
   - ☐ SREDU.7 Graduate degree
   - ☐ SREDU.88 Unknown

5. What is the family arrangement?
   - ☐ SRFAM.1 Single parent family
   - ☐ SRFAM.2 Two parent family
   - ☐ SRFAM.88 Unknown

Paternal Demographic Data:

6. Was demographic data about the **biological father** obtained?
   - ☐ SRDEMO.0 No
   - ☐ Yes SRDEMO.1

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

7. What is the father's ethnicity?
   - ☐ Hispanic or Latino ETHNIC.1
   - ☐ Not Hispanic or Latino ETHNIC.2

8. What is the father's race (check all that apply)?
   - ☐ RACENAT North American Indian/ Native Alaskan
   - ☐ RACEAS Asian
   - ☐ RACEAA Black/ African American
   - ☐ RACENH Native Hawaiian/ Other Pacific Islander
   - ☐ RACECAU White/ Caucasian
   - ☐ RACEOTH Other: QCOTHERS

9. What is the father's highest level of education?
   - ☐ SREDU.1 Less than 7th grade
   - ☐ SREDU.2 7th - 9th grade
   - ☐ SREDU.3 10-12th grade
   - ☐ SREDU.4 High school degree
   - ☐ SREDU.5 Partial college
   - ☐ SREDU.6 College degree
   - ☐ SREDU.7 Graduate degree
   - ☐ SREDU.88 Unknown

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

MATERNAL BASELINE DATA

Pregnancy History:

10. Did the mother have diabetes during pregnancy? MHDIAB.0 ☐ No ☐ Yes MHDIAB.1
    10a. If Yes, did she receive insulin for her diabetes? CMDIABMED.0 ☐ No ☐ Yes CMDIABMED.1
11. Did the mother have hypertension during pregnancy? MHHYPERT.0 ☐ No ☐ Yes MHHYPERT.1
    11a. If yes, did she receive medication to treat her hypertension? CMHYPMED.0 ☐ No ☐ Yes CMHYPMED.1
12. Did the mother have asthma during her pregnancy? MHASTHMA.0 ☐ No ☐ Yes MHASTHMA.1
    12a. If yes, did she take medication regularly to control her asthma? CMASTHMED.0 ☐ No ☐ Yes CMASTHMED.1
13. Did the mother take any medications to prolong pregnancy? CMPREG.0 ☐ No ☐ Yes CMPREG.1
    13a. If **Yes,** check all that apply:
    - MHPROG ☐ Progesterone
    - CMCYCLO ☐ Cyclooxygenase inhibitors (Indocin)
    - CMBETAM ☐ Oral betamemetics
    - CMCABLOCK ☐ Calcium Channel Blockers
    - CMOXY ☐ Oxytocin receptor antagonist
    - CMMGSULF ☐ Magnesium Sulfate
    - CMAOTH ☐ Other _____ CMAOTS
14. Was a maternal or neonatal toxicology screen performed at the time of birth? RHTOXSCR.0 ☐ No ☐ Yes RHTOXSCR.1
    14a. If **Yes,** indicate the results: RHTOXRES.0 ☐ Negative ☐ Positive RHTOXRES.1
    14b. If **Positive,** indicate the substances (check all that apply)
    - SUMETH ☐ Amphetamines
    - SUCOCAINE ☐ Cocaine
    - IEOPIATE ☐ Opiates
    - SUBARB ☐ Barbiturates
    - SUBENZO ☐ Benzodiazepines
    - SUPCP ☐ Phencyclidine (PCP)
    - SUTHC ☐ Tetrahydrocannabinol (THC)
    - SUETH ☐ Ethanol
    - SUMETHA ☐ Methadone
    - SUDRUGO ☐ Other: _____ CMOTHER
15. Did the mother smoke tobacco products during pregnancy? OSPARSMK.0 ☐ No ☐ Yes QSPARSMK.1
    15a. Did anyone else smoke tobacco regularly in the mother's home during her pregnancy? QSSMPEER.0 ☐ No ☐ Yes QSSMPEER.1
16. Indicate the mother's height and weight at the time of delivery: HEIGHT Height _____ cm ☐ Unknown PEHTUNK
    WEIGHT Weight _____ kg ☐ Unknown PEWTUNK

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

MATERNAL BASELINE DATA

Labor and Delivery Data:

17. Was there placental abruption? RHPABR.0 ☐ No ☐ Yes RHPABR.1

18. Was the membrane rupture >18 hours before delivery? RHMEM.0 ☐ No ☐ Yes RHMEM.1

18a. If Question 18 is Yes, did the membrane rupture more than 7 days before delivery? ☐ No RHRUPT.0 ☐ Yes RHRUPT.1 ☐ Unknown RHRUPT.88

19. Was there any clinical chorioamnionitis? RHCHORIO.0 ☐ No ☐ Yes RHCHORIO.1

19a. If **Yes,** was placental pathology obtained? RHPPATH.0 ☐ No ☐ Yes RHPPATH.1

19b. If Question 19a is **Yes,** was there histologic evidence of chorioamnionitis? RHHISCHO.0 ☐ No ☐ Yes RHHISCHO.1

20. Were antibiotics given? CMANTI.0 ☐ No ☐ Yes CMANTI.1

20a. If **Yes,** why were antibiotics given? (check all that apply)

- MHCHORIO ☐ Chorioamnionitis
- MHBSTREP ☐ Group B Streptococcus (GBS) prophylaxis
- MHLABOR ☐ Preterm labor
- CMDSOTH ☐ Other _____ CMDSOTS

21. Were antenatal corticosteroids given? CMSTEROID.0 ☐ No ☐ Yes CMSTEROID.1

21a. If **Yes,** total number of completed courses:

- CMCOMP.0 ☐ None
- CMCOMP.1 ☐ One course
- CMCOMP.2 ☐ Two courses
- CMCOMP.3 ☐ Three courses
- CMCOMP.4 ☐ Four courses
- CMCOMP.5 ☐ Five courses

21b. Number of incomplete courses:

- ☐ None CMINCO.0
- ☐ One or more courses CMINCO.1

22. Was magnesium sulfate given for any reasons other than tocolysis? CMTOCO.0 ☐ No ☐ Yes CMTOCO.1

22a. If **Yes,** check the primary indication:

- ☐ Preeclampsia/ eclampsia CMMGIND.1
- ☐ Prevention of Cerebral Palsy CMMGIND.2

23. Was the onset of labor spontaneous? RHNSLAB.0 ☐ No ☐ Yes RHNSLAB.1

24. What was the mode of delivery?

- RHBIRTH.1 ☐ Vaginal Vertex
- RHBIRTH.2 ☐ Vaginal Breech
- RHBIRTH.3 ☐ Caesarian Section

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCI_DATE

BABY'S BASELINE DATA

1. What is the baby's gender? SEX.M ☐ Male ☐ Female SEX.F
2. What is the baby's birth weight? WEIGHT gms
3. What is the baby's head circumference? VSHEAD cm
4. What was the baby's birth location? MHLOCAT.1 ☐ Born inside the study center
   MHLOCAT.2 ☐ Born outside the study center
5. What was the baby's expected date of birth (EDC)? RHEDC
   Month Day Year
6. Was this a multiple birth? RHMULT.0 ☐ No ☐ Yes RHMULT.1
   If Yes, answer questions 6a and 6b.
   6a. Indicate the baby's birth order RHORDER ___ Number of RHORDER ___ Number
   6b. Record the PID(s) of siblings enrolled in the PROP Multicenter core database: SRMULTID PID 1, SRMULTID PID 2
7. Were umbilical cord blood gas analyses performed? DSVBG.0 ☐ No DSVBG.1 ☐ Yes
   If **Yes,** record the result(s) of the umbilical cord blood gas analysis:
   7a. Sample pH: VSTESTB Base Deficit: LBBASED
   Type of sample: ☐ Venous BDSAMPLE.1 ☐ Arterial BDSAMPLE.2 ☐ Uncertain BDSAMPLE.3
   7b. Sample pH: VSTESTB Base Deficit: LBBASED
   Type of sample: ☐ Venous BDSAMPLE.1 ☐ Arterial BDSAMPLE.2 ☐ Uncertain BDSAMPLE.3
8. What was the APGAR Score? PEAPGAR [0-10] at 1 minute PEAPGAR [0-10] at 5 minutes
9. Were any stabilization procedures provided at birth? QSMEDPRO.0 ☐ No ☐ Yes OSMEDPRO.1
   9a. If **Yes,** check all that apply:

OSOXYGEN ☐ Supplemental Oxygen
OSCPAP ☐ CPAP
QSNIPPV ☐ Non-invasive positive pressure ventilation with flow inflating or self inflating bag
OSRESUS ☐ T-Piece resuscitator
QSINTUB ☐ Intubation
QSCHCOMP ☐ Chest Compression
QSEPIN ☐ Cardiac Drugs (Epinephrine)
OSSURF ☐ Surfactant Administration

10. What was the first temperature recorded at the first NICU admission? VSTEMP ¿ C
    10a. Indicate how the temperature was obtained: ☐ Core temperature (e.g. rectal), or PETEMPLOC.1
    ☐ Peripheral/ skin temperature (e.g. axillary) PETEMPLOC.2
11. Was Prophylactic Indomethacin given within the first 24-hours of life? CMINDOM.0 ☐ No ☐ Yes CMINDOM.1

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

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? WEIGHT _____ gms ☐ Not done WEIGHT_NA
2. What is the baby's head circumference VSHEAD _____ cm ☐ Not done VSHEADNA
3. How much milk did the baby receive today?
   - DYFEED.0 ☐ None
   - DYFEED.1 ☐ Partial Feed
   - DYFEED.2 ☐ Full Feed (no parenteral nutrition on this day)

   3a. If **Partial or Full** indicate the type of milk provided:
   - DYMILK.1 ☐ Human milk
   - DYMILK.2 ☐ Formula
   - DYMILK.3 ☐ Both

Daily Medication Data

4. Were any drugs given today? SUDRUG.0 ☐ No ☐ Yes SUDRUG.1

   If Yes, indicate which of the following drugs were given today:

5, Methylxanthine drugs CMMETH.0 ☐ No ☐ Yes CMMETH.1

   5a. If Yes, choose one:

CMCAFFEINE ☐ Caffeine Citrate Dose CMCAFDOSE _____ mg Given every CMCAFFREQ _____ hour(s) Route: CMCAFRT.1 CMCAFRT.2

CMAMINO ☐ Aminophylline Dose CMAMDOSE _____ mg Given every CMAMFREQ _____ hour(s)

CMTHEO ☐ Theophylline Dose CMTHEODOSE _____ mg Given every CMTHEOFREQ _____ hour(s)

CMMETHOTH ☐ 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: CMSTEROID.0 ☐ No ☐ Yes CMSTEROID.1

   6a. If Yes, choose one:

CMHCT ☐ Hydrocortisone Dose CMHCTDOSE _____ mg Given every CMHCTFREQ _____ hour(s) Route: CMHCTRT.1 CMHCTRT.2

CMDEXM ☐ Dexamethasone Dose: CMDEXD _____ mg Given every CMDEXMFREQ _____ hour(s) Route: CMDEXMRT.1 CMDEXMRT.2

CMPRED ☐ Prednisone/Prednisolone Dose: CMPREDDOSE _____ mg Given every CMPREDFR _____ hour(s)

CMMPR ☐ Methylprednisolone Dose: CMMPDOSE _____ mg Given every CMMPFREQ _____ hour(s)

CMSYSTOTH ☐ Other *(record on the Additional Medication Log)*

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

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 Steriod drugs CMINSTER.0 ☐ No ☐ Yes CMINSTER.1

7a. If Yes, check all that apply: CMBUDDOSE CMBUDU.1 CMBUDU.2

CMBUDE	☐ Budesonide (Nebulized or MDI)	Dose: ____	☐ mcg ☐ mg	Given every ____ hour(s) CMBUDFREQ
CMBECLO	☐ Beclomethasone	CMBECLODOSE Dose: ____	mg	Given every ____ hour(s) CMBECLOFREQ
CMCIC	☐ Ciclesonide	CMCICDOSE Dose ____	mg	Given every ____ hour(s) CMCICFREQ
CMFLU	☐ Flunisolide	CMFLUDOSE Dose: ____	mg	Given every ____ hour(s) CMFLUFREQ
CMFLUT	☐ Fluticasone	CMFLTDOSE Dose: ____	mg	Given every ____ hour(s) CMFLUTFREO
CMMOME	☐ Mometasone	CMMOMEDOSE Dose: ____	mg	Given every ____ hour(s) CMMOMEFREQ
CMTRIA	☐ Triamcinolone	CMTRIADOSE Dose: ____	mg	Given every ____ hour(s) CMTRIAFREQ
CMDEXA	☐ Dexamethasone	Dose: ____	CMDEXADOSE mg	Given every ____ hour(s) CMDEXAFREQ
CMINHSOTH	☐ 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 CMINHBRO.0 ☐ No ☐ Yes CMINHBRO

8a. If Yes, check all that apply:

CMALBU.1 CMALBU.2 CMLEVU.1 CMLEVU.2 CMIPRABU.1 CMIPRABU.2

CMALB	☐ Albuterol	CMALBDOSE Dose: ____	☐ mcg ☐ mg	Given every ____ hour(s) CMALBFREQ
CMLEV	☐ Levalbuterol	CMLEVDOSE Dose: ____	☐ mcg ☐ mg	Given every ____ hour(s) CMLEVFREO
CMIPRAB	☐ Ipratropium bromide	CMIPRABDOSE Dose: ____	☐ mcg ☐ mg	Given every ____ hour(s) CMIPRABFREQ
CMFORM	☐ Formoterol	CMFORMDOSE Dose: ____	mcg	Given every ____ hour(s) CMFORMFREQ
CMREPI	☐ Racemic epinephrine	CMREPIDOSE Dose: ____	mg	Given every ____ hour(s) CMREPIFREQ
CMIBROTH	☐ Other *(record on the Additional Medication Log)*			

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

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 CMDIUR.0 ☐ No ☐ Yes CMDIUR.1

9a. If Yes, check all that apply:

CMFUR	☐ Furosemide	Dose: CMFURDOSE mg	Given every CMFURFREQ hour(s)	Route:	☐ PO	CMFURRT.2	
					☐ IV	CMFURRT	
CMBUM	☐ Bumetanide	Dose: CMBUMDOSE mg	Given every CMBUMFREQ hour(s)	Route:	☐ PO	CMBUMRT	
					☐ IV	CMBUMRT	
CMCHLOR	☐ Chlorothiazide	Dose: CMCHLORDOSE mg	Given every CMCHLORFREQ hour(s)	Route:	☐ PO	CMCHLORRT	
					☐ IV	CMCHLORRT	
CMHCTZ	☐ Hydrochlorothiazide	Dose: CMHCTZDOSE mg	Given every CMHCTZFREQ hour(s)				
CMSPIRO	☐ Spironolactone	Dose: CMSPIRODOSE mg	Given every CMSPIROFREQ hour(s)				
CMMTZ	☐ Metolazone	Dose: CMMTZDOSE mg	Given every CMMTZFREQ hour(s)				
CMDIUROTH	☐ Other *(record on the Additional Medication Log)*						

10. Cardiovascular drugs: CMCVS.0 ☐ No CMCVS.1 ☐ Yes

10a. If Yes, check all that apply:

CMEPI	☐ Epinephrine infusion	☐ Vasopressin	CMVASO
CMDOPA	☐ Dopamine infusion	☐ Norepinephrine	CMNORE
CMDOBU	☐ Dobutamine infusion		

11. Other Cardio/Respiratory drugs: CMCVSRES.0 ☐ No CMCVSRES.1 ☐ Yes

11a. If Yes, check all that apply:

CMVITA	☐ Vitamin A IM or Oral (for prevention of BPD)	CMVDIL	☐ Other pulmonary vasodilators for treatment of pulmonary hypertension other than Nitric Oxide
CMSURF	☐ Surfactant	CMMUCO	☐ Mucolytic
CMSILD	☐ Sildenafil	CMDORN	☐ Dornase Alfa
CMMILR	☐ Milrinone		

12. Neuro-Muscular Blocking Agent CMNEURO.0 ☐ No ☐ Yes CMNEURO.1

13. Antimicrobial drugs and other agents to prevent infections: CMANTI.0 ☐ No ☐ Yes CMANTI.1

13a. If Yes, check all that apply:

CMANTIB	☐ Antibacterial
CMANTIF	☐ Antifungal
CMANTIV	☐ Antivrial
CMPVZ	☐ Palivizumab
CMPROBIO	☐ Probiotic

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCI_DATE

14. Anxiolytic, Anticonvulsant, and Narcotic Analgesic drugs: CMANX.0 ☐ No CMANX.1 ☐ Yes

14a. If Yes, check all that apply:

- CMBENZO ☐ Benzodiazepines
- CMPHNB ☐ Phenobarbital
- CMPHENY ☐ Phenytoin
- CMLEVE ☐ Levetiracetam
- CMMORPH ☐ Morphine
- CMFENT ☐ Fentanyl
- CMMETHAD ☐ Methadone
- CMDEXMED ☐ Dexmedetomidine

15. Anti-Gastroesophageal Reflex drugs: CMGERD.0 ☐ No CMGERD.1 ☐ Yes

15a. If Yes, check all that apply:

- CMPPI ☐ Proton Pump Inhibitors
- CMHRA ☐ H2 Receptor Antagonists
- CMMOTI ☐ Motility agents
- CMANGOTH ☐ Other

16. Use of blood products and Hematologic Supplements: CMHEMA.0 ☐ No CMHEMA.1 ☐ Yes

16a. If Yes, check all that apply:

- CMEPO ☐ Erythropoietin
- CMRBCT ☐ Red Blood Cell Transfusion
- CMPLT ☐ Platelets
- CMFESO ☐ Iron Supplements

17. Oral Vitamins and Electrolyte Supplements: CMORVITA.0 ☐ No CMORVITA.1 ☐ Yes

17a. If Yes, check all that apply:

- CMVITD ☐ Vitamin D
- CMVITE ☐ Vitamin E
- CMMULTIV ☐ Multivitamin
- CMKSUP ☐ Potassium Supplement
- CMNASUP ☐ Sodium Supplement

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

Daily Respiratory Data

1. Did the baby receive any supplemental oxygen today? DSOXY.0.0 ☐ No ☐ Yes DSOXY.0.1

   1a. If Yes, how long was supplemental oxygen used for? OSOXY.0.1 ☐ 12 hours or less
   QSOXY.0.2 ☐ More than 12 hours

   1b. What was the concentration of supplemental oxygen at 1200 (Noon) today? QSCOXY.0 %

QSRESSUP.0.0 QSRESSUP.0.1

2. Did the baby receive any other respiratory support today? ☐ No ☐ Yes

   If Questions 1 or 2 are Yes, answer questions 3 - 6. QSPAPT.0.0 QSPAPT.0.1

3. Was Positive Airway Pressure with Endotracheal Tube used today? ☐ No ☐ 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

OSCMV.0 ☐ Conventional Mechanical Ventilation (CMV):
Mean Airway Pressure (MAP): QSMAP.1 cmH2O
Positive End Expiratory Pressure (PEEP): QSPEEP.1 cmH2O

QSFREQO.0 ☐ High Frequency Oscillation
MAP: QSMAP.2 cm H20

QSFREQJ.0 ☐ High Frequency Jet Ventilation
MAP QSMAP.3 cm H20

QSRESSUPT.0.0 QSRESSUPT.0.1

4. Was Respiratory support without Endotracheal Tube used today: ☐ No ☐ 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

OSNIMV.0 ☐ Nasal Intermittent Mandatory Ventilation (NIMV):
MAP: QSMAP.4 cm H20
PEEP: QSPEEP.2 cm H20

OSCPAP.0 ☐ Continuous Positive Airway Pressure (CPAP):
CPAP DSCPAP.0 cm H20

OSNCAN.0 ☐ Nasal Cannula with flow rate
Nasal Cannula flow: DSNCAN.0 Lpm

5. Was inhaled nitric oxide given today? OSNOXY.0.0 ☐ No ☐ Yes QSNOXY.0.1

   5a. If Yes, record the concentration at 1200 (Noon) or closest recorded data to 12 (Noon) if noon data are not available DSNOXY.0 ppm

6. Was the baby reintubated today? OSREINTB.0.0 ☐ No ☐ Yes QSREINTB.0.1

   6a. If Yes, indicate the primary reason why the baby was reintubated:

DSREINTB.0.1 ☐ Increasing respiratory distress
DSREINTB.0.2 ☐ Stridor
DSREINTB.0.3 ☐ Apnea and Bradycardia
DSREINTB.0.4 ☐ Suspected infection
DSREINTB.0.5 ☐ For diagnostic or therapeutic procedures, including surgery
DSREINTB.0.6 ☐ Unplanned extubation(s), indicate the number of occurrences this day: DSNEXT.0
DSREINTB.0.98 ☐ Other specify SROTHS.0

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

BRAIN IMAGING DATA

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

1. Was brain imaging performed? IMBRAIN.0 ☐ No ☐ Yes IMBRAIN.1

1a. If Yes, indicate which time:

IMTIME.1 ☐ Within 7 days +/- 1 week after baby's birth

IMTIME.2 ☐ Within 30 days +/- 1 week after baby's birth

IMTIME.3 ☐ Between 34 Weeks and 40 Weeks Post-Menstrual Age

2. What imaging technique was used?

IMUSRAD.1 ☐ Head Ultrasound (HUS)

IMUSRAD.2 ☐ 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.

IMNORM ☐ Normal

IMSUBHEM ☐ Subependymal hemorrhage (Grade 1 hemorrhage)

IMIVH ☐ IVH without ventricular dilation (Grade 2 hemorrhage)

IMIVHD ☐ IVH distending at least one lateral ventricle (Grade 3 hemorrhage)

IMECHO ☐ Intraparenchymal echodense lesion (Grade 4 hemorrhage)

IMPVL ☐ Cystic Periventricular Leucomalacia (PVL)

IMCYST ☐ Porencephalic cyst

IMVENT ☐ Ventriculomegaly (with or without resolving IVH)

IMATRO ☐ Cotrical Atrophy

IMCHEM ☐ Cerebellar Hemmorrhage

IMOTH ☐ Other, specify *: _____ IMOTHS

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

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

SPECIMEN COLLECTION FORM

1. Collection Date DADTC _____ [mm/dd/yyyy]

2. Collection Time (if applicable) ASDTM _____ [24 hour clock]

3. Type of Specimen

LBTISSUE.1 ☐ Infant Tracheal Aspirate
LBTISSUE.2 ☐ Infant Urine
LBTISSUE.3 ☐ Infant Saliva for DNA
LBTISSUE.4 ☐ Mother Saliva for DNA
LBTISSUE.5 ☐ Father Saliva for DNA

4. Laboratory Accession Number (from TA or UR vial label)
Site #/ Sample Type*/ Sample # CMLOT _____
e.g. 011TA1234

4a. Enter Tracheal Aspirate **CL** Lab Accession Number
Site #/ Sample Type*/ Sample # CMLOT _____
e.g. 011CL1234

5. Number of Aliquots (for Tracheal Aspirate Supernatant and Urine) LBALNU

5a. Date Tracheal Aspirate or Urine Specimen Frozen DSDTC _____ [mm/dd/yyyy]

5b. Time Tracheal Aspirate or Urine Specimen Frozen BDFROTM _____ [24 hour clock]

6. Date sample shipped to Core Lab: GNDTC _____ [mm/dd/yyyy]

* 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

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

ADDITIONAL MEDICATION LOG

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

Medication Sequence Number	Drug Code	Drug Name
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

Non Invasive Respiratory Assessments

NOTE: Please indicate date of assessment in date field

BASELINE DATA

1. Were RIP bands placed on the baby? QSRIP.0 ☐ No QSRIP.1 ☐ Yes

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

QSRMIS.1 ☐ Baby was ineligible
OSRMIS.2 ☐ Baby was eligible but discharged
OSRMIS.3 ☐ Staff Oversight/ Staff not available to perform test
QSRMIS.98 ☐ Other, specify: QSROTH

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

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

4. Baseline Heart Rate: VSHR Beats per minute

5. Respiratory Status:
OSRESP.1 ☐ No Respiratory Support
OSRESP.2 ☐ Nasal Cannula ≤ 1 LPM

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

6. Nasogastric Tube (NGT) placement at the start of the test ☐ In QSNGTB.1 ☐ Out QSNGTB.2

OXYGENATION WHILE FEEDING [OWF]

7. Was the Oxygenation While Feeding [OWF] test performed? OSOWF.0 ☐ No OSOWF.1 ☐ Yes

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

OSFMIS.1 ☐ Baby was ineligible
OSFMIS.2 ☐ Baby was eligible but discharged
OSFMIS.3 ☐ Staff oversight/ Staff not available to perform test
OSFMIS.4 ☐ Site does not perform OWF
OSFMIS.98 ☐ Other, specify: OSFOTH

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

8. Caloric density: QSCALD cal/oz

9. Start Volume in bottle QSVOLS mL

10. End Volume in bottle QSVOLE 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	

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

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

11. Was the baby's last feed >30 minutes ago? OSFEED.0 ☐ No ☐ Yes OSFEED.1

12. Was the baby in quiet sleep state at the start of the test? QSSLP.0 ☐ No ☐ Yes QSSLP.1

13. Was the Respiratory Inductive Plethysmography [RIP] test performed? QSRPP.0 ☐ No ☐ Yes QSRPP.1

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

OSRPMS.1 ☐ Baby was ineligible
QSRPMS.2 ☐ Baby was eligible but discharged
QSRPMS.3 ☐ Staff Oversight/ Staff not available to perform test
QSRPMS.4 ☐ Baby not in quiet sleep
OSRPMS.98 ☐ Other, specify: QSRPOT _____

14. Was the Oxygenation While Sleeping [OWS] test performed? OSOWS.0 ☐ No OSOWS.1 ☐ Yes

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

QSOMIS.1 ☐ Baby was ineligible
QSOMIS.2 ☐ Baby was eligible but discharged
QSOMIS.3 ☐ Staff Oversight/ Staff not available to perform test
OSOMIS.4 ☐ Baby not in quiet sleep
QSOMIS.98 ☐ Other, specify: OSOOTH _____

BRONCHODILATOR [BD] ADMINISTRATION

15. Was Bronchodilator administered to the baby? QSBRD.0 ☐ No QSBRD.1 ☐ Yes

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

QSBMIS.1 ☐ Baby was ineligible
OSBMIS.2 ☐ Baby was eligible but discharged
QSBMIS.3 ☐ Staff Oversight/ Staff not available to perform test
OSBMIS.98 ☐ Other, specify: OSBOTH _____

16. Was entire bronchodilator dose given? QSBDOSE.0 ☐ No QSBDOSE.1 ☐ Yes

17. Treatment Response Heart Rate: QSBHR ____ BPM

POST - BRONCHODILATOR RIP DATA

18. Was bronchdilator administration terminated early? QSBTERM.0 ☐ No QSBTERM.1 ☐ Yes

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

☐ Infant woke up OSBRSN.1
OSBRSN.2 ☐ Hypoxemia
QSBRSN.3 ☐ Respiratory Distress
QSBRSN.4 ☐ Heart Rate exceeded 10% above Baseline
OSBRSN.98 ☐ Other, specify: QSBOTHS _____

18b. Total time of bronchodilator treatment QSBRODTC ____ minutes

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

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Room Air Challenge

Note: Please indicate date of assessment in date field.

BASELINE DATA

1. Indicate baby's post-menstrual age at time of assessment — SRWEEKS ___ Weeks SRDAYS ___ Day
2. What is the baby's body weight? — WEIGHT ___ gms
3. Baseline Respiratory Rate (RR) — VSRR ___ Breaths per minute
4. Baseline Heart Rate (HR) — VSHR ___ Beats per minute
5. Respiratory Status

QSRESP.1 ☐ No Continuous Respiratory Support [No BPD]
QSRESP.2 ☐ Nasal Cannula [Continue to question 5a]
QSRESP.3 ☐ CPAP, SiPAP, or MV [BPD]

5a. Oxygen Flow (nasal cannula only): QSOXFLOW ___ LPM QSCOXY ___ %

6. SpO2: QSSPO ___ %
7. Most recent PCO2: QSPCO ___ ☐ NA QSOXNA
   7a. Date of PCO2: QSPCODT ___ mm/dd/yyyy

ROOM AIR CHALLENGE [RAC]/ OXYGEN and FLOW REDUCTION to ROOM AIR

8. Was the Room Air Challenge test performed? QSRAC.0 ☐ No ☐ Yes QSRAC.1

8a. If 'No', please check primary reason infant missed test

QSRAMIS.1 ☐ Baby was ineligible [Complete item 8b.]
QSRAMIS.2 ☐ Baby was eligible but discharged or transferred
OSRAMIS.3 ☐ Staff oversight/ Staff or equipment not available to perform test
QSRAMIS.98 ☐ Other, specify: QSRAOTH _____

8b. If ineligible, please check primary reason for ineligibility

SRINELIG.1 ☐ Baby was off all continuous support
SRINELIG.2 ☐ Baby was on a higher level of support than nasal cannula
SRINELIG.3 ☐ Unable to maintain baseline saturation SpO2 ≥ 90%
SRINELIG.4 ☐ 40 weeks only: No BPD at 36 weeks (Off continuous support or passed RAC)

9. Did infant arouse (active sleep or awake) during the observation period? QSAWAKE.0 ☐ No QSAWAKE.1 ☐ Yes

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Room Air Challenge

10. Please indicate the result of the Room Air Challenge test:
- ☐ Pass [No BPD] QSRESR.1
- ☐ Fail [BPD] Complete items 10a-c QSRESR.2

10a. Record time to fail test: STTOTM minutes

10b. Please indicate primary reason for test failure:

- QSFRSN.2 ☐ Desaturation <90% for 5 consecutive minutes
- QSFRSN.3 ☐ Desaturation <80% for 15 consecutive seconds
- QSFRSN.4 ☐ Apnea
- QSFRSN.5 ☐ Bradycardia
- QSFRSN.98 ☐ Other, specify: QSFOTH _____

10c. Respiratory Support at Failure: DSNCAN LPM QSFOXY %

11. Final Respiratory Rate QSFRESP Breaths per minute
12. Final Heart Rate QSFVSHR Beats per minute
13. Final SpO2: QSFSPO %

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

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Hypoxic Challenge Test

Note: Please indicate date of assessment in date field.

BASELINE DATA

1. Indicate baby's post-menstrual age at time of assessment SRWEEKS ___ Weeks SRDAYS ___ Days
2. What is the baby's body weight? WEIGHT ___ gms
3. Baseline Respiratory Rate (RR) VSRR ___ Breaths per minute
4. Baseline Heart Rate (HR) VSHR ___ Beats per minute
5. SpO2 QSSPO ___ %

HYPOXIC CHALLENGE TEST [HCT]/ OXYGEN REDUCTION TO 15%

6. Was the Hypoxic Challenge test performed? QSHCT.0 ☐ No ☐ Yes QSHCT.1

6a. If 'No', please check primary reason infant missed test

- QSHMIS.1 ☐ Baby was ineligible [Complete item 6b.]
- QSHMIS.2 ☐ Baby was eligible but discharged or transferred
- OSHMIS.3 ☐ Staff oversight/ Staff or equipment not available to perform test
- QSHMIS.4 ☐ Baby had acute respiratory illness
- OSHMIS.98 ☐ Other, specify: QSRAOTH _____

6b. If ineligible , please check primary reason for ineligibility

- SRINELIG.1 ☐ Failed RAC
- SRINELIG.2 ☐ Not weaned off clinical respiratory support
- SRINELIG.3 ☐ Unable to maintain baseline saturation SpO2 ≥ 90%
- SRINELIG.4 ☐ On continuous respiratory support without RAC at 36 weeks PMA

7. Did infant arouse (active sleep or awake) during the observation period? QSAWAKE.0 ☐ No QSAWAKE.1 ☐ Yes

8. Please indicate the result of the Hypoxic Challenge test:
   - ☐ Pass QSRESR.1
   - ☐ Fail [Complete items 8a-b] QSRESR.2

8a. Record time to fail test: STTOTM ___ minutes

8b. Please indicate primary reason for test failure:

- QSFRSN.2 ☐ Desaturation <85% for 60 consecutive seconds
- QSFRSN.3 ☐ Desaturation <80% for 15 consecutive seconds
- OSFRSN.4 ☐ Apnea
- QSFRSN.5 ☐ Bradycardia
- OSFRSN.98 ☐ Other, specify: QSFOTH _____

9. Final Respiratory Rate QSFRESP ___ Breaths per minute
10. Final Heart Rate QSFVSHR ___ Beats per minute
11. Final SpO2: QSFSPO ___ %

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

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

Adverse Event Log

AE Seq #	AE Code	Adverse Event Description (Use for AE Codes 5 or 9)	Date of Onset [mm-dd-yyyy]	Outcome
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1
AESEQ	AETERM.1	AEVTERM	AESTDTC	AEOUT.1

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

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? QSAIRLK.0 ☐ No ☐ Yes QSAIRLK.1

If **Yes,** indicate the type(s) of air leak by answering questions 1a-1d:

1a. Pneumothorax: SGCPNEUMO.0 ☐ No ☐ Yes SGCPNEUMO.1
If **Yes,** complete 1a1 and 1a2

1a1. Was a chest tube placed? QSCTUBE.0 ☐ No ☐ Yes QSCTUBE.1

1a2. Has there been evidence of a bronchopleural fistula? QSBPF.0 ☐ No ☐ Yes QSBPF.1

1b. Pulmonary Interstitial Emphysema (PIE): QSPIE.0 ☐ No ☐ Yes QSPIE.1

1c. Pneumomediastinum: QSPNEUMOM.0 ☐ No ☐ Yes QSPNEUMOM.1

1d. Pneumopericardium: QSPNEUMOP.0 ☐ No ☐ Yes QSPNEUMOP.1

2. Did the baby have any pulmonary hemorrhages? QSPULMHEM.0 ☐ No ☐ Yes QSPULMHEM.1

If **Yes,** complete 2a and 2b.

QSTXFUSE.0 QSTXFUSE.1

2a. Did these hemorrhages require transfusion of blood products? ☐ No ☐ Yes

2b. Did these hemorrhages require increased concentrations of supplemental oxygen and/or ventilator support? QSOXYGEN.0 ☐ No ☐ Yes QSOXYGEN.1

3. Did the baby have a clinical diagnosis of Patent Ductus Arteriosus (PDA)? ☐ No QSPDA.0 ☐ Yes QSPDA.1

3a. Was the PDA confirmed by Echocardiogram? IMECHOCARD.0 ☐ No ☐ Yes IMECHOCARD.1

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): CMINDOM.0 ☐ No ☐ Yes CMINDOM.1

If **Yes,** indicate the first date of each distinct course of Indomethacin:

CMINDOCOURSE	CMINDOCOURSE	CMINDOCOURSE
Month Day Year	Month Day Year	Month Day Year
First Course	Second Course	Third Course

3c. Ibuprofen: CMNSAID.0 ☐ No ☐ Yes CMNSAID.1

If **Yes,** indicate the first date of each distinct course of Ibuprofen:

CMNSAIDCOURSE	CMNSAIDCOURSE	CMNSAIDCOURSE
Month Day Year	Month Day Year	Month Day Year
First Course	Second Course	Third Course

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST

3d. Surgical Ligation: SGLIGAT.0 ☐ No ☐ Yes SGLIGAT.1

If **Yes,** date of surgery: MHSURGDTC
Month Day Year

4. Was a diagnosis of pulmonary hypertension made by a pediatric cardiologist? MHPULMHTN.0 ☐ No ☐ Yes MHPULMHTN.1

4a. If **Yes,** was this diagnosis based on (Check all tht apply)

IMECHH ☐ Echocardiogram DCDXDTC
Month Day Year
Date of diagnosis

SRHEARTCATH ☐ Cardiac catheterization DIAGNOSIS_DT
Month Day Year
Diagnosis date

5. Was airway endoscopy performed by an ENT surgeon or pediatric pulmonologist? SGENDO.0 ☐ No ☐ Yes SGENDO.1

5a. If **Yes,** indicate the clinical findings (check all that apply):

SGNORM ☐ No abnormality noted			
SGTRACH ☐ Tracheomalacia	SGTRACHPROC Month Day Year 1st Procedure	SGTRACHPROC Month Day Year 2nd Procedure
SGLARYN ☐ Laryngomalacia	SGLARYNPROC Month Day Year 1st procedure	SGLARYNPROC Month Day Year 2nd procedure
SGSTENO ☐ Subglottic stenosis	SGSTEONPROC Month Day Year 1st procedure	SGSTEONPROC Month Day Year 2nd procedure
SGUPARA ☐ Vocal Cord Paralysis (unilateral)	SGUPARAPROC Month Day Year 1st procedure	SGUPARAPROC Month Day Year 2nd procedure
SGBPARA ☐ Vocal Cord Paralysis (bilateral)	SGBPARAPROC Month Day Year 1st procedure	SGBPARAPROC Month Day Year 2nd procedure
SGOTH ☐ Other, specify: SGOTHS	SGOTHSPROC Month Day Year 1st procedure	SGOTHSPROC Month Day Year 2nd procedure

6. Did the baby have a tracheotomy? QSTRACH.0 ☐ No ☐ Yes QSTRACH.1

6a. If Yes, indicate the procedure date: QSTRACHDTC

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER COMES FIRST

7. Was Ventilator- Associated Pneumonia (VAP) suspected in this baby? QSVAP.0 ☐ No ☐ Yes QSVAP.1

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)? QSVAPX.0 ☐ No ☐ Yes QSVAPX.1

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

- QSTEMP ☐ Temperature instability with no other recognized cause
- QSLKOP ☐ Leukopenia (<4,000 WBC/mm3)
- QSLKOC ☐ Leukocytosis (>=15,000 WBC/mm3) and left shift (>= 10% band forms)
- QSSPUTUM ☐ New onset of purulent sputum
- QSCSPUT ☐ Change in character of sputum
- QSRSEC ☐ Increased respiratory secretions
- QSSUCT ☐ Increased suctioning requirements
- QSAPNEA ☐ Apnea
- QSTACHYPNEA ☐ Tachypnea
- QSNFLARE ☐ Nasal flaring with retraction of chest wall or grunting
- STWHEEZE ☐ Wheezing
- QSRALES ☐ Rales
- QSRHONCHI ☐ Rhonchi
- PECOUGH ☐ Cough
- QSBRADYC ☐ Bradycardia (<100 beats per minute)
- QSTACHYC ☐ Tachycardia (>170 beats per minute)
- RHNADK ☐ None of the above

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

- IMNINF ☐ New infiltrate
- IMPINF ☐ Progressive and persistent infiltrate
- IMCONS ☐ Consolidation
- IMCAV ☐ Cavitation
- IMPNEUMO ☐ Pneumatoceles
- RHNADK ☐ None of the above

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

AT WEEK 36, WEEK 40 PMA OR DISCHARGE, WHICHEVER OCCURS FIRST

Infection

8. Did the baby have any blood culture-proven sepsis — MBCSEPSIS.0 ☐ No MBCSEPSIS.1 ☐ Yes

8a. If **Yes,** indicate the type(s) of Sepsis:

MBBACT ☐ Bacterial Number of distinct episodes: MBBACTE

MBFUN ☐ Fungal Number of distinct episodes: MBFUNE

MBVIR ☐ Viral Number of distinct episodes: MBVIRE

8b. Presumed, but not culture-proven Sepsis? — MBSEPSIS.0 ☐ No MBSEPSIS.1 ☐ Yes

If **Yes,** number of distinct episodes MBSEPSISE

9. Did the baby have any culture-proven Meningitis? — MBCMENINGES.0 ☐ No MBCMENINGES.1 ☐ Yes

9a. If **Yes,** indicate the type(s) of Meningitis:

MBMBAC ☐ Bacterial Number of distinct episodes: MBMBACE

MBMFUN ☐ Fungal Number of distinct episodes: MBMFUNE

MBMVIR ☐ Viral Number of distinct episodes: MBMVIRE

9b. Presumed, but not culture-proven Meningitis? — MBMENINGES.0 ☐ No MBMENINGES.1 ☐ Yes

If **Yes,** number of distinct episodes MBMENINGESE

10. Did the baby have upper respiratory tract infection of confirmed viral etiology? — MBVURI.0 ☐ No MBVURI.1 ☐ Yes

10a. If **Yes,** indicate the confirmed viral etiologies (check all that apply):

		1st Diagnosis	2nd Diagnosis
MBINFLU	☐ Influenza	MBINFLUDTC	MBINFLUDTC
MBPARAFLU	☐ Parainfluenzae	MBPARADTC	MBPARADTC
MBRHINO	☐ Rhinovirus	MBRHINODTC	MBRHINODTC
MBRSV	☐ Respiratory Syncytial virus	MBRSVDTC	MBRSVDTC
MBAOTH	☐ Other, specify MBAOTHS	MBOTHSDTC	MBOTHSDTC

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER OCCURS FIRST

AEINFECT.0 AEINFECT.1

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

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

		1st Diagnosis	2nd Diagnosis
MBUTI	☐ Urinary Tract Infection	MBUTIDTC	MBUTIDTC
MBCELL	☐ Cellulitis	MBCELLDTC	MBCELLDTC
MBOSTEO	☐ Osteomyelitis	MBOSTEODTC	MBOSTEODTC
MBCMV	☐ Cytomegalovirus (CMV)	MBCMVDTC	MBCMVDTC
MBSURG	☐ Surgical Wound Infection	MBSURGDTC	MBSURGDTC
MBBOTH	☐ Other, specify MBBOTHS	MBBOTHSDTC	MBBOTHSDTC

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

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? QSNEC.0 ☐ No QSNEC.1 ☐ Yes

12a. If **Yes,** date of first medical diagnosis: QSNECDTC
Month Day Year

12b. Were there any bowel perforations? QSNECPERF.0 ☐ No ☐ Yes QSNECPERF.1

12c. Did the baby have surgery for NEC? SGNEC.0 ☐ No ☐ Yes SGNEC.1

If **Yes,** indicate the surgical procedure(s) performed (check all that apply) and provide the date(s) of surgery:

SGNECPERI ☐ Peritoneal Drain	SGNECPERIDTC Month Day Year 1st Surgery	SGNECPERIDTC Month Day Year 2nd Surgery
SGNECLAP ☐ Laparotomy	SGNECLAPDTC Month Day Year 1st Surgery	SGNECLAPDTC Month Day Year 2nd Surgery
SGBOWEL ☐ Bowel Resection	SGBOWELDTC Month Day Year 1st Surgery	SGBOWELDTC Month Day Year 2nd Surgery
SGADH ☐ Repair of adhesion/ Strictures	SGADHDTC Month Day Year 1st Surgery	SGADHDTC Month Day Year 2nd Surgery

13. Did the baby have any Isolated Bowel Perforations not considered to be associated with NEC? QSPERF.0 ☐ No ☐ Yes QSPERF.1

13a. If **Yes,** date of first medical diagnosis: QSPERFDTC
Month Day Year

13b. Did the baby receive any surgery for Isolated Bowel Perforations not considered to be associated with NEC? SGPERF.0 ☐ No ☐ Yes SGPERF.1

If **Yes,** indicate the surgical procedure(s) performed (check all that apply) and provide the date(s) of surgery:

SGPERI ☐ Peritoneal Drain	SGPERIDTC Month Day Year 1st Surgery	SGPERIDTC Month Day Year 2nd Surgery
SGLAP ☐ Laparotomy	SGLAPDTC Month Day Year 1st Surgery	SGLAPDTC Month Day Year 2nd Surgery

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

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? QSROP.0 ☐ No QSROP.1 ☐ Yes

15. Was this baby diagnosed with ROP? QSDXROP.0 ☐ No QSDXROP.1 ☐ Yes

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

15a. What was the worst stage ever reported in any zone?

QSLROP ___ Left eye (1-5)

QSRROP ___ Right eye (1-5)

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

Left eye: SGLROP.0 ☐ No SGLROP.1 ☐ Yes Date of procedure SGLROPDTC ___ Month Day Year

Right eye: SGRROP.0 ☐ No SGRROP.1 ☐ Yes Date of procedure SGRROPDTC ___ Month Day Year

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

Left eye: QSLAVAST.0 ☐ No QSLAVAST.1 ☐ Yes Date of Procedure QSLAVASTDTC ___ Month Day Year

Right eye: QSRAVAST.0 ☐ No QSRAVAST.1 ☐ Yes Date of Procedure QSRAVASTDTC ___ Month Day Year

15d. Did the baby undergo vitrectomy?

Left eye: SGLVIT.0 ☐ No SGLVIT.1 ☐ Yes Date of Procedure SGLVITDTC ___ Month Day Year

Right eye: SGRVIT.0 ☐ No SGRVIT.1 ☐ Yes Date of Procedure SGRVITDTC ___ Month Day Year

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

COMORBIDITIES OF PREMATURITY

AT WEEK 36, WEEK 40 PMA OR DISCHARGE,
WHICHEVER OCCURS FIRST

Neurologic

16. Did the baby receive a ventricular shunt? SGVENT.0 ☐ No ☐ Yes SGVENT.1

    16a. If **Yes,** provide the date of first shunt placement: SGVENTDTC
    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: SGTYPE _____ Date of Surgery: SGODTC
   Month Day Year
2. Type of Surgery: SGTYPE _____ Date of Surgery: SGODTC
   Month Day Year
3. Type of Surgery: SGTYPE _____ Date of Surgery: SGODTC
   Month Day Year
4. Type of Surgery: SGTYPE _____ Date of Surgery: SGODTC
   Month Day Year
5. Type of Surgery: SGTYPE _____ Date of Surgery: SGODTC
   Month Day Year

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

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. Weight WEIGHT gms (Complete at W36, W40 or DC
   SRWEIGHT kg (Complete at M12 Follow Up)
2. What is the baby's length? HEIGHT cm
3. What is the baby's chest circumference? VSCHEST cm
4. Respiratory Rate (awake) VSRR Breaths per minute
5. Infant status during Physical Exam SVCONFIRM.0 ☐ Quiet Sleep ☐ Active Sleep SVCONFIRM.1
   SVCONFIRM.2 ☐ Awake, Quiet ☐ Awake, Active SVCONFIRM.3
   SVCONFIRM.4 ☐ Other, specify SVPROTS
6. SpO2 in Room Air QSCOXY % ☐ NA QSOXNA
   If 'NA' is checked, answer questions 6a and 6b.
   6a. What was the concentration of supplemental oxygen at time of exam? QSFOXY %
   6b. Select ventilation mode and record the associated values for respiratory support:

QSNIMV ☐ Positive Pressure Ventilation QSCPAP ☐ Continuous Positive Airway Pressure (CPAP)

MAP: QSMAP cmH2O CPAP: DSCPAP cmH2O

PEEP: QSPEEP cmH2O

QSNCAN ☐ Nasal Cannula with flow rate:

Nasal Cannula flow: DSNCAN Lpm

Focused Pulmonary Exam Parameters

7. Retractions
   a. Suprasternal PESUPRTX.0 ☐ Absent ☐ Present PESUPRTX.1
   b. Intercostal PEINTRTX.0 ☐ Absent ☐ Present PEINTRTX.1
   c. Subcostal PESUBRTX.0 ☐ Absent ☐ Present PESUBRTX.1
8. Thoraco- abdominal Movement ☐ Synchronous ☐ Asynchronous PEMOVE.0 PEMOVE.1
9. Accessory Muscle Use
   a. Head Bobbing PEHEAD.0 ☐ Absent ☐ Present PEHEAD.1
   b. Nasal Flaring PENASL.0 ☐ Absent ☐ Present PENASL.1
   c. Expiratory Abdominal Muscle Use PEMUSC.0 ☐ Absent ☐ Present PEMUSC.1
10. Wheezy/Noisy Breathing
    a. Monophonic PEMONO.0 ☐ Absent PEMONO.1 ☐ Present without chest compressions ☐ Present with chest compressions PEMONO.2
    b. Polyphonic PEPOLY.0 ☐ Absent PEPOLY.1 ☐ Present without chest compressions ☐ Present with chest compressions PEPOLY.2
11. Crackles PECRAC.0 ☐ Absent ☐ Localized PECRAC.1 ☐ Diffuse PECRAC.2
12. Stridor PESTRDR.0 ☐ Absent ☐ Present PESTRDR.1
13. Point of Maximal Impulse (PMI) PEPMI.0 ☐ Left Chest ☐ Subxiphoid PEPMI.1
14. Digital Clubbing PECLUB.0 ☐ Absent ☐ Present PECLUB.1
15. Examiner's Initials RC_INITIALS

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

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

RECORD OF DEATH

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

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

3. Was an autopsy perfomed? ☐ No ☐ Yes ☐ Unknown
   QCAUTO.0 QCAUTO.1 QCAUTO.88

   3a. If **Yes,** what were the findings: COVAL.0

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

4. Please provide a short description of the infant's underlying condition prior to the events leading to the infant's death and circumstances leading to the infant's death.

DSDESC.1

DSDESC.2

DSDESC.3

5. Do you think that a cardiopulmonary disorder contributed to the death of this infant? ☐ No ☐ Yes ☐ Cannot make this determination
   QCDEATH.0 QCDEATH.1 QCDEATH.88

Signature of Principal Investigator: _____ Date: _____

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PATIENT

Date: DCM_DATE

DISCHARGE FORM

1. What was the baby's discharge date? HPDISDTC.0
   Month Day Year

2. Where was the baby discharged to?
   - OCDIS.0.1 ☐ Home
   - OCDIS.0.2 ☐ Transfer to another hospital
   - OCDIS.0.3 ☐ Baby died at study center*
   - QCDIS.0.98 ☐ Other, specify: QCOTHERS.0

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? OSTOLS.0.0 ☐ No ☐ Yes OSTOLS.0.1
   3a. If **Yes,** provide study specific Partipant ID COVAL.3

4. Was this baby enrolled in the NRN Hydrocortisone for Extubation Trial? OSNRNX.0.0 ☐ No ☐ Yes QSNRNX.0.1
   4a. If **Yes,** provide study specific Partipant ID COVAL.4

5. Was this baby enrolled in the NRN Generic database? OSNRN.0.0 ☐ No ☐ Yes QSNRN.0.1
   5a. If **Yes,** provide study specific Partipant ID COVAL.5

6. Was this baby enrolled in any other randomized clinical treatment trials? DMNOCT.0.0 ☐ No ☐ Yes DMNOCT.0.1
   6a. If **Yes,** provide clinical trial name(s): COVAL.1

7. Was this baby enrolled in any other long term follow-up studies? OSLTFUP.0.0 ☐ No ☐ Yes OSLTFUP.0.1
   7a. If **Yes,** provide study name(s): COVAL.2

8. How many people normally live in your home including your baby (for at least 6 months of the year)? (Please select one)
   - ☐ 2-3 OSLIVE.0.1
   - ☐ 4-6 QSLIVE.0.2
   - ☐ 7-10 OSLIVE.0.3
   - ☐ >10 OSLIVE.0.4

   8a. How many other children under 5 years old live in <baby's name>'s home? QSULIV.0 children

   8b. How many children between ages 5-12 years old live in <baby's name>'s home? QSOLIV.0 children

9. Is baby exposed to dogs, cats, or other furry animals at home? OSEXPAN.0.0 ☐ No ☐ Yes OSEXPAN.0.1

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PATIENT

Date: DCM_DATE

DISCHARGE FORM

10. Will your baby receive any care outside of the home in the next year?

QSCARE.0.0 ☐ No QSCARE.0.1 ☐ Yes QSCARE.0.88 ☐ Unknown

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

OSEXPHOME.0.1 ☐ Smoking is allowed anywhere in the home
OSEXPHOME.0.2 ☐ Smoking is limited to part of the house where <baby's name> rarely goes
OSEXPHOME.0.3 ☐ Smoking is not allowed inside the home at all

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

OSEXPCAR.0.0 ☐ Child rarely travels by car.
QSEXPCAR.0.1 ☐ There is no smoking inside the car.
OSEXPCAR.0.2 ☐ Smoking occurs in the car only when <baby's name> is not inside.
OSEXPCAR.0.3 ☐ Smoking is sometimes allowed in the car.
OSEXPCAR.0.4 ☐ 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	QSASTNA.0 ☐	QSASTSIB.0 ☐	QSASTPAR.0 ☐
b. Allergies/ Hayfever	OSALLNA.0 ☐	OSALLSIB.0 ☐	OSALLPAR.0 ☐
c. Eczema	QSECZNA.0 ☐	QSECZSIB.0 ☐	QSECZPAR.0 ☐

14. How will <baby's name>'s health care be paid for primarily:
(Select only one)

☐ No Insurance (self pay) OSINSUR.0.0
☐ Private Insurance OSINSUR.0.1
☐ Medicaid/ Public Insurance OSINSUR.0.2

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

STUDY STATUS

NOTE: This form must be completed when the infant's participation in the study ends early.

1. Date of last contact? DSLSDTC
   Month Day Year

2. Indicate the primary reason participation stopped:
   REASON_STOP.1 ☐ Unable to contact parents/caregivers
   REASON_STOP.2 ☐ Parents/Caregivers refuse further participation
   REASON_STOP.98 ☐ Other, specify: SVOTHER

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

STANDARD VISIT

Please Note: All efforts should be made to conduct the interview with the child's primary caregiver or the indivdual who is able to provide information about the child's health since the <last contact>.

1. Was this interview conducted?

☐ No (Skip to 1c) SVINTER.0

☐ Yes (Continue with 1a) SVINTER.1

If Yes, answer questions 1a and 1b.

a. Visit month

SVVISIT.1 ☐ Month 3 ☐ Month 6 SVVISIT.2

SVVISIT.3 ☐ Month 9 ☐ Month 12 SVVISIT.4

b. Date of Interview: DSDTC

Month Day Year

c. If No, indicate reason why interview was not conducted. (Please select only one)

SVMISSED.1 ☐ Unable to contact

SVMISSED.2 ☐ Refused interview

SVMISSED.3 ☐ Child died
(Please complete Record of Death form)

SVMISSED.98 ☐ Other, specify QSOTHS

2. Initials of person completing this form QCCOMINITS

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Follow Up Interview

1. Please indicate how interview was conducted.
   - QSINTER.1 ☐ Over the phone
   - QSINTER.2 ☐ In person
   - QSINTER.3 ☐ In hospital

Section I: Hospitalizations and Urgent Care Visits

Since our <last contact> with you about <baby's name>...

2. How many times has <baby's name> been admitted to a hospital for one or more nights in a row outside of the Emergency Room? HUADMIT _____ times ☐ Don't Know HUADMITUNK
   a. How many times were because of wheezing, breathing problems or a change in his/her breathing? HUWHEEZE _____ times ☐ Don't Know HUWHEEZEUNK
   b. Did any of these times require admission to an intensive care unit (NICU, PICU, OR Critical Care Unit)? HUICU.0 ☐ No HUICU.1 ☐ Yes ☐ Don't Know HUICU.88
   c. Were any of the admissions due to Respiratory Syncytial Virus (RSV)? HURSV.0 ☐ No HURSV.1 ☐ Yes ☐ Don't Know HURSV.88

3. How many times has <baby's name> had a sick visit to a doctor's office, clinic or Emergency Room? HUERVT _____ times ☐ Don't Know HUERVTUNK
   a. How many times were because of wheezing, breathing problems or a change in his/her breathing? HUERWZ _____ times ☐ Don't Know HUERWZUNK

Section II: Breathing, Wheezing, and Coughing Assessment

4. Has <baby's name>'s chest sounded wheezy or whistling? SSWHEEZE.0 ☐ No SSWHEEZE.1 ☐ Yes ☐ Don't Know SSWHEEZE.88

   If Yes, answer questions a-d.
   a. Has this occurred with colds? SSCOLD.0 ☐ No SSCOLD.1 ☐ Yes ☐ Don't Know SSCOLD.88
   b. Has <baby's name>'s chest sounded wheezy or whistling apart from colds? SSACOLD.0 ☐ No SSACOLD.1 ☐ Yes ☐ Don't Know SSACOLD.88
   c. How often has <baby's name>'s chest sounded wheezy during the day time?
      - SSWDAY.0 ☐ Less than once per week
      - SSWDAY.1 ☐ 1-2 times per week
      - SSWDAY.2 ☐ 3-6 times per week
      - SSWDAY.3 ☐ Daily, but not all the time
      - SSWDAY.4 ☐ Daily, all the time
   d. How often has <baby's name>'s chest sounded wheezy during the night time?
      - SSWNIGHT.0 ☐ Less than once per week
      - SSWNIGHT.1 ☐ 1-2 times per week
      - SSWNIGHT.2 ☐ 3-6 times per week
      - SSWNIGHT.3 ☐ Daily, but not all the time
      - SSWNIGHT.4 ☐ Daily, all the time

5. Since our <last contact> has <baby's name> been diagnosed with wheezing by a doctor? SSDXW.0 ☐ No SSDXW.1 ☐ Yes ☐ Don't Know SSDXW.88

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Follow Up Interview

Since our <last contact> with you about <baby's name>...

SSCOUGH.0 SSCOUGH.1 SSCOUGH.88

6. Has <baby's name> had a cough without a cough? ☐ No ☐ Yes ☐ Don't Know

   If Yes, answer questions a-b.

   a. How often has <baby's name> had coughing during the day time? SSCDAY.0
   - ☐ Less than once per week
   - SSCDAY.1 ☐ 1-2 times per week
   - SSCDAY.2 ☐ 3-6 times per week
   - SSCDAY.3 ☐ Daily, but not all the time
   - SSCDAY.4 ☐ Daily, all the time

   b. How often has <baby's name> had coughing during the night time? SSCNIGHT.0
   - ☐ Less than once per week
   - SSCNIGHT.1 ☐ 1-2 times per week
   - SSCNIGHT.2 ☐ 3-6 times per week
   - SSCNIGHT.3 ☐ Daily, but not all the time
   - SSCNIGHT.4 ☐ Daily, all the time

Since our <last contact> with you about <baby's name>...

7. How many head colds (common colds) has <baby's name> had? SSHCOLD.0
   - ☐ 0
   - SSHCOLD.1 ☐ 1
   - SSHCOLD.2 ☐ 2
   - SSHCOLD.3 ☐ 3
   - SSHCOLD.4 ☐ 4 or more

Section III: Respiratory Medications

[Please ask parent to collect all medications that the baby is currently using or has used since [discharge or the last contact] and identify them by reading the medication label or package. Record the medication name (generic or brand name) in the Respiratory Medication worksheet. There is no need to record dose unit, frequency or route of administration. Use the Respiratory Medication worksheet as a guide to determine which medications should be recorded in the database. Please complete the Follow Up Medication Log (MEDLOG) in the database.]

Section IV: Home Technology Dependence

8. Since our <last contact> has <baby's name> used any medical equipment or any of the following in the home?

a.	Breathing and Heart Rate monitor	QSMONITOR.0	☐ No	☐ Yes	QSMONITOR.1
b.	Oxygen Therapy	OSOXYGEN.0	☐ No	☐ Yes	QSOXYGEN.1
c.	CPAP or BIPAP	OSCPAP.0	☐ No	☐ Yes	OSCPAP.1
d.	Ventilator	QSVENT.0	☐ No	☐ Yes	QSVENT.1
e.	Trach or breathing tube	QSTRACH.0	☐ No	☐ Yes	QSTRACH.1
f.	Feeding Tube in nose	QSNGTB.0	☐ No	☐ Yes	QSNGTB.1
g.	Feeding Tube in stomach	QSGASTRO.0	☐ No	☐ Yes	QSGASTRO.1
h.	Other QSOTHS	QSOTH.0	☐ No	☐ Yes	QSOTH.1

NOTE- The Month 3 and Month 9 questionnaires end here.
Complete the entire form at Months 6 and 12.

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

FOLLOW- UP INTERVIEW

Section V: Nutrition

9. Since our <last contact>, did <baby's name> receive mother's breast milk, either at breast, from a bottle or through a tube? DYMILK.0 DYMILK.1 DYMILK.88
   ☐ No ☐ Yes ☐ Don't Know
   a. If Yes, for how many months did <baby's name> receive any breast milk for more than half of the feedings?
   ☐ Less than 1 DYFEED.0
   ☐ 1 DYFEED.1
   ☐ 2 DYFEED.2
   ☐ 3 DYFEED.3

Section VI: Exposure to Tobacco products and Respiratory Irritants

10. How often has the mother or primary caregiver smoked in the last 6 months?
   ☐ Never QSPARSMK.0
   ☐ Monthly QSPARSMK.1
   ☐ Weekly QSPARSMK.2
   ☐ Daily QSPARSMK.3

11. How many people who live in <baby's name>'s home smoke? QSLIVE _____ people

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

QSEXPHOME.1 ☐ Smoking is allowed in the home
QSEXPHOME.2 ☐ Smoking is limited to part of the house where <baby's name> rarely goes
QSEXPHOME.3 ☐ Smoking is not allosed inside the home at all

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

QSEXPCAR.0 ☐ Child rarely travels by car
QSEXPCAR.1 ☐ There is no smoking inside the car
QSEXPCAR.2 ☐ Smoking occurs in the car only when <baby's name> is not inside
QSEXPCAR.3 ☐ Smoking is sometimes allowed in the car
QSEXPCAR.4 ☐ Smoking is usually or always allowed in the car

14. a. How many children under 5 years old live in <baby's name>'s home? QSULIV _____ children
    b. How many children between 5-12 years old live in <baby's name>'s home? QSOLIV _____ children

Please indicate if <baby's name> is exposed to the following at HOME

15. Smoke from cigarettes or other tobacco products? OSHCIG.0 ☐ No ☐ Yes QSHCIG.1
    a. If yes, how often is it used?
    QSHUSE.1 ☐ Daily
    QSHUSE.2 ☐ Weekly
    QSHUSE.3 ☐ Monthly

16. Kersone heater, wood burning stove or fireplace QSHKER.0 ☐ No ☐ Yes QSHKER.1
    a. If yes, how often is it used?
    QSHUSE.1 ☐ Daily
    QSHUSE.2 ☐ Weekly
    QSHUSE.3 ☐ Monthly

17. Dogs, cats, and other furry animals QSHFUR.0 ☐ No ☐ Yes QSHFUR.1
    a. If yes, how many pets? QSHPET _____ pets

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

FOLLOW- UP INTERVIEW

18. Does your child receive regular care (at least once a week) outside the home? QSCARE.0 ☐ No ☐ Yes QSCARE.1

    a. If Yes, are there children that are not siblings also present at the outside care site? QSCSIB.0 ☐ No ☐ Yes QSCSIB.1

If response to Question 18 is Yes and <baby's name> attends DAY CARE, please answer questions 19-21, if not, please skip to question 22. Please indicate if <baby's name> is exposed to the following at DAY CARE

19. Smoke from cigarettes or other tobacco products? QSDCIG.0 ☐ No ☐ Yes ☐ N/A QSDCIG.99 QSDCIG.1
    a. If yes, how often is it used?
    QSDUSE.1 ☐ Daily
    QSDUSE.2 ☐ Weekly
    QSDUSE.3 ☐ Monthly

20. Kersone heater, wood burning stove or fireplace QSDKER.0 ☐ No ☐ Yes ☐ N/A QSDKER.99 QSDKER.1
    a. If yes, how often is it used?
    QSDUSE.1 ☐ Daily
    QSDUSE.2 ☐ Weekly
    QSDUSE.3 ☐ Monthly

21. Dogs, cats, and other furry animals QSDFUR.0 ☐ No ☐ Yes ☐ N/A QSDFUR.99 QSDFUR.1
    a. If yes, how many pets? QSDPET pets

If response to Question 18 is Yes and <baby's name> goes to the HOME of a Babysitter or Other Regular Caregiver, please answer questions 22-24, if not, please skip to question 25. Please indicate if <baby's name> is exposed to the following at the HOME of BABYSITTER or Other REGULAR CAREGIVER

22. Smoke from cigarettes or other tobacco products? OSBCIG.0 ☐ No ☐ Yes ☐ N/A OSBCIG.99 OSBCIG.1
    a. If yes, how often is it used?
    OSBUSE.1 ☐ Daily
    OSBUSE.2 ☐ Weekly
    OSBUSE.3 ☐ Monthly

23. Kersone heater, wood burning stove or fireplace QSBKER.0 ☐ No ☐ Yes ☐ N/A QSBKER.99 QSBKER.1
    a. If yes, how often is it used?
    OSBUSE.1 ☐ Daily
    QSBUSE.2 ☐ Weekly
    QSBUSE.3 ☐ Monthly

24. Dogs, cats, and other furry animals QSBFUR.0 ☐ No ☐ Yes ☐ N/A QSBFUR.99 QSBFUR.1
    a. If yes, how many pets? QSBPET pets

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

FOLLOW- UP INTERVIEW

Section VII: Respiratory Treatments

25. Has <baby's name> had regular shots to prevent Respiratory Syncytial Virus (RSV)?
QSRSV.0 ☐ No QSRSV.1 ☐ Yes ☐ Don't Know QSRSV.88

26. Has <baby's name> had a flu shot?
QSFLU.0 ☐ No QSFLU.1 ☐ Yes ☐ Don't Know QSFLU.88
QSFLU.99 ☐ N/A (for children <6 months chronological age)

27. Are <baby's name>'s immunizations up to date?
QSIMM.0 ☐ No QSIMM.1 ☐ Yes ☐ Don't Know QSIMM.88

a. If not, why not?
QSIMNO.1 ☐ Illness
QSIMNO.2 ☐ Refused
QSIMNO.3 ☐ Other

28. How much does <baby's name>'s health and healthcare needs disrupt your own lifestyle or other planned activities? (For example, ability to attend work or school)
☐ Not at all QSPLANS.0
☐ Infrequently QSPLANS.1
☐ Half the time QSPLANS.2
☐ Frequently QSPLANS.3
☐ All of the time QSPLANS.4

Section VIII: Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R)

Please complete the Gastroesophageal Reflux Questionnaire

Section IX: Atopy and Allergy Assessment (Completed at Month 12 ONLY)

29. Has <baby's name> had a new diagnosis of asthma or reactive airways disease diagnosed by a doctor?
DIAGNOSIS.0 ☐ No DIAGNOSIS.1 ☐ Yes DIAGNOSIS.88 ☐ Don't Know

30. Has <baby's name> had a runny, stuffy or itchy nose, or watery eyes apart from a cold?
QSALLER.0 ☐ No QSALLER.1 ☐ Yes QSALLER.88 ☐ Don't Know

31. Has <baby's name> ever been allergic to any food?
MHALLER.0 ☐ No MHALLER.1 ☐ Yes MHALLER.88 ☐ Don't Know

32. Has <baby's name> been diagnosed with eczema (allergic skin rash)?
QSECZ.0 ☐ No QSECZ.1 ☐ Yes QSECZ.88 ☐ Don't Know

CRF Blank BLANK_FLAG

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

Infant Gastroesophageal Reflux Questionnaire

1. During the past week, how often did the baby spit-up (anything coming out of the mouth) during a 24-hour period?
   - ☐ Less than once — QSDSPIT.0
   - ☐ 1 to 3 times — QSDSPIT.1
   - ☐ 4 to 6 times — QSDSPIT.2
   - ☐ More than 6 times — QSDSPIT.3

2. During the past week, how much did the baby spit-up (anything coming out of the mouth) during a typical episode?
   - ☐ Did not spit up — QSESPIT.0
   - ☐ Less than 1 tablespoonful — QSESPIT.1
   - ☐ 1 tablespoonful to 2 ounces — QSESPIT.2
   - ☐ More than 2 ounces to half the feeding — QSESPIT.3
   - ☐ More than half the feeding — QSESPIT.4

3. During the past week, how often did spitting up (anything coming out of the mouth) seem to be uncomfortable for the baby, for example, crying, fussing, irritability, etc?
   - QSIRRIT.0 ☐ Never
   - QSIRRIT.1 ☐ Rarely
   - QSIRRIT.2 ☐ Sometimes
   - QSIRRIT.3 ☐ Often
   - QSIRRIT.4 ☐ Always

4. During the past week, how often did the baby refuse a feeding even when hungry?
   - QSRFEED.0 ☐ Never
   - QSRFEED.1 ☐ Rarely
   - QSRFEED.2 ☐ Sometimes
   - QSRFEED.3 ☐ Often
   - QSRFEED.4 ☐ Always

5. During the past week, how often did the baby stop eating soon after starting even when hungry?
   - QSSFEED.0 ☐ Never
   - QSSFEED.1 ☐ Rarely
   - QSSFEED.2 ☐ Sometimes
   - QSSFEED.3 ☐ Often
   - QSSFEED.4 ☐ Always

6. During the past week, did the baby cry a lot during or within 1 hour after feedings?
   - QSCFEED.0 ☐ Never
   - QSCFEED.1 ☐ Rarely
   - QSCFEED.2 ☐ Sometimes
   - QSCFEED.3 ☐ Often
   - QSCFEED.4 ☐ Always

7. During the past week, did the baby cry or fuss more than usual?
   - QSCRY.0 ☐ Never
   - OSCRY.1 ☐ Rarely
   - OSCRY.2 ☐ Sometimes
   - OSCRY.3 ☐ Often
   - QSCRY.4 ☐ Always

PROP **Prematurity and Respiratory Outcomes Program** PID: PATIENT

Date: DCI_DATE

Infant Gastroesophageal Reflux Questionnaire

8. During the past week, on average how long did the baby cry or fuss during a 24 hour period?

- QSHCRY.1 ☐ Less than 10 minutes
- QSHCRY.2 ☐ 10 minutes to 1 hour
- QSHCRY.3 ☐ More than 1 hour but less than 3 hours
- QSHCRY.4 ☐ 3 or more hours

9. During the past week, how often did the baby have hiccups?

- QSHICCUP.0 ☐ Never
- QSHICCUP.1 ☐ Rarely
- QSHICCUP.2 ☐ Sometimes
- QSHICCUP.3 ☐ Often
- QSHICCUP.4 ☐ Always

10. During the past week, how often did the baby have episodes of arching back?

- QSARCH.0 ☐ Never
- QSARCH.1 ☐ Rarely
- QSARCH.2 ☐ Sometimes
- QSARCH.3 ☐ Often
- QSARCH.4 ☐ Always

11. During the past week, has the baby stopped breathing while awake or struggled to breathe?

- OSSBREATH.0 ☐ No
- QSSBREATH.1 ☐ Yes

12. During the past week, has the baby turned blue or purple?

- QSBLUE.0 ☐ No
- QSBLUE.1 ☐ Yes

1 Translated versions of the I-GERQ-R are available on request from Dr. Susan Orenstein at the University of Pittsburgh Infant Gastroesophageal Reflux Questionnaire Revised (I-GERQ-R, Author I-GERQ, Susan Orenstein, MD, ¿ 2004, University of Pittsburgh)

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PATIENT

Date: DCM_DATE

FOLLOW UP MEDICATION LOG

Medication Sequence #	Drug Code	Drug Name (Brand Name or Generic)
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT
CMSEQ	CMCODE	CMTRT

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

Infant Pulmonary Function Test Eligibility Form

Note: Indicate date of assessment in date field.

Eligibility

1. Was child eligibility assessed with the parent(s)? SRELIG.0 ☐ No SRELIG.1 ☐ Yes
   a. If No, select primary reason eligibility was not assessed:

SVCONSENT.1 ☐ Parent refused at initial PROP Cohort consent
SVCONSENT.2 ☐ Staff Oversight
SVCONSENT.3 ☐ Physician did not recommend
SVCONSENT.4 ☐ Known exclusion criteria, specify: SRNOCON _____
SVCONSENT.5 ☐ Parent refused
SVCONSENT.98 ☐ Other, specify: SRELIGOTH _____

2. Dose the child have a history of adverse reaction or allergy to chloral hydrate sedation? CMALLER.0 ☐ No CMALLER.1 ☐ Yes
3. Does the child have clinically significant upper airway obstruction as determined by the Site Investigator? ☐ No ☐ Yes
   a. If Yes, specify (check all that apply) PERESP.0 PERESP.1

SGLARYN ☐ Severe laryngomalacia
PETNSIL ☐ Markedly enlarged tonsils
MHSNORE ☐ Significant snoring
MHSLEEP ☐ Diagnosed Obstructive Sleep Apnea
INOTHER ☐ Other, specify: INOTHS _____

4. Does the child have severe gastroesophageal reflux, defined as persistent frequent emesis despite anti-reflux therapy? MHVOMIT.0 ☐ No ☐ Yes MHVOMIT.1
5. Does the child have hydrocephalus? MHHYDRO.0 ☐ No ☐ Yes MHHYDRO.1
6. Does the child have a congenital heart defect? IECONGDZ.0 ☐ No ☐ Yes IECONGDZ.1
7. Does the child have a neuromuscular disease? IECNS.0 ☐ No ☐ Yes IECNS.1
8. Does the child have pulmonary hypertension? MHPULMHTN.0 ☐ No ☐ Yes MHPULMHTN.1
9. Does the child have current symptoms of nasal obstruction or discharge? PENASL.0 ☐ No ☐ Yes PENASL.1
10. Does the child have acute intercurrent respiratory infection, defined as an increase in cough, wheezing or respiratory rate with onset of 2 weeks preceeding visit? MBVURI.0 ☐ No ☐ Yes MBVURI.1
11. Does the child have any physical findings or conditions that would compromise the safety of the child or the quality of the study data as determined by the site investigator? IELUNGS.0 ☐ No ☐ Yes IELUNGS.1
    a. If yes, specify findings or conditions: IMOTHERS _____
12. Does the child meet the inclusion criteria and none of the exclusion criteria and is therefore eligible for Infant Pulmonary Function Test [iPFT]? IEORRES.0 ☐ No ☐ Yes IEORRES.1

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

Infant Pulmonary Function Test Eligibility Form

Consent

13. Was Infant Pulmonary Function Test [iPFT] informed consent signed? IECONSENT.0 ☐ No ☐ Yes IECONSENT.1

a. If No, select reason consent was not signed (Check **all** that apply)

SRCONSENT ☐ Parents were not available/ could not be reached

LBOVER ☐ Oversight

OSAUTO ☐ Parents cannot travel to test site because of distance, transportation limitations, work schedule

SVREFUSE ☐ Parents felt test was not useful

CMCHLY ☐ Not willing to have Chloral Hydrate sedation

CMALB ☐ Not willing to have Albuterol

AEDYSP ☐ Child has not experienced any respiratory problems since discharge

OSBMIS ☐ Other, specify: QSOMIS _____

14. Is the child eligible to proceed with the Infant Pulmonary Function Test [iPFT]? ☐ No ☐ Yes

IEMET.0 IEMET.1

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program PID: PID

Date: DCM_DATE

INFANT PULMONARY FUNCTION TEST

1. Was Infant Pulmonary Function Tests [iPFT] performed? SVPULM.0.0 ☐ No ☐ Yes SVPULM.0.1

(If **YES,** proceed to **Question 2)**

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

QSFMIS.0.1 ☐ Baby was ineligible [Complete item 1b]
QSFMIS.0.2 ☐ Staff oversight/ Staff or equipment not available to perform test
QSFMIS.0.3 ☐ Parent/ guardian refused
QSFMIS.0.98 ☐ Other, specify: _____ QSBOTHS.0

b. If ineligible, check primary reason for ineligibility

SRINELIG.0.1 ☐ Did not meet NPO status as required
SRINELIG.0.2 ☐ Vital signs unstable
SRINELIG.0.3 ☐ Patient ineligible for sedation
SRINELIG.0.4 ☐ Physician did not recommend
SRINELIG.0.98 ☐ Other, specify _____ QSFOTH.0

2. If test was performed, provide baseline vital signs

a. Weight WEIGHT.0 kg
b. Height HEIGHT.0 cm
c. Blood Pressure VSBPS.0 / VSBPD.0
d. Heart Rate VSHR.0 Beats per minute
e. Respiratory Rate VSRR.0 Breaths per minute
f. Oxygen Saturation VSOXSAT.0 %

3. Was patient on supplemental O2? OSOXYGEN.0.0 ☐ No ☐ Yes QSOXYGEN.0.1

If 'Yes', provide the following

a. Flow QSOXFLOW.0 Lpm
b. FiO2 VSTESTA.0 %

4. Was oral Chloral Hydrate sedation administered? CMCHLY.0.0 ☐ No ☐ Yes CMCHLY.0.1

a. If Yes, indicate the time of administration and dose DSTIME.1 (24 hr clock)
CMCHLORDOSE.0 mg

b. Was an extra dose given? OSMEDCH.1.0 ☐ No ☐ Yes QSMEDCH.1.1

If Yes, provide time of administration and dose DSTIME.2 (24 hr clock)
CMDOSE.0 mg

5. Was Hydroxyzine sedation administered? CMHYDROX.0.0 ☐ No ☐ Yes CMHYDROX.0.1

a. If Yes, indicate the time of administration and dose DSTIME.3 (24 hr clock)
CMHDOSE.1 mg

b. Was an axtra dose given? OSMEDCH.2.0 ☐ No ☐ Yes OSMEDCH.2.1

If Yes, provide time of administration and dose DSTIME.4 (24 hr clock)
CMHDOSE.2 mg

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

6. Was another type of sedation administered? CMSED.0.0 ☐ No ☐ Yes CMSED.0.1
   a. If Yes, specify drug that was given CMDSO.0
   b. If Yes, indicate the time of administration and dose DSTIME.5 (24 hr clock)
   CMNDOSE.0 mg
7. Was Albuterol administered? CMALB.0.0 ☐ No ☐ Yes CMALB.0.1
   If 'Yes', provide the following
   CMALBU.0.1 ☐ MDI QSBDOSE.0 puffs (total)
   CMALBU.0.2 ☐ Nebulizer CMALBDOSE.0 mg
8. Post bronchodilator (BD) Heasrt Rate (measured 10 minutes after initiation of Albuterol administration) QSBHR.1 Beats per minute
9. Post Test
   a. Final heart rate QSFVSHR.0 Beats per minute
   b. Respiratory Rate QSBHR.2 Breaths per minute
   c. Oxygen Saturation QSFSPO.0 %

Were the following measurements obtained?

10. FRC (Functional Residual Capacity) QSFRC.1.0 ☐ No ☐ Yes OSFRC.1.1
    a. If NO, check the primary reason
    QSRSN.1.1 ☐ Sedation was not successful/ Patient awakened prematurely
    OSRSN.1.2 ☐ Equipment malfunction
    QSRSN.1.3 ☐ Adverse Event
    QSRSN.1.98 ☐ Other, specify _____ QSBOTH.1
11. ERV (Expiratory Reserve Volume) QSERV.1.0 ☐ No ☐ Yes OSERV.1.1
    a. If NO, check the primary reason
    QSRSN.2.1 ☐ Sedation was not successful/ Patient awakened prematurely
    OSRSN.2.2 ☐ Equipment malfunction
    QSRSN.2.3 ☐ Adverse Event
    QSRSN.2.98 ☐ Other, specify _____ QSBOTH.2
12. CR (Total Respiratory Compliance) QSCRM.0.0 ☐ No ☐ Yes QSCRM.0.1
    a. If NO, check the primary reason
    QSRSN.3.1 ☐ Sedation was not successful/ Patient awakened prematurely
    OSRSN.3.2 ☐ Equipment malfunction
    QSRSN.3.3 ☐ Adverse Event
    QSRSN.3.98 ☐ Other, specify _____ QSBOTH.3

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

13. RR (Total Resistance) QSRRM.0.0 ☐ No ☐ Yes QSRRM.0.1

a. If NO, check the primary reason

QSRSN.4.1 ☐ Sedation was not successful/ Patient awakened prematurely
QSRSN.4.2 ☐ Equipment malfunction
QSRSN.4.3 ☐ Adverse Event
QSRSN.4.98 ☐ Other, specify _____ QSBOTH.4

14. Raised Volume Rapid Thoracic Compression QSRVRT.1.0 ☐ No ☐ Yes QSRVRT.1.1

a. If NO, check the primary reason

OSRSN.5.1 ☐ Sedation was not successful/ Patient awakened prematurely
OSRSN.5.2 ☐ Equipment malfunction
OSRSN.5.3 ☐ Adverse Event
OSRSN.5.98 ☐ Other, specify _____ QSBOTH.5

15. Tpef / Te QSTPEF.0.0 ☐ No ☐ Yes QSTPEF.0.1

a. If NO, check the primary reason

OSRSN.6.1 ☐ Sedation was not successful/ Patient awakened prematurely
OSRSN.6.2 ☐ Equipment malfunction
QSRSN.6.3 ☐ Adverse Event
QSRSN.6.98 ☐ Other, specify _____ QSBOTH.6

Post BD, were the following measurements obtained?

16. FRC (Functional Residual Capacity) OSFRC.2.0 ☐ No ☐ Yes OSFRC.2.1

a. If NO, check the primary reason

OSRSN.7.1 ☐ Sedation was not successful/ Patient awakened prematurely
OSRSN.7.2 ☐ Equipment malfunction
QSRSN.7.3 ☐ Adverse Event
QSRSN.7.98 ☐ Other, specify _____ QSBOTH.7

17. ERV (Expiratory Reserve Volume) OSERV.2.0 ☐ No ☐ Yes OSERV.2.1

a. If NO, check the primary reason

QSRSN.8.1 ☐ Sedation was not successful/ Patient awakened prematurely
QSRSN.8.2 ☐ Equipment malfunction
QSRSN.8.3 ☐ Adverse Event
QSRSN.8.98 ☐ Other, specify _____ QSBOTH.8

18. Raised VolumeRapid Thoracic Compression OSRVRT.2.0 ☐ No ☐ Yes QSRVRT.2.1

a. If NO, check the primary reason

OSRSN.9.1 ☐ Sedation was not successful/ Patient awakened prematurely
OSRSN.9.2 ☐ Equipment malfunction
OSRSN.9.3 ☐ Adverse Event
QSRSN.9.98 ☐ Other, specify _____ QSBOTH.9

19. Examiner's Initials RC_INITIALS.0

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

IPFT ADVERSE EVENT LOG

Line #	AE Description	Grade	Serious	Outcome	Relationship	Start Date [mm/dd/~~yyyy~~y]	Stop Date [mm/dd/yyyy]
AESEQ.1	AETERM.1	AE_GRADE.1	AESER.1	AE_OUTCOME.1	AEREL.1	AESTDTC.1	AEENDTC.1
AESEQ.10	AETERM.10	AE_GRADE.10	AESER.10	AE_OUTCOME.10	AEREL.10	AESTDTC.10	AEENDTC.10

IPFT AE

CRF Blank BLANK_FLAG

Prematurity and Respiratory Outcomes Program

PID: PID

Date: DCM_DATE

IPFT MEASUREMENTS

NOTE: This form is to be entered by the INDIANA/ UNC READING CENTER ONLY.
Date recorded above is the IPFT Test Date.

1. Date IPFT Reviewed QCREVDTC.0
2. Reviewed By IMREV.0

Measurements	Pre-Bronchodilator		
Tidal Volume (mL)	QCTDVL.0	☐ N/A	MBNAPPL.1
Respiratory Rate Breaths per minute	VSRR.0	☐ N/A	MBNAPPL.2
Expiratory Time (sec)	IMTIME.0	☐ N/A	MBNAPPL.3
Tpef/Te	QCTPEF.0	☐ N/A	MBNAPPL.4
# of accept. Breaths (Total)	QCTOT.0	☐ N/A	MBNAPPL.5
Total Respiratory Compliance (CR) (mL/cmH2O)	QCCRS.0	☐ N/A	MBNAPPL.6
Total Resistance (RR) (cmH2O/L/s)	QCRRS.0	☐ N/A	MBNAPPL.7

Measurements	Pre-Bronchodilator			Post- Bronchodilator		
TLC (RV+ VC) (mL)	QCTLC.1	☐ N/A	MBNAPPL.8	QCTLC.2	☐ N/A	MBNAPPL.18
FRC (mL)	QCFRC.1	☐ N/A	MBNAPPL.9	QCFRC.2	☐ N/A	MBNAPPL.19
RV (mL)	QCRVS.1	☐ N/A	MBNAPPL.10	QCRVS.2	☐ N/A	MBNAPPL.20
ERV ((mL)	QCERV.1	☐ N/A	MBNAPPL.11	QCERV.2	☐ N/A	MBNAPPL.21
FVC (mL)	QCFVC.1	☐ N/A	MBNAPPL.12	QCFVC.2	☐ N/A	MBNAPPL.22
FEV 0.4 (mL)	QCFEV.1	☐ N/A	MBNAPPL.13	QCFEV.2	☐ N/A	MBNAPPL.23
FEV 0.5 (mL)	QCFEVX.1	☐ N/A	MBNAPPL.14	QCFEVX.2	☐ N/A	MBNAPPL.24
FEF 50 (mL/s)	QCFEF.1	☐ N/A	MBNAPPL.15	QCFEF.2	☐ N/A	MBNAPPL.25
FEF 75 (mL/s)	QCFEFX.1	☐ N/A	MBNAPPL.16	QCFEFX.2	☐ N/A	MBNAPPL.26
FEF 25-75 (mL/s)	QCFEFZ.1	☐ N/A	MBNAPPL.17	QCFEFZ.2	☐ N/A	MBNAPPL.27