



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

PID: \_\_\_\_\_

BABY'S BASELINE DATA

DATE: \_\_\_ / \_\_\_ / \_\_\_\_\_

- 1. What is the baby's gender?
2. What is the baby's birth weight?
3. What is the baby's head circumference?
4. What was the baby's birth location?
5. What was the baby's expected date of birth (EDC)?
6. Was this a multiple birth?
6a. Indicate the baby's birth order:
6b. Record the PID(s) of siblings enrolled in the PROP multicenter core database:

- 7. Were umbilical cord blood gas analyses performed?

If Yes, record the result(s) of the umbilical cord blood gas analysis:

7a. Sample pH: ... | Base Deficit: ...
Type of sample: [ ]1 Venous [ ]2 Arterial [ ]3 Uncertain

7b. Sample pH: ... | Base Deficit: ...
Type of sample: [ ]1 Venous [ ]2 Arterial [ ]3 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?

9a. If Yes, check all that apply:

- [ ]1 Supplemental O2
[ ]1 CPAP
[ ]1 Non-invasive positive pressure ventilation with flow inflating or self inflating bag
[ ]1 T-Piece resuscitator
[ ]1 Intubation
[ ]1 Chest compression
[ ]1 Cardiac drugs (Epinephrine)
[ ]1 Surfactant administration

- 10. What was the first temperature recorded at the first NICU admission? ... ° C

10a. Indicate how the temperature was obtained:

- [ ]1 Core temperature (e.g. rectal), or
[ ]2 Peripheral / skin temperature (e.g. axillary)

- 11. Was Prophylactic Indomethacin given within the first 24-hours of life?



**PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM**

**SCREENING FOR ELIGIBILITY AND CONSENT**

PID: \_\_\_\_\_

Date: \_\_\_ / \_\_\_ / \_\_\_\_\_

1. Indicate the baby's data set (check all that apply):

- PROP Core Database  
 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:

- <sub>1</sub> Male      <sub>2</sub> Female

5. Infant Ethnicity (reported by parent)

- <sub>1</sub> Hispanic/Latino  
<sub>2</sub> Not Hispanic/Latino

6. Infant Race  
(reported by parent- check all that apply)

- North American Indian/Native Alaskan  
 Asian  
 Black / African American  
 Native Hawaiian / Other Pacific Islander  
 White / Caucasian  
 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 weeks and 0/7 days and 28 weeks and 6/7 days?

- <sub>0</sub> No      <sub>1</sub> 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?

- <sub>1</sub> Early dating ultrasound (<20 weeks)  
<sub>2</sub> Certain LMP date (if early dating ultrasound is not available)  
<sub>3</sub> Best clinical estimate (if certain LMP date is not available)

8. Is the baby's postnatal age less than or equal to 7 Days?

- <sub>0</sub> No      <sub>1</sub> Yes

**Exclusion Criteria:**

9. Is the baby considered not to be viable (decision not to administer effective therapies)?

- <sub>0</sub> No      <sub>1</sub> Yes

10. Does the baby have congenital heart disease (not including PDA and hemodynamically insignificant VSD or ASD)?

- <sub>0</sub> No      <sub>1</sub> Yes



**PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM**

**SCREENING FOR ELIGIBILITY AND CONSENT**

PID: \_\_\_\_\_

Date: \_\_\_ / \_\_\_ / \_\_\_\_\_

11. Does the baby have any structural abnormalities of the upper airway or lungs? <sub>0</sub> No <sub>1</sub> Yes
12. Does the baby have any other congenital malformations or syndromes that adversely affect life expectancy or development? <sub>0</sub> No <sub>1</sub> Yes
13. Is the baby unlikely to be available for long-term follow-up? <sub>0</sub> No <sub>1</sub> 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? <sub>0</sub> No <sub>1</sub> 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? <sub>0</sub> No <sub>1</sub> Yes

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

- <sub>1</sub> Research staff was not available  
<sub>2</sub> Parents were not available  
<sub>3</sub> Screening oversight  
<sub>4</sub> On request of responsible physician  
<sub>98</sub> Other, specify: \_\_\_\_\_

- 15b. If **Yes**, was parental consent obtained? <sub>0</sub> No <sub>1</sub> Yes

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

- <sub>1</sub> Parents object to participation in research studies  
<sub>2</sub> Baby was enrolled in another research study  
<sub>3</sub> Parents objected to long term follow-up  
<sub>98</sub> Other, specify: \_\_\_\_\_

16. Was parental consent obtained for DNA sample collections? <sub>0</sub> No <sub>1</sub> 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? <sub>0</sub> No <sub>1</sub> 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



**MATERNAL BASELINE DATA**

DATE: \_\_\_ / \_\_\_ / \_\_\_\_\_

Maternal Demographic Data:

1. What is the mother's date of birth? \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
Month / Day / Year
2. What is the mother's ethnicity?
  - <sub>1</sub> Hispanic / Latino
  - <sub>2</sub> Not Hispanic / 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?
  - <sub>1</sub> Less than 7<sup>th</sup> grade
  - <sub>2</sub> 7<sup>th</sup> – 9<sup>th</sup> grade
  - <sub>3</sub> 10<sup>th</sup> – 12<sup>th</sup> grade
  - <sub>4</sub> High school degree
  - <sub>5</sub> Partial college
  - <sub>6</sub> College degree
  - <sub>7</sub> Graduate degree
  - <sub>88</sub> Unknown
5. What is the family arrangement?
  - <sub>1</sub> Single parent family
  - <sub>2</sub> Two parent family
  - <sub>88</sub> Unknown

Paternal Demographic Data:

6. Was demographic data about the **biological father** obtained? <sub>0</sub> No      <sub>1</sub> Yes  
 If Yes, please complete questions #7-9, regarding the **biological father**.
7. What is the father's ethnicity?
  - <sub>1</sub> Hispanic / Latino
  - <sub>2</sub> Not Hispanic / 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?
  - <sub>1</sub> Less than 7<sup>th</sup> grade
  - <sub>2</sub> 7<sup>th</sup> – 9<sup>th</sup> grade
  - <sub>3</sub> 10<sup>th</sup> – 12<sup>th</sup> grade
  - <sub>4</sub> High school degree
  - <sub>5</sub> Partial college
  - <sub>6</sub> College degree
  - <sub>7</sub> Graduate degree
  - <sub>88</sub> Unknown



MATERNAL BASELINE DATA

DATE: \_\_\_ / \_\_\_ / \_\_\_\_\_

Pregnancy History:

10. Did the mother have diabetes during pregnancy? <sub>0</sub> No <sub>1</sub> Yes  
 10a. If Yes, did she receive insulin for her diabetes? <sub>0</sub> No <sub>1</sub> Yes
11. Did the mother have hypertension during pregnancy? <sub>0</sub> No <sub>1</sub> Yes  
 11a. If Yes, did she receive medication to treat her hypertension? <sub>0</sub> No <sub>1</sub> Yes
12. Did the mother have asthma during pregnancy? <sub>0</sub> No <sub>1</sub> Yes  
 12a. If Yes, did she take medication regularly to control her asthma? <sub>0</sub> No <sub>1</sub> Yes
13. Did the mother take any medications to prolong pregnancy? <sub>0</sub> No <sub>1</sub> Yes  
 13a. If Yes, check all that apply:  
 Progesterone  
 Cyclooxygenase inhibitors (Indocin)  
 Oral betamemetics  
 Calcium Channel Blockers  
 Oxytocin receptor antagonist  
 Magnesium Sulfate  
 Other: \_\_\_\_\_
14. Was a maternal or neonatal toxicology screen performed at the time of birth? <sub>0</sub> No <sub>1</sub> Yes  
 14a. If Yes, indicate the results: <sub>0</sub> Negative <sub>1</sub> Positive  
 14b. If **Positive**, indicate the substances (check all that apply):  
 Amphetamines  
 Cocaine  
 Opiates  
 Barbiturates  
 Benzodiazepines  
 Phencyclidine (PCP)  
 Tetrahydrocannabinol (THC)  
 Ethanol  
 Methadone  
 Other: \_\_\_\_\_
15. Did the mother smoke tobacco products during pregnancy? <sub>0</sub> No <sub>1</sub> Yes  
 15a. Did anyone else smoke tobacco regularly in the mother's home during her pregnancy? <sub>0</sub> No <sub>1</sub> Yes
16. Indicate the mother's height and weight at the time of delivery: Height: \_\_\_ \_\_\_ cm <sub>88</sub> Unknown  
 Weight: \_\_\_ \_\_\_ . \_\_\_ kg <sub>88</sub> Unknown



**MATERNAL BASELINE DATA**

DATE: \_\_\_ / \_\_\_ / \_\_\_\_\_

Labor and Delivery Data:

17. Was there placental abruption? <sub>0</sub> No <sub>1</sub> Yes
18. Did the membrane rupture > 18 hours before delivery? <sub>0</sub> No <sub>1</sub> Yes
- 18a. If Question 18 is **Yes**, did the membrane rupture more than 7 days before delivery? <sub>0</sub> No <sub>1</sub> Yes <sub>88</sub> Unknown
19. Was there any clinical chorioamnionitis? <sub>0</sub> No <sub>1</sub> Yes
- 19a. If **Yes**, was placental pathology obtained? <sub>0</sub> No <sub>1</sub> Yes
- 19b. If Question 19a is **Yes**, was there histologic evidence of chorioamnionitis? <sub>0</sub> No <sub>1</sub> Yes
20. Were antibiotics given? <sub>0</sub> No <sub>1</sub> Yes
- 20a. If **Yes**, why were antibiotics given (check all that apply)?
- Chorioamnionitis
  - Group B Streptococcus (GBS) prophylaxis
  - Preterm labor
  - Other: \_\_\_\_\_
21. Were antenatal corticosteroids given? <sub>0</sub> No <sub>1</sub> Yes
- 21a. If **Yes**, total number of completed courses:
- <sub>0</sub> None
  - <sub>1</sub> One course
  - <sub>2</sub> Two courses
  - <sub>3</sub> Three courses
  - <sub>4</sub> Four courses
  - <sub>5</sub> Five courses
- 21b. Number of incomplete courses:
- <sub>0</sub> None
  - <sub>1</sub> One or more courses
22. Was magnesium sulfate given for any reasons other than tocolysis? <sub>0</sub> No <sub>1</sub> Yes
- 22a. If **Yes**, check the primary indication:
- <sub>1</sub> Preeclampsia / eclampsia
  - <sub>2</sub> Prevention of Cerebral Palsy
23. Was the onset of labor spontaneous? <sub>0</sub> No <sub>1</sub> Yes
24. What was the mode of delivery?
- <sub>1</sub> Vaginal Vertex
  - <sub>2</sub> Vaginal Breech
  - <sub>3</sub> Caesarian Section