



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

PID: _____

NONINVASIVE RESPIRATORY ASSESSMENTS [NIRA]

DATE: ___ / ___ / _____

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
 - 1 Baby was ineligible
 - 2 Baby was eligible but discharged
 - 3 Staff oversight/Staff not available to perform test
 - 98 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: 1 No Respiratory Support 2 Nasal cannula ≤ 1 LPM

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

6. Nasogastric Tube (NGT) placement at the start of the test 1 In 2 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
 - 1 Baby was ineligible
 - 2 Baby was eligible but discharged
 - 3 Staff oversight/Staff not available to perform test
 - 4 Site does not perform OWF
 - 98 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 Feeding or Bronchodilator	D= Disconnect
Q= Infant is in quiet sleep state	A= Infant is awake or active sleep	



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

11. Was the baby's last feed >30 minutes ago? ₀ No ₁ Yes
12. Was the baby in quiet sleep state at the start of the test? ₀ No ₁ Yes
13. Was the Respiratory Inductive Plethysmography [RIP] test performed? ₀ No ₁ Yes
- 13a. If 'No', please check primary reason infant missed test
- ₁ Baby was ineligible
 - ₂ Baby was eligible but discharged
 - ₃ Staff oversight/Staff not available to perform test
 - ₄ Baby not in quiet sleep
 - ₉₈ Other, specify: _____

14. Was the Oxygenation While Sleeping [OWS] test performed? ₀ No ₁ Yes
- 14a. If 'No', please check primary reason infant missed test
- ₁ Baby was ineligible
 - ₂ Baby was eligible but discharged
 - ₃ Staff oversight/Staff not available to perform test
 - ₄ Baby not in quiet sleep
 - ₉₈ Other, specify: _____

BRONCHODILATOR [BD] ADMINISTRATION

15. Was bronchodilator administered to the baby? ₀ No ₁ Yes
- 15a. If 'Not Done', please check primary reason infant missed test
- ₁ Baby was ineligible
 - ₂ Baby was eligible but discharged
 - ₃ Staff oversight/Staff not available to perform test
 - ₉₈ Other, specify: _____

16. Was entire bronchodilator dose given? ₀ No ₁ Yes
17. Treatment Response Heart Rate _____ BPM

POST- BRONCHODILATOR RIP DATA

18. Was bronchodilator administration terminated early? ₀ No ₁ Yes
- 18a. If 'Yes', check primary reason for early termination:
- ₁ Infant woke up
 - ₂ Hypoxemia
 - ₃ Respiratory Distress
 - ₄ Heart Rate exceeded 10% above baseline
 - ₉₈ Other, please specify _____

18b. Total time of bronchodilator treatment. _____ minutes

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



NOTE: Please indicate date of assessment in date field

BASELINE DATA

- 1. Indicate baby's post-menstrual age at time of assessment ___ Weeks ___ Day
- 2. What is the baby's body weight? _____ gms
- 3. Baseline Respiratory Rate (RR) _____ Breaths per minute
- 4. Baseline Heart Rate _____ Beats per minute
- 5. Respiratory Status
 - ₁ No Continuous Respiratory Support [No BPD]
 - ₂ Nasal Cannula [Continue to question 5a]
 - ₃ CPAP, SiPAP or MV [BPD]
- 5a. Oxygen flow (nasal cannula only): ___ LPM ___ %
- 6. SpO₂: _____ %
- 7. Most recent PCO₂ _____ ₉₉ NA
- 7a. Date of PCO₂ ___/___/_____
mm/dd/yyyy

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

- 8. Was the Room Air Challenge test performed? ₀ No ₁ Yes
 - 8a. If 'No' please check primary reason infant missed test
 - ₁ Baby was ineligible [Complete item 8b.]
 - ₂ Baby was eligible but discharged or transferred
 - ₃ Staff oversight/Staff or equipment not available to perform test
 - ₉₈ Other, specify: _____
 - 8b. If ineligible, please check primary reason for ineligibility
 - ₁ Baby was off all continuous support
 - ₂ Baby was on higher level of support than nasal cannula
 - ₃ Unable to maintain baseline saturation SpO₂ ≥90%
 - 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? ₀ No ₁ Yes



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

PID: _____

ROOM AIR CHALLENGE

DATE: ___ / ___ / _____

10. Please indicate the result of the Room Air Challenge test:

- ₁ Pass [No PBD]
₂ Fail [BPD] Complete items 10a-c

10a. Record time to fail test:

_____ minutes

10b. Please indicate primary reason for test failure:

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

10c. Respiratory Support at Failure:

____.____ LPM _____. ____%

11. Final Respiratory Rate

_____ Breaths/minute

12. Final Heart Rate

_____ Beats/minute

13. Final SpO₂

_____%

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



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM
ROOM AIR CHALLENGE WORKSHEET

PID: _____

DATE: ___ / ___ / _____

Complete this form for all infants on whom you initiate a Room Air Challenge test.

Instructions: Notify physician responsible for the infant’s care (attending or fellow), and obtain MD order to perform room air challenge.

- Challenge should be done with a pulse oximeter that has been getting a good signal for at least 5 minutes.
- Position infant supine, with any feedings or medications given 30 minutes prior to evaluation.
- Infant in Quiet Sleep (QS) at study initiation (Criteria: 1) Eyes closed and without movement, 2) Steady breathing, 3) Not vocalizing, and 4) No twitching of limbs (startles acceptable))
- Baseline data collection is done in infant’s current oxygen
- Record oxygen saturation every 1 minute x 5 minutes
- Assess if infant is in Quiet Sleep (QS) every 5 minutes

Baseline Measurements

Heart Rate: _____ (bpm)

RR: _____ (breaths per minute. Count for a full minute.)

Baseline Data	FiO ₂ : _____ Liter flow: _____					
	0 min	1 min	2 min	3 min	4 min	5 min
Time	:	:	:	:	:	:
Saturation						
QS (Y/N)						

Continue to oxygen reduction phase if all saturations are ≥ 90%

If unable to maintain saturations ≥ 90% continue to monitor for additional 10 minutes

	6 min	7 min	8 min	9 min	10 min	11 min	12 min	13 min	14 min	15 min
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

If infant fails to proceed to Oxygen and Flow reduction phase, record Infant as **Ineligible** and indicate reason for failure:

“Unable to maintain baseline SpO₂ ≥ 90%”



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

ROOM AIR CHALLENGE WORKSHEET

PID: _____

DATE: ___ / ___ / _____

Oxygen and Flow Reduction Phase:

1. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

2. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

3. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

Continue wean if all saturations are ≥ 90%. Stop Wean and record as FAIL if:

Saturation <90% for 5 consecutive minutes

OR

Saturation <80% for 15 seconds

Record time to fail test

Record any adverse event (AE) with time of event:

Apnea > 20 seconds

Bradycardia HR < 80 for > 10 seconds

Wean instructions:

If the infant is receiving supplemental oxygen by cannula:

- A) Wean FiO₂ by 0.20 every 5 minutes until FiO₂ 0.21
- B) Record saturation every minute

Then wean the flow:

- A) If the flow is ≥ 1.5 LPM, reduce flow by 1LPM. Monitor infant on reduced flow for 10 minutes.
- B) Record saturation every minute
- C) Once flow is < 1.5LPM reduce flow by 50%. Monitor infant on reduced flow for 10 minutes.
- D) Record saturation every minute.
- E) Gently remove nasal cannula from nares

After the nasal cannula has been removed, record saturations every 5 minutes until 60 minutes have elapsed



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

ROOM AIR CHALLENGE WORKSHEET

PID: _____

DATE: ___ / ___ / _____

4. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

5. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

6. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

7. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

Continue wean if all saturations are ≥ 90%. Stop Wean and record as

FAIL if:

Saturation <90% for 5 consecutive minutes

OR

Saturation <80% for 15 seconds

Record time to fail test

Record any adverse event (AE) with time of event:

Apnea >20 seconds

Bradycardia HR < 80 for > 10 seconds

Wean instructions:

If the infant is receiving supplemental oxygen by cannula:

C) Wean FiO₂ by 0.20 every 5 minutes until FiO₂ 0.21

D) Record saturation every minute

Then wean the flow:

F) If the flow is ≥ 1.5 LPM, reduce flow by 1LPM. Monitor infant on reduced flow for 10 minutes.

G) Record saturation every minute

H) Once flow is < 1.5LPM reduce flow by 50%. Monitor infant on reduced flow for 10 minutes.

I) Record saturation every minute.

J) Gently remove nasal cannula from nares

After the nasal cannula has been removed, record saturations every 5 minutes until 60 minutes have elapsed



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

ROOM AIR CHALLENGE WORKSHEET

PID: _____

DATE: ___ / ___ / _____

8. Step _____ FiO₂ _____ Liter flow _____

	Minutes									
	1	2	3	4	5	6	7	8	9	10
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

Begin Room Air Observation

PASS: All saturations ≥ 90% for 1 hour
FAIL: Saturation < 90% for 5 consecutive minutes

OR

Saturation < 80% for 15 consecutive seconds

Record saturation every 5 minutes until 60 minutes have elapsed
Return infant to previous level of supplemental oxygen and flow

Results of Room Air Challenge
 Pass Fail (note reason for failure)

Notify clinical care team of test results

	Minutes					
	5 min	10 min	15 min	20 min	25 min	30 min
1. Time	:	:	:	:	:	:
2. Saturation						
3. QS (Y/N)						

	Minutes					
	35 min	40 min	45 min	50 min	55 min	60 min



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM
ROOM AIR CHALLENGE WORKSHEET

PID: _____

DATE: ___ / ___ / _____

1. Time	:	:	:	:	:	:
2. Saturation						
3. QS (Y/N)						

At conclusion of test:

Heart Rate: ___ ___ ___ (bpm)

RR: ___ ___ (breaths per minute. Count for a full minute.)

If FAIL, time to failure from initiation of oxygen/flow wean: ___ ___ ___ (in minutes)

If any AE occur, please complete AE Log. Record details below, as available.

AE (from time of initiation of wean through completion of Room Air Observation phase):

1. Apnea (cessation of breathing > 20 secs). Time ___ ___ : ___ ___
2. Bradycardia (HR < 80 bpm > 10 secs). Time ___ ___ : ___ ___



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

HYPOXIC CHALLENGE TEST

PID: _____

DATE: ____ / ____ / ____

NOTE: Please indicate date of assessment in date field

BASELINE DATA

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

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

- 6. Was the Hypoxic Challenge test performed? ₀ No ₁ Yes
 - 6a. If 'No' please check primary reason infant missed test
 - ₁ Baby was ineligible [Complete item 6b.]
 - ₂ Baby was eligible but discharged or transferred
 - ₃ Staff oversight/Staff or equipment not available to perform test
 - ₄ Baby had acute respiratory illness
 - ₉₈ Other, specify: _____
 - 6b. If ineligible, please check primary reason for ineligibility
 - ₁ Failed RAC
 - ₂ Not weaned off clinical respiratory support
 - ₃ Unable to maintain baseline saturation SpO₂ ≥90%
 - ₄ On continuous respiratory support without RAC at 36 weeks PMA
- 7. Did Infant arouse (active sleep or awake) during the observation period? ₀ No ₁ Yes
- 8. Please indicate the result of the Hypoxic Challenge test:
 - ₁ Pass
 - ₂ Fail [Complete items 8a-b]
- 8a. Record time to fail test: _____ minutes
- 8b. Please indicate primary reason for test failure:
 - ₂ Desaturation <85% for 60 consecutive seconds
 - ₃ Desaturation <80% for 15 consecutive seconds
 - ₄ Apnea
 - ₅ Bradycardia
 - ₉₈ Other, specify: _____
- 9. Final Respiratory Rate _____ Breaths/minute
- 10. Final Heart Rate _____ Beats/minute
- 11. Final SpO₂ ___ . ___ %

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



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

HYPoxic CHALLENGE TEST WORKSHEET

PID: _____

DATE: ___ / ___ / _____

Complete this form for all infants on whom you initiate a Hypoxic Challenge Test.

Instructions: Notify physician responsible for the infant's care (attending or fellow), and obtain MD order to perform Hypoxic Challenge Test.

- Challenge should be done with a pulse oximeter that has been getting a good signal for at least 5 minutes.
- Position infant supine, with any feedings or medications given 30 minutes prior to evaluation.
- Infant in Quiet Sleep (QS) at study initiation (Criteria: 1) Eyes closed and without movement, 2) Steady breathing, 3) Not vocalizing, and 4) No twitching of limbs (startles acceptable))
- Baseline data collection is done with the infant on room air
- Record oxygen saturation every 1 minute x 20 minutes
- Assess if infant is in Quiet Sleep (QS) every 5 minutes

Baseline Measurements

Heart Rate: _____ (bpm)

RR: _____ (breaths per minute. Count for a full minute.)

Baseline Data	0 min	1 min	2 min	3 min	4 min	5 min
	Time	:	:	:	:	:
Saturation						
QS (Y/N)						

	6 min	7 min	8 min	9 min	10 min	11 min	12 min	13 min	14 min	15 min
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

Continue to the oxygen reduction phase if after 15 minutes all saturations recorded are $\geq 90\%$. If oxygen saturations are not maintained $\geq 90\%$, record infant as **Ineligible** for the Hypoxic Challenge and indicate reason for failure: **“Unable to maintain baseline SpO₂ $\geq 90\%$ ”**



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

HYPOXIC CHALLENGE TEST WORKSHEET

PID: _____

DATE: ___ / ___ / _____

Oxygen Reduction Phase

- Place infant in high flow oxygen hood with oxygen sensor reading 15±1%
- Ensure oxygen analyzer reading has stabilized prior to initiation of data collection
- Record FiO₂, Time, Saturation every minute for maximum of 20 minutes
- If infant has apnea during test, provide stimulation as per routine care.
- For persistent apnea or bradycardia turn off nitrogen, remove hood, may treat with supplemental oxygen if needed.
- At conclusion of test, turn off nitrogen gas and remove oxyhood.
- Record Heart Rate and Respiratory Rate
- Observe to assure saturation level return to baseline or > 85% on room air
- Supplemental oxygen may be used for persistent desaturation, until infant recovers to saturation > 85%

	Minutes									
	1	2	3	4	5	6	7	8	9	10
FiO ₂										
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

	Minutes									
	11	12	13	14	15	16	17	18	19	20
FiO ₂										
Time	:	:	:	:	:	:	:	:	:	:
Saturation										
QS (Y/N)										

Record as PASS if saturations are ≥ 85 % for 20 minutes

Stop challenge and record as FAIL if:

Saturation <85% for 60 consecutive seconds

OR

Saturation < 80% for 15 consecutive seconds

OR

Any need to prematurely terminate the test
(bradycardia or persistent apnea)

Record time to fail test (in minutes)

Record any adverse event (AE) with time of event:

Apnea >20 seconds

Bradycardia HR <80 for >10 seconds

**Additional AE/SAE following termination of exposure to
FiO₂ 0.15, below**



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

HYPOXIC CHALLENGE TEST WORKSHEET

PID: _____

DATE: ___ / ___ / _____

Results of Hypoxic Challenge Test

Pass or **Fail** (note reason for failure)

Desaturation

Persistent apnea > 20 secs

Bradycardia < 80 bpm x 10 secs

Notify clinical care team of the test results

At conclusion of test:

Heart Rate: _____ (bpm)

RR: _____ (breaths per minute. Count for a full minute.)

If FAIL, time to failure from initiation of exposure to FiO_2 0.15: _____ (in minutes)

If any AE or SAE occur, please complete AE/SAE Log. Record details below, as available.

AE (from time of initiation of FiO_2 0.15):

1. Apnea (cessation of breathing > 20 secs). Time _____ : _____
2. Bradycardia (HR < 80 bpm > 10 secs). Time _____ : _____

AE (following completion of test):

1. Supplemental oxygen of $\text{FiO}_2 \geq 0.10$ above baseline persisting for > 1 hour after test is concluded or terminated.
2. Tachycardia (> 200 bpm) persisting for > 1 hour after test is concluded or terminated.



PREMATURITY AND RESPIRATORY OUTCOMES PROGRAM

HYPOXIC CHALLENGE TEST WORKSHEET

PID: _____

DATE: ___ / ___ / _____

SAE (to be reported if possibly or probably related to study procedures):

1. Any need for CPR within 12 hours after test is concluded or terminated (*i.e.*, chest compressions or cardiac medications given for resuscitation). Date ___ / ___ / ___ Time ___ : ___
2. The addition of mechanical ventilation within 12 hours after the test is concluded or terminated.
Date ___ / ___ / ___ Time ___ : ___
3. Supplemental oxygen of $FiO_2 \geq 0.10$ above baseline persisting for ≥ 12 hours after test is concluded or terminated.
Date ___ / ___ / ___ Time ___ : ___
4. Any additional event deemed to be serious by the site Principal Investigator and possibly or probably related to study procedure. Date ___ / ___ / ___ Time ___ : ___