

Neonatal Research Network

GENERIC DATABASE (GDB)
BASELINE FORM (NG02)

NG0 vs .0
January 1, 01
Revised October, 01
Page 1 of 2

Center: _____ Site: _____ Network No: _____ BN
Mother's Initials (optional): _____

A. MATERNAL INFORMATION

1. Mother's age (years): _____
2. Pregnancy history (include this pregnancy):
a. Gravidity: _____
b. Parity: _____
3. Marital Status: _____
1 = Married 2 = Single 6 = Unknown
4. Highest level of education achieved by the Biological Mother: _____
1 = 8th grade or less 5 = Partial college or Associate's degree
2 = 9th to 12th grade 6 = College degree
3 = High School diploma 7 = Graduate degree
4 = Trade or Technical School 8 = Unknown
5. Mother's medical insurance: _____, _____
10 = Public Insurance 5 = Self-pay uninsured
3 = Private 6 = Unknown 9 = Other
6. Mother's ethnic categories: _____
1 = Hispanic or Latino 2 = Not Hispanic or Latino 3 = Unknown or Not Reported
7. Mother's racial categories: _____
1 = Black 4 = Asian
2 = White 5 = Native Hawaiian or Other Pacific Islander
3 = American Indian or Alaskan Native 6 = More than One Race
7 = Unknown or Not Reported
8. Mother's height _____ in _____ cm
9. Mother's weight prior to pregnancy _____ lb _____ kg
10. Mother's weight at delivery _____ lb _____ kg

B. PREGNANCY COMPLICATIONS

1. Multiple birth? Y N
If YES,
a. Number of fetuses: _____
2. Is there evidence of prenatal health care in this pregnancy? _____
1 = No 2 = Limited 3 = Adequate

3. Diabetes prior to pregnancy? Y N

If YES,

- a. Type of diabetes? _____
1 = Type 1 2 = Type 2 3 = Unknown
- b. Treatment given _____
1 = Insulin 2 = Oral hypoglycemic medication 3 = Diet only 4 = None Unknown

4. Gestational diabetes (diagnosed during the pregnancy)? Y N Unk

If YES,

- a. Treatment given _____
1 = Insulin 2 = Oral hypoglycemic medication 3 = Diet only 4 = None Unknown

5. Hypertension? Y N

If YES,

- a. Hypertension existed prior to pregnancy? Y N Unk

6. Antepartum hemorrhage? Y N

7. Was chorioamnionitis documented in the mother's medical record? Y N

8. Was placental pathology performed? Y N

If YES,

- a. Was histologic chorioamnionitis documented? Y N
b. Was acute funisitis documented? Y N

C. LABOR AND DELIVERY

1. Was there rupture of membranes (ROM) prior to delivery? Y N Unk

If YES,

- a. Date: _____/_____/_____
Month Day Year b. Time: _____:_____
Hour Min
- c. If date and/or time unknown, was ROM estimated at >1 hours? Y N Unk

2. Were antenatal steroids given to accelerate fetal maturity? Y N Unk

If YES,

- a. Type of antenatal steroid given: _____
1 = Betamethasone 2 = Dexamethasone 3 = Both = Unknown

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Mother's Initials (optional): _____		

- b. Was a complete course of antenatal steroids given? Y N Unk
- c. Was more than one course of antenatal steroids given? Y N Unk
- d. When was the last dose of antenatal steroids given?
- i. Date ____/____/____ ii. Time: ____:____
- Month Day Year Hour Min
3. Were maternal antibiotics given within 72 hours prior to birth? Y N Unk
- If YES,**
- a. List antibiotics given: (See Code Sheet in Appendix B)
- 1.____ 3.____ 5.____
- 2.____ 4.____ 6.____
4. Was magnesium sulfate given during this admission prior to delivery? Y N Unk
5. Was there documentation of electronic fetal heart rate monitoring within 12 hours prior to birth? Y N Unk
6. Final mode of delivery: _____
- 1 = Vaginal vertex 2 = Vaginal breech 3 = Cesarean section 5 = Unknown

D. NEONATAL INFORMATION

1. Date and time of birth:
- a. Date: ____/____/____ b. Time: ____:____
- Month Day Year Hour Min
2. Was the infant outborn? Y N
- If YES,**
- a. Date admitted to NICU: ____/____/____
- Month Day Year
3. Was a prenatal diagnosis made that influenced the decision to withdraw or limit intensive care? Y N
- If YES,**
- a. Diagnosis: _____; _____; _____; _____; _____
- i. If 'Other' specify: _____
4. Did the infant die ≤ 12 hours after birth? Y N
5. Sex: _____
- 1 = Male 2 = Female 3 = Ambiguous

6. Gestational age: Weeks ____ Days ____
- a. Method used to determine reported gestational age
- 1 = Obstetric Estimate 2 = Neonatal Estimate
7. Apgar score - 1 minute: ____
8. Apgar score - 5 minutes: ____
9. Birth resuscitation/stabilization
- a. Oxygen? Y N
- b. Positive pressure ventilation? Y N
- c. CPAP? Y N
- d. Intubation? Y N
- e. Chest compression? Y N
- f. Epinephrine? Y N
10. Is there documentation of delayed cord clamping? Y N
11. Is there documentation of cord milking? Y N
12. Birth weight (grams): _____
13. Length (cm): _____
14. Head circumference (cm): _____
15. Was any thermal product used to improve temperature regulation? Y N Unk
16. Record infant's first temperature documented after admission to nursery
- a. Celsius: ____ . ____ b. Fahrenheit: ____ . ____
- c. Date: ____/____/____ d. Time: ____:____
- Month Day Year Hour Min
- e. Source: _____
- 1 = Rectal 2 = Axillary 3 = Skin
- Initials of person completing form: _____

Mother's Initials(*optional*): _____

Y N

Y N Y N

e. Porencephalic/posthemorrhagic cyst/multicystic encephalomalacia?

1 = Not Done	3 = Gram Positive	5 = Yeast
2 = Negative	4 = Gram Negative	6 = Other (Specify)

Mother's Initials(*optional*): _____

5. Last hemoglobin or hematocrit before discharge, _____ (g dL) _____
6. Did the infant receive erythropoietin or another erythropoiesis stimulating agent? _____

Y N T

- Y N

- Mature Vessels (fully vascularized)
- Immature Vessels in zone III for two consecutive exams
- ROP of stage 1 or 2 in zone III for two consecutive exams
- ROP in zone II or zone III but determined to be clearly regressing

- ROP surgery
- Retinal detachment
- Avastin injection or anti-VEGF

1. Immature Vessels in zone I and II
2. Immature vessels reaching zone III for only 1 exam
3. Stage 1 or 2 ROP in zone III for only 1 exam
4. Stage 3 ROP in zone III
5. ROP in zone I or zone II
6. Plus disease

1. Blood Type

a. Rh (Rhesus) factor

2. Was the infant transfused with pRBC?	Y	N
---	---	---

If YES,

a. Date of first pRBC transfusion _____ / _____ / _____
Month Day Year

b. Lowest hemoglobin OR hematocrit prior to first transfusion _____ (g/dL) _____

3. Was the infant transfused with other blood product ?

	Y	N
a. Fresh Frozen Plasma		

	Y	N
b. Platelets		

4. Highest total serum bilirubin in first 14 days (mg/dL) _____.

1. Syndromes and/or major malformations?

a. If **YES**, code:

1) = 2) = 3) =

4) = 5) = 6) =

b. If a syndrome is coded as 'Other', specify:

1. Did the infant have surgery?

a. If **YES**, code:

i. Date (mm/dd yyyy)

ii. Surgery code()

iii. Surgical Site Infection?

1. ____/____/____; ____; Y N Unk

2. _____ / _____ / _____ _____ ; _____ ;
_____ ; _____

Y N Unk

3. / / ; ; ; Y N Unk

4. / / ; ; Y N Unk

5. _____ / _____ / _____ _____; _____;
_____ ; _____

Y N Unk

6. _____ / _____ / _____ _____ ; _____ ; Y N Unk
_____ ; _____

b. If a surgery is coded as 'Other' (codes ending in 99), specify:

Neonatal Research Network Center: _____	Site: _____	Network No: _____	GENERIC DATABASE (GDB) EARLY DEATH FORM (NG0 E)	NG0 E vs .0 January, 20 Page 1 of 1
			Mother's Initials(<i>optional</i>): _____	

To be completed if the infant died at ≤ 12 hours of age.

1. Medical therapy initiated:

- | | | |
|------------------------------------|---|---|
| a. Antibiotics? | Y | N |
| b. Surfactant replacement therapy? | Y | N |
| c. Pressor support? | Y | N |
| d. Volume support? | Y | N |
| e. Intubation and Ventilation? | Y | N |
| f. IV fluids? | Y | N |

2. Autopsy performed?

Y N

3. At any time after birth (prior to NG03E Status), was there documentation of discussion with parents to limit, withdraw or not escalate care?

Y N

4. Were the following treatments withheld, limited or withdrawn at any time with the intent to limit care?

- | | | |
|---------------------------|---|---|
| a. Intubation/ventilation | Y | N |
| b. Nutrition/hydration | Y | N |
| c. Medication | Y | N |

5. No intention to resuscitate (comfort care only)

Y N

6. Contributory cause of death: _____

<u>Malformation</u> 10 = Congenital malformation <u>Pulmonary</u> 20 = RDS 21 = RDS with severe intracranial hemorrhage 22 = RDS with infection 23 = RDS with massive pulmonary hemorrhage <u>Infection</u> 30 = Suspect sepsis/infection 31 = Proven sepsis/infection	<u>CNS Insult</u> 50 = Severe intracranial hemorrhage 51 = Severe intracranial hemorrhage with infection <u>Other</u> 60 = Immaturity without active neonatal treatment 90 = Other 99 = Unknown
---	---

7. If contributory cause of death is code "10" (Congenital malformation) or code "90" (other), specify:

Initials of person completing this form: _____

Center: _____

Site: _____

Network No: _____

Mother's Initials (optional): _____

BN

This form is to be used for infants who are in this hospital for greater than 120 days. Form NG03 should be completed through day 120. This form should be completed after the infant dies, is discharged, is transferred or reaches one year post-natal age.

A. STATUS

1. Status of infant at time of completion of form _____

1 = Discharged to home	5 = Death
3 = Transferred to another facility	6 = Remains in hospital at one year

2. Date of status: _____ / _____ / _____
Month Day Year

3. Weight at status (grams): _____

4. Length at status (cm): _____

5. Head circumference at status (cm): _____

B. EXTENDED STAY INFORMATION1. What problem (s) caused hospitalization greater than 120 days:
(answer all that apply)

a. Pulmonary?	Y	N
b. Cardiac?	Y	N
c. Neurologic?	Y	N
d. Gastrointestinal?	Y	N
e. Multiple Malformations?	Y	N
f. Social?	Y	N
g. Ophthalmologic?	Y	N
h. Sepsis/infection?	Y	N
i. Renal?	Y	N
j. Other?	Y	N

1) If YES, specify: _____

2. Did either eye receive therapy for ROP after 120 days? Y N T

If YES, a. List all therapies done for either eye (Use codes below).

1 = Laser	3 = Scleral buckling	5 = Avastin or anti-VEGF
2 = Cryotherapy	4 = Vitrectomy	6 = Other (specify) for either eye

3. Was a hearing screen performed after 120 days? Y N

If YES,

a. Was otoacoustic emissions (OAE) testing performed? Y N

1. Was OAE failed? Y N

If YES,

i. Unilateral or bilateral fail? _____

1 = Unilateral	2 = Bilateral
----------------	---------------

b. Was automated auditory brainstem response (AABR) performed? Y N

1. Was AABR failed? Y N

If YES,

i. Unilateral or bilateral fail? _____

1 = Unilateral	2 = Bilateral
----------------	---------------

4. Was a diagnostic auditory brainstem response (ABR) performed prior to discharge? Y N

If YES,

a. Was hearing loss documented? Y N Unk

If YES,

1. Unilateral or bilateral hearing loss? _____

1 = Unilateral	2 = Bilateral
----------------	---------------

Center: ____

Site: ____

Network No: ____

Mother's Initials (optional): ____

BN

C. ETHICS/PALLIATIVE CARE

1. Was there documentation of discussion with parents to limit, withdraw or not escalate care after 120 days? Y N

2. Were the following treatments withheld, limited or withdrawn after 120 days with the intent to limit care?

a. Intubation/ventilation Y N
b. Nutrition/Hydration Y N
c. Medication Y N

D. TRANSFER

Complete this section if status of infant is '3=Transferred to another facility'

1. Date of transfer: ____ / ____ / ____
Month Day Year

2. Final outcome: ____

1 = Died in hospital 2 = Discharged to home 3 = Remains in hospital at one year

E. DISCHARGE ALIVE

Complete this section if status of infant at time of completion of this form is '1= Discharged to home'

1. Date of discharge to home: ____ / ____ / ____
Month Day Year

2. Discharged home on continuous oxygen? Y N

3. Discharged home on any of the following medications? Y N

If YES,

a. Diuretics? Y N T
b. Bronchodilators? Y N T
c. Anticonvulsants? Y N T
d. Antireflux medications? Y N T
e. Antihypertensive medications? Y N T
f. Methylxanthines? Y N T
g. Other, specify ____ Y N T

4. Discharged home receiving any human milk? Y N Un

a. If YES, type of milk

1 = Maternal Milk 2 = Donor Milk = oth 4 = Unknown

F. DEATH

Complete this section if status of infant is '5=Death'

1. Date of death: ____ / ____ / ____
Month Day Year

2. Autopsy performed? Y N

3. Contributory Cause of death: ____

GI

40 = NEC
41 = NEC with sepsis
42 = Spontaneous perforation
43 = Short bowel syndrome
44 = Liver failure

Malformation

10 = Congenital malformation

Pulmonary

25 = BPD
26 = BPD with infection
27 = BPD with severe CNS insult
28 = PPHN - Pulmonary

Renal

70 = Renal failure

CNS Insult

50 = Severe intracranial hemorrhage
51 = Severe intracranial hemorrhage with infection

Other

90 = Other
99 = Unknown

Infection

30 = Suspect sepsis/infection
31 = Proven sepsis/infection

4. If cause of death is code "10" (Congenital malformation), or "90" (Other) specify: ____

Initials of person completing this form: ____

Center: ____

Site: ____

Study No. T ____

Network No. ____

BN

Mother's Initials (optional): ____

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This form should be completed for all infants listed on the screening log.

A. INCLUSION CRITERIA*(Items 1-4 must be answered "Yes")*

- | | | |
|---|---|---|
| 1. Birth weight $\leq$ 1000 grams? | Y | N |
| 2. Gestational age between 22 0/7 – 28 6/7 weeks? | Y | N |
| 3. Admitted to the center NICU $\leq$ 48 hours of life? | Y | N |
| 4. Ability to randomize by 48 hours of life? | Y | N |

B. EXCLUSION CRITERIA*(Items 1-10 must be answered "No")*

- | | | |
|---|---|---|
| 1. Considered nonviable by the attending neonatologist? | Y | N |
| 2. Cyanotic congenital heart disease? | Y | N |
| 3. Parents opposed to the transfusion of blood? | Y | N |
| 4. Parents with hemoglobinopathy or congenital anemia? | Y | N |
| 5. <i>In-utero</i> fetal transfusion? | Y | N |
| 6. Twin-to-twin transfusion syndrome? | Y | N |
| 7. Isoimmune hemolytic disease? | Y | N |
| 8. Any blood transfusion between 6 hours of life and time of randomization? | Y | N |
| 9. Unlikely that family will be available for follow-up at 22-26 months? | Y | N |
| 10. Did patient receive erythropoietin or will receive erythropoietin? | Y | N |

C. CONSENT

1. Check the appropriate consent status:

- | | |
|--|---|
| ☐ Not eligible | ☐ Parent not approached |
| ☐ Consent granted | ☐ Physician refused consent |
| ☐ Parent refused consent | ☐ Infant died prior to consent |
| ☐ Parent refused consent, not willing to randomize multiples separately | ☐ Other |
| ☐ Parent unavailable | |

a. If parent unavailable, parent not approached, physician refused consent, or other indicate reason: _____

D. RANDOMIZATION (complete if C.1 = consent granted)

1. Was infant randomized into the study? Y N

- a. If
- No**
- , select the reason and form is complete

- ☐ Parent withdrawal of consent
- ☐ Physician refusal to randomize
- ☐ Infant died prior to randomization
- ☐ Research staff unavailable
- ☐ Other (Specify) _____

If **Yes**,

- b. Date of randomization: ____ / ____ / ____

- c. Time of randomization: ____ : ____

- d. Birth weight strata:
- ☐ < 750 grams
- ☐ 750-1000 grams

- e. Randomization number: _____

- f. Randomization assignment
- ☐ High Transfusion Threshold
- ☐ Low Transfusion Threshold

E. DATA BETWEEN BIRTH AND RANDOMIZATION (complete if D.1 = Y)

- | | | |
|---|---|---|
| 1. Did the baby have a documented delayed cord clamping? | Y | N |
| 2. Did the baby have documented cord milking? | Y | N |
| 3. Was surfactant given between birth and randomization? | Y | N |
| 4. Any supplemental oxygen (> 21%) at time of randomization? | Y | N |
| 5. Any positive airway pressure (including CPAP, NIMV, SiPAP, MV and any NC flow > 0.5 lpm at time of randomization)? | Y | N |
| a. If yes , Was an endotracheal tube in place? | Y | N |

Initials of person completing this form: ____

Center: _____ Site: _____ Study No. T **TOPSID** Network No. _____ Mother's Initials (optional): _____

Page 1 of 1

This form should be completed for all infants listed on the screening log.

A. INCLUSION CRITERIA

(Items 1-4 must be answered "Yes")

- | | | | |
|---|-----------------|---|---|
| 1. Birth weight $\leq$ 1000 grams? | TP2IBTWT | Y | N |
| 2. Gestational age between 22 0/7 – 28 6/7 weeks? | TP2IGAGE | Y | N |
| 3. Admitted to the center NICU $\leq$ 48 hours of life? | TP2IAD48 | Y | N |
| 4. Ability to randomize by 48 hours of life? | TP2IRN48 | Y | N |

B. EXCLUSION CRITERIA

(Items 1-11 must be answered "No")

- | | | | |
|---|-----------------|---|---|
| 1. Considered nonviable by the attending neonatologist? | TP2ENONV | Y | N |
| 2. Cyanotic congenital heart disease? | TP2ECCHD | Y | N |
| 3. Parents opposed to the transfusion of blood? | TP2EPOPB | Y | N |
| 4. Parents with hemoglobinopathy or congenital anemia? | TP2EPHCA | Y | N |
| 5. In-utero fetal transfusion? | TP2EIUFT | Y | N |
| 6. Twin-to-twin transfusion syndrome? | TP2ETWTS | Y | N |
| 7. Isoimmune hemolytic disease? | TP2EISHD | Y | N |
| 8. Any blood transfusion ordered between 6 hours of life and time of randomization? | TP2E6HBT | Y | N |
| 9. Unlikely that family will be available for follow-up at 22-26 months? | TP2EFU26 | N | |
| 10. Did patient receive erythropoietin or will receive erythropoietin? | TP2EERYT | N | |
| 11. Congenital condition? | TP2ECONG | Y | N |

C. CONSENT

1. Check the appropriate consent status: **TP2CONS**

- | | |
|--|---|
| ☐ Not eligible | ☐ Parent not approached |
| ☐ Consent granted | ☐ Physician refused consent |
| ☐ Parent refused consent | ☐ Infant died prior to consent |
| ☐ Parent refused consent, not willing to randomize multiples separately | ☐ Other |
| ☐ Parent unavailable | |

a. If parent unavailable, parent not approached, physician refused consent, or other indicate reason: **TP2CONSR**

D. RANDOMIZATION (complete if C.1 = consent granted)

1. Was infant randomized into the study? **TP2RAND** Y N
- a. If No, select the reason and form is complete **TP2RANDR**
- ☐ Parent withdrawal of consent
- ☐ Physician refusal to randomize
- ☐ Infant died prior to randomization
- ☐ Research staff unavailable
- ☐ Other (Specify) **TP2RANDO**
- If Yes,
- b. Date of randomization: **TP2RANDT** ____/____/____
- c. Time of randomization: **TP2RANTM** ____:____
- d. Birth weight strata: **TP2STRAT** ☐ < 750 grams ☐ 750-1000 grams
- e. Randomization number: **TP2RANDN** _____
- f. Randomization assignment **TP2ASSGN** ☐ High Transfusion Threshold ☐ Low Transfusion Threshold

E. DATA BETWEEN BIRTH AND RANDOMIZATION (complete if D.1 = Y)

- | | |
|---|---------------------|
| 1. Did the baby have a documented delayed cord clamping? | TP2CRDCL |
| 2. Did the baby have documented cord milking? | TP2CRDML |
| 3. Was surfactant given between birth and randomization? | TP2SURF |
| 4. Any supplemental oxygen (> 21%) at time of randomization? | TP2SUPOX |
| 5. Any positive airway pressure (including CPAP, NIMV, SiPAP, MV and any NC flow > 0.5 lpm at time of randomization)? | TP2PAP |
| a. If yes, Was an endotracheal tube in place? | TP2ENDT |
| Initials of person completing this form: | TP2INIT ____ |

Center: ____

Site: ____

Study No. T TOPSIDNetwork No. _____
BNMother's Initials (*optional*): ____

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This form should be completed for all randomized infants. The SNAP score will be computed by RTI. Please indicate the lowest value for each physiologic measurement within the first 12 hours of life.

A. SNAP

1. Lowest mean blood pressure (mm Hg)

TP3LMBP

2. Lowest Temperature (°C) or (° F)

TP3LTCTP3LTF

____ C or ____ F

3. Lowest PaO₂TP3PAO24. Corresponding FiO₂ for the lowest PaO₂TP3FI02

5. Lowest Serum pH (includes cord gas)

TP3LSPH

6. Multiple Seizures (any suspected/ documented)

TP3SEIZ☐ Multiple Seizures ☐ None/Single

7. Urine Output (ml within the first 12 hours)

TP3URINE

Initials of person completing this form:

TP3INIT

Center: ____

Site: ____

Study No. T ____

Network No. _____
BNMother's Initials (*optional*): ____

Page _ of _

This form should be completed for all randomized infants; please record all ordered hemoglobin/hematocrit tests from birth through 36 weeks PMA or discharge (whichever occurs first).

1. Test #	2. Date	3. Time	4. Hemoglobin OR Hematocrit (need enter only one)	
			Hemoglobin (g/dL)	Hematocrit (%)
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---
----	___/___/_____	__:__	____.____	---

Initials of person completing this form: ____

Center: ____

Site: ____

Study No. T ____

Network No. _____
BNMother's Initials (*optional*): ____

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This form should be completed for all randomized infants; please record all ordered hemoglobin/hematocrit tests from birth through 36 weeks PMA or discharge (whichever occurs first).

1. Test #	2. Date	3. Time	4. Hemoglobin OR Hematocrit (need enter only one)	
			Hemoglobin (g/dL)	Hematocrit (%)
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____
----	___/___/_____	__:__	____.____	____.____

Initials of person completing this form: _____

Center: ____

Site: ____

Study No. T ____

Network No. _____
BN

Mother's Initials (optional): ____

Page _ of _

This form should be completed for all randomized infants; please record all ordered hemoglobin/hematocrit tests from birth through 36 weeks PMA or discharge (whichever occurs first).

1. Test #	2. Date	3. Time	4. Hemoglobin OR Hematocrit (need enter only one)		5. Source (select one)
			Hemoglobin (g/dL)	Hematocrit (%)	
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas
_____	___/___/_____	__:__	____. __	____. __	☐ CBC ☐ Part of blood gas

Initials of person completing this form: _____

Center: ____

Site: ____

Study No. T TOPSID _____Network No. _____
BN

Mother's Initials (optional): ____

Page _ of _

This form should be completed for all randomized infants; please record all ordered hemoglobin/hematocrit tests from birth through 36 weeks PMA or discharge (whichever occurs first).

1. Test #	2. Date	3. Time	4. Hemoglobin OR Hematocrit (need enter only one)		5. Source (select one)
			Hemoglobin (g/dL)	Hematocrit (%)	
TP4TNUM ____	TP4DATE ____/____/____	TP4TIME ____:____	TP4HEMO ____.____	TP4HEMA ____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other
____	____/____/____	____:____	____.____	____.____	☐ CBC ☐ Part of blood gas ☐ Other

Initials of person completing this form:

TP4INIT

Center: ____

Site: ____

Study No. ____

TP05SID

TRANSFUSION FORM

Network No. ____

BN

Mother's Initials (optional): ____

October 8, 2012, June 19, 2014

Report TP5RNUM of 1

This form should be completed for all randomized infants. Please record ALL transfusions from birth through 36 weeks PMA death, or discharge (whichever occurs first).

A. RBC Transfusion Record

1. Date of transfusion: TP5TRADT 2. Donor Unit ID: TP5DONID 3. Aliquot #: TP5ALQNM
4. Last known Weight (g): TP5LKWGT 5. Blood Source: ☐ Blood Bank (non-directed) or ☐ Directed Donor 6. Volume given (mL): TP5BLVOL
7. Is infant receiving enteral feeds? TP5ENTFD 7a. If yes, were enteral feeds withheld during this transfusion? Y N TP5ENTWH
8. Reason(s) for transfusion (select all that apply): ☐ as per randomization scheme, Hgb/Hct trigger, test # ____ (from TOP04) ☐ bleeding; ☐ pre-op; ☐ exchange transfusion, indicate reason TP5TRARS_1 TP5TRARS_2 TP5TRARS_3 TP5TRARS_4 TP5TRARS_5 TP5TRARS_6 TP5TRARX TP5TRARC TP5TRARO
9. Is infant currently receiving caffeine or methylxanthine? Y N TP5CAFMX

B: Clinical Observations Before, During and After Transfusion

1. START TIME: TP5CSTTM 2. END TIME: TP5CEDTM 3. Did a new IV have to be established to deliver this blood transfusion? TP5NEWIV

Observations	Prior to Transfusion (at any point 6 hours prior to transfusion)	Start of Transfusion	6 hours after end of transfusion (at any point 6 hours post end transfusion)
4. lowest Mean BP (mmHg)	TP5BLMBP ____	TP5SLMBP ____	TP5ALMBP ____
5. highest HR / min	TP5BHHR ____	TP5SHHR ____	TP5AHHR ____
6. highest RR / min	TP5BHRR ____	TP5SHRR ____	TP5AHRR ____
7. On Supplemental O ₂ (includes NC)? (Y/N; if yes, FiO ₂)	TP5BOSPO If yes, TP5BSUPO	TP5SOSPO N If yes, TP5SSUPO	TP5AOSPO If yes, TP5ASUPO
8. lowest SpO ₂ (%)	TP5BLSPO ____	TP5SLSPO ____	TP5ALSPO ____
9. Receiving CPAP or PEEP? (cm H ₂ O)	TP5BRCCP If yes, TP5BCPAP	TP5SRCCP N If yes, TP5SCPAP	TP5ARCCP If yes, TP5ACPAP
10. IPPV (Y/N; if yes, highest MAP)	TP5BIPPV If yes, TP5BIMAP	TP5SIPPV N If yes, TP5SIMAP	TP5AIPPV If yes, TP5AIMAP
11. HFV (Y/N; if yes, highest MAP)	TP5BHFV If yes, TP5BHMAP	TP5SHFV N If yes, TP5SHMAP	TP5AHFV If yes, TP5SHMAP
12. Inotropic support (any drug given for blood pressure)	TP5BINOS N	TP5SINOS N	TP5AINOS N
13. Apnea (requiring more than mild tactile stimulation)	TP5BAPNE N	TP5SAPNE N	TP5AAPNE N
14. nurse : infant ratio(highest nurse to infant ratio during the transfusion)		TP5SNIR ____ : ____	

Initials of person completing this form:

TP5INIT

NICU Network	Transfusion of Prematurity (TOP) Trial GROWTH AND THERAPY FORM	TOP06 Version 1.1 October 8, 2012, revised February 8, 2013
Center: ____	Site: ____ Study No. TOPSID Network No. _____	Mother's Initials _____ (optional)
	BN	Page 1 of 1

This form should be completed for all randomized infants.

Section A: Growth Data - Complete weekly from birth until 36 weeks PMA, death or discharge (whichever occurs first)

	1. Week of life	2. body weight (g)	3. head circumference (cm)
TP6WOL	1	TP6BDWGT	TP6HCIRC
	2	_____	____.____
	3	_____	____.____
	4	_____	____.____
	5	_____	____.____
	6	_____	____.____
	7	_____	____.____
	8	_____	____.____
	9	_____	____.____
	10	_____	____.____
	11	_____	____.____
	12	_____	____.____
	13	_____	____.____

Section B. Therapy Data

1. Was the infant ever started on caffeine?
 - a. If yes, was the infant still on caffeine at status (36 wks PMA, death or discharge)?
 - i. If no, Date of final caffeine dose _____
2. Did the infant ever have an endotracheal tube?
 - a. If yes, was the infant still intubated at status (36 wks PMA, death or discharge)?
 - i. If no, Date of final tracheal extubation _____

Y	TP6STCAF	N
Y	TP6CAF36	N
	TP6CAFDT	_____
Y	TP6INTUB	N
Y	TP6INT36	N
	TP6TRADT	_____

Initials of person completing this form:

TP6INIT

Center: ____

Site: ____

Study No. T

TOPSID

Network No. ____

BN

Mother's Initials (optional): ____

Page 1 of 1

This form should be completed for all randomized infants.

A. Pre-Randomization HUS Results (Only if available per clinical orders, please record the most recent HUS results before randomization in TOP)

1. Was a pre-randomization head US performed?

TP7PRAND

Y

N

If no, form is complete.

If yes:

a) Date of Study

TP7STYDT

____ / ____ / ____

Y

N

2. Was the HUS normal?

TP7HUSNM

If yes, the form is complete

TP7HUSRS_1

☐ Subependymal hemorrhage

☐ Cystic PVL (periventricular leukomalacia)

TP7HUSRS_5

a. if no, please record all results (check all that apply)

TP7HUSRS_2

☐ IVH with or without ventricular dilatation

☐ Porencephalic cyst

TP7HUSRS_6

☐ Intraparenchymal echodense lesion

☐ Ventriculomegaly

TP7HUSRS_7

☐ Cerebellar hemorrhage

☐ Other, specify

TP7HUSRS_8

TP7HUSRS_3

TP7HUSSP

TP7INIT

Initials of person completing this form:

Transfusion of Prematures (TOP) Trial

Center: _____

Site: **SITE**

Study ID: T **TOPSID**

Network Number: _____

In-Hospital Cost of Care Questionnaire

The following questions will help us to understand the costs to you and your family of caring for your baby while he or she is in the hospital. All of your responses will be kept completely confidential and you will be identified only by a study identification number. If you feel uncomfortable answering a question, please feel free to leave it blank.

Please indicate your relationship with the child in the study:

☐ Mother

☐ Father

TP8RELC

☐ Other spouse or partner of baby's mother

☐ Other, specify:

TP8RELO

What is Today's Date?

TP8TDAT

/ ____ / ____

Please answer the following questions for the period since the birth of your baby.

1. Have you taken time off work because of the baby's birth?

TP8TOWY

☐ No, not taking time off work

☐ No, not employed

☐ Yes

If **Yes**, how many weeks from birth to now:

☐ ☐ weeks

TP8WOWY

Is the time taken off work by you considered:

☐ Sick leave, maternity/paternity leave or personal time paid by your employer

TP8WOCY

☐ Vacation

☐ Time off with no pay

☐ I am self-employed

☐ Don't know

Please tell us your total personal income from all sources:

TP8INCY

(note: all your responses are completely confidential)

☐ Less than \$15,000

☐ \$15,000 to \$24,999

☐ \$25,000 to \$49,999

☐ \$50,000 to \$99,999

☐ \$100,000 to \$149,999

☐ \$150,000 to \$199,999

☐ \$200,000 or more

☐ prefer not to answer

Transfusion of Prematures (TOP) Trial

Center: _____

Site: _____

Study ID: T _____

Network Number: _____

2. Is your partner/spouse taking time off from work because of the baby's birth?

TP8TOWS

- ☐ No, not taking time off work
- ☐ No, not employed
- ☐ Not applicable
- ☐ Yes

If **Yes**, how many weeks from birth to now:

weeks

TP8WOWS

Is the time taken off work by your partner/spouse considered:

TP8WOCS

- ☐ Sick leave, maternity/paternity leave or personal time paid by your employer
- ☐ Time off with no pay
- ☐ Vacation
- ☐ I am self-employed
- ☐ Don't know

Please tell us your partner's total personal income from all sources:

(note: all your responses are completely confidential)

TP8INCS

- ☐ Less than \$15,000
- ☐ \$15,000 to \$24,999
- ☐ \$25,000 to \$49,999
- ☐ \$50,000 to \$99,999
- ☐ \$100,000 to \$149,999
- ☐ \$150,000 to \$199,999
- ☐ \$200,000 or more
- ☐ prefer not to answer

3. Sometimes family members or friends take time off work to help a mother with her new baby.

Did your family members or friends (other than your spouse/partner) take time off work to help you/your family?

☐ No ☐ Yes

TP8TOWF

If **Yes**, how many weeks from birth to now:

weeks

TP8WOWF

Was the time taken off work by your family member or friend considered:

TP8WOCF

- ☐ Sick leave, maternity/paternity leave or personal time paid by your employer
- ☐ Vacation
- ☐ Time off with no pay
- ☐ My family member or friend is self-employed
- ☐ Don't know

Transfusion of Prematures (TOP) Trial

Center: _____

Site: _____

Study ID: T _____

Network Number: _____

4. Have you received household help (housekeeping, cleaning, etc) that you paid for?

☐ No TP8HOH

☐ Yes, starting before pregnancy

☐ Yes, starting during pregnancy

☐ Yes, starting after delivery

If **Yes**, how many hours per week: hours TP8HOHH

how many weeks since birth: weeks TP8HOHW

how much does this cost: cost per hour: TP8HOHCH or

cost per week: TP8HOHCW

5. Do you or your partner travel to the hospital to visit your baby, other than by walking?

☐ No ☐ Yes TP8TRAVH

If **Yes**, by **car**? ☐ No ☐ Yes TP8TRAVC

If by **car**, total number of miles driven by you or your spouse: miles TP8TRMDR

number of round trips by you or your spouse: trips TP8TRCTR

cost of parking (each trip by you or your spouse): TP8TRPRK _____

If **Yes**, by **public transit**? ☐ No ☐ Yes TP8TRPT

If **public transit**, cost per trip (each direction by you or your spouse): TP8TRPTC _____

number of one-way trips by you or your spouse: trips TP8OWT

If **Yes**, by public **taxi**? ☐ No ☐ Yes TP8OWTTX

If by **taxi**, cost per trip (each direction by you or your spouse): TP8TXCPT _____

number of one-way taxi trips by you or your spouse: trips TP8TXTR

Transfusion of Prematures (TOP) Trial

Center: _____

Site: _____

Study ID: T _____

Network Number: _____

6. Have you hired caretakers or babysitters for your other children in order to visit your baby?

☐ No (or not applicable) ☐ Yes **TP8CARET**

If **Yes**, how many hours per week: hours **TP8CAREH**

how many weeks since birth: weeks **TP8CAREW**

how much does this cost: cost per hour: **TP8CARCH** _____ or

cost per week: **TP8CARCW** _____

7. Have you paid for hotel or other accommodations in order to visit your baby?

☐ No ☐ Yes **TP8HOTEL**

If **Yes**, how many nights since birth: nights **TP8HOTNT**

cost per night: **TP8HOTCS** _____

8. Have you paid for meals when you are in the hospital or away from home in order to visit your baby?

☐ No ☐ Yes **TP8MEALS**

If **Yes**, how many meals in the past week: meals **TP8MEALN**

average cost per meal for your family: **TP8MEALC** _____

9. Have you received any bills from your insurance company for services that were not covered by your insurance (co-insurance, copayment or uncovered services)?

☐ No ☐ Yes **TP8INSB**

If **Yes**, what is the total amount of those bills to date?

amount: **TP8INSC** _____

Transfusion of Prematures (TOP) Trial

Center: _____

Site: _____

Study ID: T _____

Network Number: _____

10. Did you have other expenses related to your baby's hospitalization that were not reimbursed? ☐ No ☐ Yes **TP80TEXP**

If **Yes**, describe expense #1: **TP80EXD1**

amount: **TP80EXA1** _____

describe expense #2: **TP80EXD2**

amount: **TP80EXA2** _____

describe expense #3: **TP80EXD3**

amount: **TP80EXA3** _____

Thank you for taking the time to respond.

Center: ____

Site: ____

Study No. T. **TP9SID**

Network No. ____

Mother's Initials (optional): ____

Report #: **TP9RNUM** 1

10/08/12, Revised 05/24/13, 04/09/14

Complete this form for all randomized infants.

A. 1. Are there any adverse events to report for this infant? Please refer to the MOP for specific adverse events.

TP9AE96

Y N

TP9TRAN1 **TP9TRAN2** **TP9TRAN3**

1. Transfusion # 's from TOP05 ____, ____, ____ (if more than one, record all)

(2) ADVERSE * EVENT	(3) ONSET DATE mm/dd/yyyy	(4) DATE RESOLVED mm/dd/yyyy or ongoing	(5) RELATIONSHIP (code both columns)		(6) INTENSITY STATUS	(7) SERIOUS STATUS*	(8) EXPECTATIONS	(9) ACTIONS TAKEN	(10) FINAL OUTCOM E	(11) COMMENTS PI INITIALS
	(3a) ONSET TIME NEC and SIP hh:mm		To Study Therapy	To Study Procedur es						
☐ NEC (Bell's stage II or greater) between birth and 37 weeks PMA ☐ SIP between birth and 37 weeks PMA ☐ Respiratory Deterioration (up to 24 hours post tx) ☐ Nosocomial sepsis(up to 24 hours post tx) ☐ Hyperkalemia - non-hemolyzed specimen (up to 24 hours post tx) ☐ Other, TP9AEOTH	____/____/____ TP9ONDT	____/____/____ TP9RSDT	TP9RELST	TP9RELSP	TP9INTSE	TP9SERS	TP9EXPT	TP9ACT	TP9OUTC	TP9COMM
	TP9ONTM ____ : ____	or ongoing ☐ TP9ONG								

(5) RELATIONSHIP	(6) INTENSITY STATUS	(7) SERIOUS ADVERSE EVENT (SAE) STATUS*	(8) EXPECTATIONS	(9) ACTIONS TAKEN	(10) FINAL OUTCOME
0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	1= Mild 2= Moderate 3= Severe 4= Life Threatening* 5=Death*	1= Results in death 2= Is life-threatening, 3= Requires prolongation hospitalization, 4= Results in persistent or significant disability/incapacity 5 = Other serious important medical events 6= Not classified as serious	1=Expected 2= Unexpected	1 = No change 2 = Supportive Rx 3 = Extensive Rx or Surgery	1= Completely resolved; no residual effects. 2 = Resolved with sequelae 3 = Patient died 4 = Ongoing

** See MOP chapter 13. Event(s) that are life threatening, result in death, or classified as a Serious Adverse Events per ICH E2A (which may include mild, moderate or severe intensity and regardless of expectedness or attribution to study) require notification to NICHD and RTI within one business day of discovery. The Medwatch (FDA Form 3500A) should be completed and faxed or emailed to:

NICHD, Attn: Rosemary Higgins, M.D., (301) 496-3790 (higginsr@mail.nih.gov) and

RTI, Attn: Meg Crawford (919) 485-7762 (NRNProtocolSupport@rti.org)

Initials of person completing this form:

TP9INIT

ADVERSE EVENT FORM

10/08/12, Revised 05/24/13

Center: ____

Site: ____

Study No. T ____

Network No. ____

Mother's Initials (optional): ____

Report #: ____ Page 1 of 1

BN

Complete this form for all randomized infants.

A. 1. Are there any adverse events to report for this infant? Please refer to the MOP for specific adverse events.

Y N

1. Transfusion # 's from TOP05 ____ (if more than one, record all)

(2) ADVERSE * EVENT	(3) ONSET DATE mm/dd/yyyy	(4) DATE RESOLVED mm/dd/yyyy or ongoing	(5) RELATIONSHIP (code both columns)		(6) INTENSITY STATUS	(7) SERIOUS STATUS*	(8) EXPECTATIONS	(9) ACTIONS TAKEN	(10) FINAL OUTCOM E	(11) COMMENTS PI INITIALS	
			To Study Therapy	To Study Procedur es							
☐ NEC (Bell's stage II or greater) up to 96 hours post-tx ☐ Respiratory Deterioration (up to 24 hours post tx) ☐ Nosocomial sepsis(up to 24 hours post tx) ☐ Hyperkalemia - non-hemolyzed specimen (up to 24 hours post tx) ☐ Other, _____	____/____/____	____/____/____ or ongoing ☐	____	____	____	____	____	____	____		
(5) RELATIONSHIP 0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely		(6) INTENSITY STATUS 1= Mild 2= Moderate 3= Severe 4= Life Threatening* 5=Death*		(7) SERIOUS ADVERSE EVENT (SAE) STATUS* 1= Results in death 2= Is life-threatening, 3= Requires prolongation hospitalization, 4= Results in persistent or significant disability/incapacity 5 = Other serious important medical events 6= Not classified as serious		(8) EXPECTATIONS 1=Expected 2= Unexpected		(9) ACTIONS TAKEN 1 = No change 2 = Supportive Rx 3 = Extensive Rx or Surgery		(10) FINAL OUTCOME 1= Completely resolved; no residual effects. 2 = Resolved with sequelae 3 = Patient died 4 = Ongoing	

** See MOP chapter 13. Event(s) that are life threatening, result in death, or classified as a Serious Adverse Events per ICH E2A (which may include mild, moderate or severe intensity and regardless of expectedness or attribution to study) require notification to NICHD and RTI within one business day of discovery. The Medwatch (FDA Form 3500A) should be completed and faxed or emailed to:

NICHD, Attn: Rosemary Higgins, M.D., (301) 496-3790 (higginsr@mail.nih.gov) and

RTI, Attn: Meg Cunningham (919) 485-7762 (mcunningham@rti.org)

Initials of person completing this form: ____

ADVERSE EVENT FORM

October 8, 2012

Center: ____

Site: ____

Study No. T ____

Network No. ____

Mother's Initials (optional): ____

Report #: ____ Page 1 of 1

BN

Complete this form for all randomized infants up to 96 hours after each transfusion.

A. 1. Did this infant experience any adverse events up to 96 hours after transfusion? Please refer to the MOP for specific adverse events.

Y

N

(if yes, record all events below)

1. Transfusion # 's from TOP05 ____, ____, ____ (if more than one, record all)

(2) ADVERSE * EVENT	(3) ONSET DATE mm/dd/yyyy	(4) DATE RESOLVED mm/dd/yyyy or ongoing	(5) RELATIONSHIP (code both columns)		(6) INTENSITY STATUS	(7) SERIOUS STATUS*	(8) EXPECTATIONS	(9) ACTIONS TAKEN	(10) FINAL OUTCOM E	(11) COMMENTS PI INITIALS
			To Study Therapy	To Study Procedur es						
☐ NEC (Bell's stage II or greater) ☐ Respiratory Deterioration ☐ Nosocomial sepsis ☐ Hyperkalemia ☐ Other, _____	____/____/____	____/____/____ or ongoing ☐	____	____	____	____	____	____	____	

(5) RELATIONSHIP	(6) INTENSITY STATUS	(7) SERIOUS ADVERSE EVENT (SAE) STATUS*	(8) EXPECTATIONS	(9) ACTIONS TAKEN	(10) FINAL OUTCOME
0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening* 5 = Death*	1 = Results in death 2 = Is life-threatening, 3 = Requires prolongation hospitalization, 4 = Results in persistent or significant disability/incapacity 5 = Other serious important medical events 6 = Not classified as serious	1 = Expected 2 = Unexpected	1 = No change 2 = Supportive Rx 3 = Extensive Rx or Surgery	1 = Completely resolved; no residual effects. 2 = Resolved with sequelae 3 = Patient died 4 = Ongoing

** See MOP chapter 13. Event(s) that are life threatening, result in death, or classified as a Serious Adverse Events per ICH E2A (which may include mild, moderate or severe intensity and regardless of expectedness or attribution to study) require notification to NICHD and RTI within one business day of discovery. The Medwatch (FDA Form 3500A) should be completed and faxed or emailed to: NICHD, Attn: Rosemary Higgins, M.D., (301) 496-3790 (higginsr@mail.nih.gov) and RTI, Attn: Meg Cunningham (919) 485-7762 (mcunningham@rti.org)

Initials of person completing this form: ____

Center: _____ Site: _____ Study No. T **TOPSID** Network No. _____ Report No. **TP10RNUM** Initials (optional): _____ Page 1 of 1

This form should be completed for all randomized patients whenever a protocol violation/deviation is encountered by the study personnel.

A. Occurrence of Protocol Violation/Deviation Events During Study Intervention (record Section B once per infant case)

1. Did any protocol violations or deviations occur for this infant?

Y N

TP10PVIO

If Yes, specify the event below. Subsequent events should be recorded on a separate form.

B. Protocol Violation/Deviation Event

1. Date of Event:

TP10VDATE

____ / ____ / ____
MM DD YYYY

2. Type of Event:

1 = Protocol Violation: A deviation from the IRB approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy or reliability of the study data.

2 = Minor Protocol Deviation: A deviation from the IRB approved protocol that DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

TP10VTYP

C. Protocol Violation/Deviation Details

1. Ineligible infant randomized?

Y

N

TP10INEL

2. Lack of consent?

Y

N

TP10NOCO

3. Infant randomized to wrong birth weight strata?

Y

N

TP10WBWS

4. Infant not transfused per protocol? (i.e. infant was not seriously ill and not going to the OR)

Y

N

TP10NTTF

If yes, check circumstance **TP10NTR**

☐ Transfused > 12 hours after threshold reached

☐ Transfusion skipped, no IV access

☐ Volume of transfusion incorrect

☐ Threshold met, no transfusion given

☐ Infant transfused, clinician preference

☐ Other, specify

TP10NTRS

5. Other violation? (please describe): **TP100THD**

Y

N

TP100THE

D. Event Circumstances

1. Circumstances of the Protocol Violation/Deviation: **TP10CIRC**

2. Additional Comments: **TP10COMM**

3. Name of person who reported the deviation from protocol: **TP10NAME**

Initials of person completing this form: **TP10INIT**

Center: ____

Site: ____

Study No. T **TPSID**

Network No. _____

BN

Mother's Initials (optional): ____

Page 1 of 1

Complete this form when a randomized infant has been withdrawn from study participation.

ALL ATTEMPTS MUST BE MADE TO AVOID THIS. Please contact PI prior to withdrawal.

A. Withdrawal

TP11WDAT____/____/____
MM DD YYYY

1. Date infant withdrawn

2. Check the withdraw status appropriate for this infant: **TP11WSTA**

☐ Withdrawn from study with permission to continue data collection per protocol (i.e. no additional study-specific assessments will be completed but data collected as part of standard clinical practice may be used for study purposes).

☐ Withdrawn from study with discontinuation of further data collection (i.e. no further data to be reported about this infant for this study)

3. Infant withdrawn by (select one)

TP11WBY☐ Parent(s) or Legal Guardian(s)☐ Physician☐ Other, specify **TP11WBYO**

4. Reason(s) infant was withdrawn (select all that apply)

TP11WRES_1☐ Infant too medically unstable to continue study participation**TP11WRES_2**☐ Reason not requested**TP11WRES_3**☐ Reason not stated**TP11WRES_4**☐ Other, specify **TP11WREO**

B. Additional Comments

1, Comments:

TP11COMM

2. Name of Person Reporting Withdrawal:

TP11NAME

Initials of person completing this form

TP11INIT

Center: ____ Site No: ____ Network No: ____ Birth No: ____ Mother's Initials: ____ Follow-up No.: ____

This form should be completed for all children who are examined at the Follow-up visit.

A. MEDICAL HISTORY

1. Has the child been rehospitalized since discharge to home or chronic care facility? Y N

IF YES, COMPLETE THE NF04A FORM

- a. If Yes, How many times has the child been rehospitalized? _____
2. Has your child taken any of the following medications repeatedly in the last 3 months? Y N

If YES, use following to code answers

1=No	2=Yes, but stopped	3=Yes, still using
------	--------------------	--------------------

- a. Anti-reflux medications? _____
- b. Asthma/BPD medications? _____
- c. Anticonvulsants/Seizure medications? _____
- d. Thyroid medications? _____
- e. Muscle relaxants and/or antispasticity medications? _____
3. Has the child had one or more seizures since discharge? Y N
4. Has the child been diagnosed with (or suspected to have) Autism Spectrum Disorders? Y N
5. Is the child currently using any of the following:
- | | | |
|---|---|---|
| a. Apnea monitor | Y | N |
| b. Oxygen | Y | N |
| c. Ventilator/CPAP | Y | N |
| d. Gastrostomy tube and/or tube feeding | Y | N |
| e. Tracheostomy | Y | N |
| f. Pulse Oximeter | Y | N |

6. Oral Motor Skills (*choose one*) _____
- 1=Independently feeds self most foods/liquids by mouth
- 2=Dependent oral feeding: all p.o., but requires more than occasional assistance
- 3=Limited oral feeding (requires some food via alternate route; *sp c i y o*)
- 4=No oral feeding

If 3 or 4 for Q6 Oral Motor Skills answer Y or N to 6a and 6b:

- | | | |
|--|---|---|
| 6a. Tube (NG/ND, G-tube/button, other enteral) | Y | N |
| 6b. TPN | Y | N |
7. Feeding behaviors/behavioral difficulties (*answer Yes or No to each*)
- | | | |
|--|---|---|
| a. Resists/refuses some/all food by mouth (due to oral aversion) | Y | N |
| b. Difficulty with swallowing food (at mouth or throat level due to dysphagia) | Y | N |
| c. Documented aspiration (food down windpipe) | Y | N |
8. High calorie oral supplements Y N
9. Oral diet texture (*answer a-d below; more than one YES may be applicable*)
- | | | |
|---|---|---|
| a. Thin liquids | Y | N |
| b. Thickened liquids | Y | N |
| c. Soft solids (baby food, pureed food) | Y | N |
| d. Table food (requiring chewing) | Y | N |
10. Does your child use any of the following equipment or has any been ordered? If YES,
- | | | |
|-----------------------------------|---|---|
| a. Adapted stroller/wheelchair? | Y | N |
| b. Braces/orthotics? | Y | N |
| c. Walker? | Y | N |
| d. Stander? | Y | N |
| e. Corner chairs or tumbler form? | Y | N |

Center: ___ Site No: ___ Network No: ___ Birth No: ___ Mother's Initials: ___ Follow-up No.: ___

11. Has the child had any operations since discharge to home or chronic care

facility? Y N

If YES, has the child had:

a. Tympanostomy tubes placed? Y N

b. Tracheostomy? Y N

c. Eye surgery? Y N

c1. If Yes, indicate reason(s): ___

1=strabismus 2=cataract 3=ROP 4=other (specify)___

d. Hernia surgery? Y N

e. Gastrostomy tube placed? Y N

f. Fundoplication? Y N

g. Shunt for hydrocephalus? Y N

h. Reanastomosis of large or small intestine? Y N

i. Stricture repair/lysis of adhesions? Y N

j. Bowel lengthening surgery? Y N

j1.Specify type (i.e., STEP, Bianchi)___

k. Other bowel surgery? (specify)___ Y N

l. Bronchoscopy? Y N

m. Other? (specify)___ Y N

B. FORM COMPLETION

1. Where was interview conducted: ___

1=Clinic	3=Telephone	9=Other_____
2=Home	4=Hospital	

2. Date when Medical History obtained:

Month ___/___/___
Day ___ Year ___

3. Initials of person administering Medical History Form: ___

Center: ___ Site No: ___ Network No: ___ Birth No: ___ Mother's Initials: ___ Follow-up No.: ___

If the child has been rehospitalized (readmissions to any hospital since discharge to home or chronic care that required at least one overnight stay) complete the following:

A. HOSPITALIZATIONS

1. Date of discharge to home or chronic care:

___/___/___
Month Day Year

2. Date of first birthday:

___/___/___
Month Day Year

3. Readmission	4. Time Period: (see codes below)	5. Primary Cause: (see codes below)	6. Length of hospital stay (see codes below)	7. Did child spend any time in the ICU? (Circle Yes, No, or Don't Know)
01	___	___	___	Y N DK
02	___	___	___	Y N DK
03	___	___	___	Y N DK
04	___	___	___	Y N DK
05	___	___	___	Y N DK
06	___	___	___	Y N DK
07	___	___	___	Y N DK
08	___	___	___	Y N DK
09	___	___	___	Y N DK

TIME PERIOD CODES

1 = Prior to or on 1st birthday

2 = After 1st birthday

1 = Respiratory

2 = CNS

3 = Surgery

4 = Infection

PRIMARY CAUSE CODES

5 = Growth and Nutrition

6 = Environmental

7 = Other;
specify: _____

8 = Apnea/Apparent life threatening event

9 = Reflux

11 = Trauma (Accidental)

12 = Trauma (Non accidental)

13 = Vomiting/diarrhea/dehydration

14 = Sleep study

LENGTH OF STAY CODES

1 = 1 week or less

2 = More than 1 week

B. FORM COMPLETION

1. Where was interview conducted: _____

1 = Clinic 3 = Telephone 9 = Other

2 = Home 4 = Hospital

2. Date Readmission information obtained:

___/___/___
Month Day Year

3. Initials of person administering Readmission form: _____

Center No. ____ Site No. ____ Network No. ____ Birth No: ____ Mother's Initials: ____ Follow-up No: ____

This form should be completed for all children examined at the Follow-up visit.

A. PHYSICAL EXAMINATION

1. Weight: ____ . ____ kg
2. Recumbent length: ____ . ____ cm
3. Occipital-frontal circumference: ____ . ____ cm

B. NEUROLOGIC EXAMINATION (performed by certified examiner)

1. Eye Right Left
- a. Strabismus (any kind) ____ ____
- b. Nystagmus ____ ____
- c. Roving Eye Movements ____ ____

1 = Yes 2 = No 3 = Suspect 4 = Unstable

- d. Tracks 180° (Record as 1, 2, or 4) ____ ____

1 = Yes 2 = No 4 = Unstable

- e. Vision: ____ ____

1 = Normal	4 = Blind some functional vision
2 = Wears or was prescribed corrective lenses	5 = Blind no useful vision
3 = Other abnormality	

2. Hearing

- a. Was a Follow-up audiologic assessment completed since initial discharge to home? Y N

- 1) If NO, is consult pending for assessment? Y N

If YES, follow-up audiologic assessment completed, specify type of testing (2-4)

If the type of hearing exam is unknown, **skip to question 2.a.4) Unknown type of hearing test.**

- 2) Visual Reinforcement Audiometry (VRA)? Y N

If Yes,

a. Right ____ b. Left ____ c. Sound field only ____

Results: 1=Pass 2=Fail 3=Equivocal 4=Unknown

- 3) Auditory Brainstem Response (ABR)? Y N

If Yes,

a. Right ____ b. Left ____

1=Pass 2=Fail 3=Equivocal 4=Unknown

- 4) Unknown type of hearing test? Y N

If Yes,

a. Right ____ b. Left ____

1=Pass 2=Fail 3=Equivocal 4=Unknown

- b. Hearing impaired (based on observation +/- history)? ____

1 = No apparent functional impairment +/- amplification
2 = Impairment +/- amplification

- 1) Hearing aid requirement (*use codes below*): ____

- 2) Cochlear implant requirement (*use codes below*): ____

0 = None 1 = Right only 2 = Left only 3 = Both

4. Nature of motor involvement with child in any comfortable position:

- a. Observed abnormal movements? Y N

If Yes, abnormal,

- 1) Short -jerky Y N

- 2) Slow, writhing? Y N

- 3) Tremor Y N

- 4) Ataxia Y N

- b. Passive muscle tone: (*use codes below for questions B.4.b. 2-3*)

1 = Normal	4 = Suspect Decreased
2 = Suspect Increased	5 = Definite Decreased
3 = Definite Increased	6 = Varying tone

- 2) Upper extremity passive muscle tone: Right Left

- 3) Lower extremity passive muscle tone:
- a. Hips and knees ____ ____
- b. Ankles ____ ____

5. Is there scissoring of the legs on vertical suspension? Y N

Center No. _____ Site No. _____ Network No. _____ Birth No: _____ Mother's Initials: _____ Follow-up No: _____

Page 2

Complete Quemi 6 for all children Examined neck muscle level according to the child's age. Key term key corresponding DMS code. n

18 Months - 21 Months 29 Days **22-26 Months**

6. Gross Motor Function Level (18 Months - 21 Months 29 Days)

	DMS m Code m
___ Normal (Walks 10 steps independently and fluently)	=1 m
___ Possible Level I (Walks 10 steps independently but not fluently; child exhibits toe walking or asymmetric walking)	=2 m
___ Level I (Moves in/out of sitting and floor-sit with both hands free to manipulate objects. Infants creep or crawl on hands and knees, pull to stand and take steps holding onto furniture. Infants walk between 18 mo and 2 years without holding on.)	=3 m
___ Level II (Maintains floor sitting but may need to use hands for support to maintain balance. Creeps on stomach or crawls on hands and knees. May pull to stand and take steps holding onto furniture)	=4 m
___ Level III (Maintains floor sitting when the low back is supported. Rolls and creeps forward on stomach)	=5 m
___ Level IV (Has head control but trunk support is required for floor sitting. Can roll to supine and may roll to prone)	=6 m
___ Level V (Unable to maintain anti-gravity head and trunk postures in prone or sitting; little or no voluntary movement)	=7 m

OR n

6. Gross Motor Function Level (22-26 Months)

	DMS m Code m
___ Level "0" (Walks independently, normal and fluent gait)	=1 m
___ Level I (Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk 10 steps independently, with hands free, but with some gait abnormalities – includes toe walking, asymmetric walking, wide based gait with coordination or ataxic gait.)	=3 m
___ Level II (Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees with reciprocal leg movement. Infants may pull to stand and take steps holding on to furniture.)	=4 m
___ Level III (Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs, or may crawl with or without reciprocal leg movements.)	=5 m
___ Level IV (Infants have head control but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.)	=6 m
___ Level V (Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.)	=7 m

↓ If > 24 Mm al m answer 6.a m

6a. Gross Motor Function Level (>24 Months). **For children examined after 24 months, questions 6 and 6a should be completed.**

	DMS m Code m
___ Level "0" (Walks independently, normal and fluent gait)	=1 m
___ Level I (Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.)	=3 m
___ Level II (Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.)	=4 m
___ Level III (Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.)	=5 m
___ Level IV (Children floor sit when placed, but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.	=6 m
___ Level V (Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.)	=7 m

7. Hand preference _____

1 = None	3 = Exaggerated Left
2 = Exaggerated Right	4 = Untestable

C. REFLEXES / MOTOR SKILLS / DIAGNOSES

1. Protective reactions (anterior, lateral and parachute) _____

1 = Symmetric	2 = Asymmetric	3 = Not present
---------------	----------------	-----------------

2. Limb movements _____

1 = Symmetric	2 = More on right	3 = More on left
---------------	-------------------	------------------

a. Upper limbs _____

b. Lower limbs _____

For questions C.3 – 5 use the following codes

1 = Normal (1 to 3+)	2 = Absent (0)	3 = Hyperactive (4+)
----------------------	----------------	----------------------

Right Left

3. Deep tendon reflexes – upper extremities _____

4. Deep tendon reflexes – knees _____

5. Deep tendon reflexes – ankles _____

6. Ankle clonus _____

1 = None (≤ 4 beats)	2 = Present (> 4 beats)	3 = Sustained
----------------------------	----------------------------	---------------

7. Plantar reflexes _____

1 = Flexor plantar response	3 = Spontaneous extension $\pm$ fanning	5 = Absent
2 = Extensor plantar response	4 = Inconsistent results	

8. Functional gross motor skills _____

a. Axis-head and neck: _____

1 = Normal head control
2 = Abnormal, but can hold head up for extended period (≥ 5 min.)
3 = Poor head control but can hold head up for short period
4 = No obvious head control

b. Axis-trunk: _____

1 = No apparent problem
2 = Can sit unsupported but less secure and stable than normal child of same age
3 = Cannot be left in sitting position unless self-supported
4 = Severe impairment: Difficult to place or maintain in sitting position

c. Lower limb function-gait: _____

1 = No significant problem with gait; walks fluently
2 = Gait functional but not fluent, no device required
3 = Gait functional, non-fluent and requires device or hand held
4 = No independent walking even with device or hand held

d. Upper limb function: _____

1 = No apparent problem with bimanual tasks
2 = Some difficulty using both hands together
3 = No functional bimanual task

1) Right 2) Left

e. Hand function: _____

1 = Fine pincer grasp	5 = Does not attempt to grasp
2 = Finger-Thumb grasp	6 = Refusal
3 = More than one finger-thumb (rake) grasp	7 = Cannot assess
4 = Tries but unable to grasp	

9. Diagnoses: Neurologic/Motor disorder

a. Is the neurological exam Normal? Y N

If YES, skip to question C10 (Does the child have CP?) and code NO.

If NO, go to C.9.b.

b. Is the neurologic exam SUSPECT (suspect or definite increased or decreased tone or reflexes with **no functional impairment**)? Y N

If YES, skip to question C10 (Does the child have CP?) and code NO. If NO, go to either C.9.c or C.9d

c. If Neuro ABNORMAL (OTHER THAN CEREBRAL PALSY). **Choose only one** then skip to C10 and code NO. Finding is associated with mild, moderate or severe functional impairment. ____

1 = Hypotonia

3 = Other

If Other, describe:

d. If Neuro ABNORMAL (CEREBRAL PALSY). **Choose only one** and go to question C10 (Does the child have CP?) and code YES: ____

1 = Spastic diplegia

2 = Spastic hemiplegia – right

3 = Spastic hemiplegia – left

4 = Spastic quadriplegia

6 = Athetosis/dystonia with varying tone

7 = Hypotonic with + ataxia

9 = Mixed cerebral palsy

If mixed CP, identify 2 categories from answer codes 1-7 above that reflect findings in order of prominence:

____, ____

10. Does this child have cerebral palsy? Y N

If YES, classification of cerebral palsy: ____

1 = Mild (GMFCS Level 1)

2 = Moderate (GMFCS Level 2-3)

3 = Severe (GMFCS Level 4-5)

11. Congenital and/or acquired abnormalities? Y N

11a. If YES, enter codes from Manual-App D or describe, if no codes apply:

____, _____, _____

1) Describe: _____

11b. If YES, does the abnormality affect neurodevelopmental assessment? Y N

D. FORM COMPLETION

1. Where was exam completed: ____

1 = Clinic

2 = Home

3 = Other Clinic

4 = Hospital

9 = Other (specify): _____

2. Quality of the exam? ____

1 = Good

2 = Fair

3 = Poor

If Fair (2) or Poor (3), factors affecting the exam? ____

Codes for reasons quality of exam is Fair (2) or Poor (3):

1 = Illness

2 = Language other than English and interpreter not available

3 = Behavioral problems

4 = Severely developmentally delayed plus may have sensory impairment (Bayley score of 49)

5 = Sensory impairment - appears mild or moderately delayed for age

6 = Sensory impairment - but appears to be within normal limits for age

9 = Other: (Specify) _____

3. Date exam completed: ____/____/____

Month Day Year

4. Initials of person administering Infant examination: ____

Center: _____ Site No: _____ Network No: _____ Birth No: _____ Mother's Initials: _____ Follow-up No.: _____

This form should be completed for all children who have taken the Bayley III exam at the Follow-up visit. Record the scores for adjusted age.

A. Bayley III Information

1. Was the child successfully tested for the following?

a. Cognitive Subtest:

Y N

1. If NO, reason not successfully tested (see codes below) _____

a. if coded as 9, "Other", specify reason:

b. Language (Receptive Communication) Subtest:

Y N

1. If NO, reason not successfully tested (see codes below) _____

a. if coded as 9, "Other", specify reason:

c. Language (Expressive Communication) Subtest:

Y N

1. If NO, reason not successfully tested (see codes below) _____

a. if coded as 9, "Other", specify reason:

d. Motor (Fine) Subtest

Y N

1. If NO, reason not successfully tested (see codes below) _____

a. if coded as 9, "Other", specify reason:

e. Motor (Gross) Subtest

Y N

1. If NO, reason not successfully tested (see codes below) _____

a. if coded as 9, "Other", specify reason:

Codes for reasons not successfully tested

1 = Illness

2 = Language other than English and interpreter not available

3 = Behavioral problems

4 = Severely developmentally delayed, and/or legally blind and/or profound hearing loss
 - assigned a composite score of 54 for Cognitive, 46 for Language, 46 for Motor

5 = Severe cerebral palsy

6 = anatomic abnormalities of hands/feet i.e. club feet, dislocated hips, arthrogryposis

9 = Other (i.e. children in body cast, children who are absent extremities)

Complete items f - i if successfully tested or severely developmentally delayed (Code 4)

f. Adjusted age

1. Adjusted age for Cognitive subtest

 Months

2. Adjusted age for Receptive Communication

 Months

3. Adjusted age for Expressive Communication

 Months

4. Adjusted age for Motor (Fine) subtest

 Months

5. Adjusted age for Motor (Gross) subtest

 Months

g. Bayley Scales of Infant Development

Raw Scaled Score

1. Cognitive

2. Cognitive Composite
 Score

3. Receptive

4. Expressive

5. Summed Language Score
 (Scaled Receptive + Scaled Expressive)

6. Language Composite

Raw

Scaled Score

7. Fine Motor

8. Gross Motor

9. Summed Motor Score
 (Scaled Fine & Gross)

10. Motor composite

h. Was the Bayley Exam conducted in English?

Y N

1. If NO, was an interpreter required?

Y N

i. Was the Bayley administrator masked to the
 child's medical history?

Y N

B. Form Completion

1. Where was the Bayley III exam completed?

1 = Clinic 3 = Other Clinic 9 = Other
 2 = Home 4 = Hospital

2. Date the Bayley III exam was completed?

____/____/____
 Month Day Year

3. Initials of person administering Bayley III exam

Center: ___ Site No: ___ Network No: _____ Birth No: ___ Mother's Initials: _____ Follow-up No.: _____

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This form should be completed for all children at the Follow-up visit.

A. STATUS INFORMATION1. Date of birth: _____
Month Day Year

2. Final Status of Child: _____

1=Child seen, Follow-up visit completed
3=Died after GDB status
4=Lost to follow-up
5=Follow-up visit completed at another NICU Network center
6=Child seen, but incomplete visit

B. FORM COMPLETION1. Date form completed: _____
Month Day Year

2. Center number where child was seen: _____

3. Initials of person completing this form: _____

IF FOLLOW-UP VISIT IS COMPLETED AS MUCH AS POSSIBLE, FILL OUT FORM NF11.

a. If final status is, died after GDB status (3):

1. Date of death _____
Month Day Year

b. If final status is lost to follow-up (4):

1. Give reason lost to follow-up: _____

1=Adopted	4-Refused informed consent for FU
2=Out of area	5=Non compliant
3=Lost	6=Foster care