6.1.2. **Maternal Data**

A1. Mother’s date of birth __/__/____ M M / D D / Y Y Y Y

6.1.3 **Pregnancy History (including current pregnancy):**

A2. Gravida: __ __

*Gravida refers to the number of confirmed pregnancies, including the current one.*

A3. Parity: __ __

*Parity refers to the number of products of conception delivered after 20 weeks gestation, resulting in the birth of a child, including this delivery. This includes live births only. Each infant of a multiple birth has the same parity. For example, if twins were born and it was the first delivery, the parity for each twin would be 2. The parity for a subsequent singleton would be 3.*

A4. Previous preterm birth (≤ 36 weeks) Y N

A4a. If YES, number previous preterm births __ __

A5. History of any miscarriages Y N

*Code “Y” if the infant’s mother has a history of spontaneous loss of pregnancy prior to 20 week’ gestation.*

A5a. If YES, number previous miscarriages __ __

A6. Previous induced abortions Y N

A6a. If YES, number previous induced abortions __ __
A7. Highest level of education achieved:  

1 = < HS  
2 = HS grad or GED  
3 = some college, associates degree, or post-high school technical certification  
4 = ≥ college degree  

A8. Mother's primary medical insurance:  

1 = Medicaid  
2 = Private  
3 = Self-pay  
4 = Uninsured  
5 = Unknown  
6 = Other  

6.1.4 Pregnancy Complications  

B1. Multiple gestation  

Y N  

B1a. If YES, number of fetuses:  

B2. History of death of co-twin/triplet/etc during this pregnancy  

Y N UNK  

B3. Reduction of a multi-fetal pregnancy  

Y N UNK  

B4. Mother has evidence of at least one prenatal visit in this pregnancy  

Y N UNK  

Code YES only if there is specific documentation of at least one prenatal care visit prior to delivery even if the only documented visit resulted in hospitalization and delivery.  

B5. 17-hydroxy-progesterone-caproate administered during this pregnancy  

Y N UNK  

B6. Diabetes  

Y N UNK  

B6a. If YES, gestational insulin-dependent  

Y N UNK  

B6b. If YES, non-gestational insulin dependent  

Y N UNK  

40
Code “Y” for B6 if the mother had a history of diabetes at any time, including non-insulin dependent gestational diabetes. However, if the mother’s diabetes is diet-controlled, code “N” for B6a and B6b.

B7. Hypertension

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

**B7a. If YES, hypertension existed prior to pregnancy**

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

Code “Y” if hypertension prior to pregnancy was recorded in the mother’s chart, regardless of whether the patient was treated for the condition.

**B7b. If YES, pregnancy-induced hypertension**

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

Pregnancy-induced hypertension is defined as sustained elevation in BP of >140 systolic and/or >90 diastolic, in the absence of proteinuria, in a previously normotensive woman. Code “Y” if pregnancy-induced hypertension is recorded in the mother’s hospital chart during the present pregnancy on at least 2 occasions.

B8. HELLP Syndrome diagnosed

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

Code “Y” for HELLP Syndrome if this diagnosis is written in the mother’s hospital chart.

B9. Pre-eclampsia diagnosed

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

Code “Y” for pre-eclampsia if there is documentation in the mother’s hospital chart of sustained elevation in BP of >140 systolic and/or >90 diastolic, accompanied by proteinuria (≥ 1+ on dipstix or >300 mg/24 hours), after 20 weeks gestation in a previously normotensive woman.

B10. Eclampsia diagnosed

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

Code “Y” when the mother’s hospital chart documents seizures and/or coma occur in the setting of diagnosed pre-eclampsia, and the absence of any other neurological explanation.
B11. Antepartum hemorrhage

Code ‘Y’ for antepartum hemorrhage when external, vaginal bleeding at > 20 weeks pregnancy and/or for placental abruption on ultrasound without vaginal bleeding is documented in the mother’s hospital chart. Code “N” when bloody show is the only form of external bleeding.

B12. Thrombocytopenia diagnosed during this pregnancy

Thrombocytopenia is defined as a circulating maternal platelet count < 100,000/mm³ at any time during the pregnancy that is documented in the mother’s hospital chart.

B13. Alloimmune thrombocytopenia diagnosed

Code “Y” for Alloimmune thrombocytopenia when maternal antibodies, accompanied by low infant platelet count and normal maternal platelet count are documented in the mother’s and infant’s hospital charts.

6.1.5 Labor and Delivery

C1. Rupture of membranes (ROM) prior to delivery

IF YES,

C1a1. Date ___/____/______ M M/ D D/ Y Y Y Y

C1a2. Time: ____ : ____

Hour : Min

For hours, use a 24-hour clock with midnight coded as 00:00

C1b. If date and time unknown, ROM estimated at > 18 hours
C2. Labor

Y N UNK

Code "Y" if patient experienced labor regardless of whether it was spontaneous or induced.

C3. Steroids given prior to delivery for lung maturation

Y N UNK

Code "Y" for question C3 even if the mother received only one dose of steroids immediately before delivery.

C3a. If YES, type of antenatal steroid given: ____

1 = Betamethasone
2 = Dexamethasone
3 = Both
4 = Unknown

C3b. If YES, steroids given within 7 days prior to delivery

Y N UNK

C3c. If YES, number of complete courses of steroids ____

A complete course of antenatal steroids is defined as follows:

• 2 doses of betamethasone were given 12 or 24 hours apart specifically to promote lung maturity.
• 4 doses of dexamethasone were given 6 hours apart specifically to promote lung maturity and at least 12 hours from the second dose or 24 hours from the first dose, or if 24 hours from the first dose elapsed before delivery. If the time elapsed was less, this indicates that there was insufficient time for the drug to have an effect and would be considered incomplete.

Information regarding steroid exposure may be obtained from the maternal and/or infant chart.

When responding to Question C3c, count only doses that occurred during the time period between one week prior to delivery and delivery.

If some steroids were administered, but not a sufficient amount to qualify as a complete dose, answer “0” to Question C3c.
C4. Maternal antibiotics used during the admission resulting in this delivery

Y N UNK

C4a. If YES, antibiotics were given within 72 hours prior to delivery

Y N UNK

C5. Medications administered within 72 hours prior to delivery

Y N

If YES,

C5a. Magnesium sulfate

Y N

C5b. Nonsteroidal anti-inflammatories (i.e. Indocin)

Y N

C5c. Other tocolytics

Y N

C5c1. If YES, nifedipine (procardia)

Y N

C5c2. If YES, terbutaline

Y N

C5d. Narcotics

Y N

If the only medications administered within 72 hours prior to delivery were antibiotics, code ‘N’ to Question C5 as antibiotics are addressed in Question C4. If any other medications were administered during this time frame, C5 should be coded as “Y.”

C6. Mode of delivery: ___

1 = Vaginal vertex
2 = Vaginal breech
3 = Cesarean section

C6a. Assisted delivery

Y N UNK

C6a1. If YES, vacuum assisted

Y N UNK

C6a2. If YES, forceps assisted

Y N UNK
C7. Hemorrhage during hospitalization for delivery  Y  N

Hemorrhage is defined as excessive intrapartum or postpartum blood loss. Code “Y” if any of the following criteria are present:

1. >500ml during or following vaginal delivery
2. >1000 ml during or following cesarean delivery
3. >10% drop in maternal Hct after delivery
4. Maternal blood transfusion

In the event that there is no estimate for the amount of blood lost, code “Y” if either criteria number 3 or 4 are met. In the event that none of the above criteria are met, code “N.”

Would vomiting blood after delivery be coded as “Y” for question C7?

Hemorrhages directly related to delivery and meeting the criteria listed above should be coded as “Y.” Hemorrhages that occur during hospitalization for delivery but are unrelated to delivery should be coded as “N.”

C8. Chorioamnionitis documented or noted in the mother’s medical record  Y  N

Code “Y” for Chorioamnionitis if two of the following criteria are met and documented in the medical record in the absence of other diseases: Fetal tachycardia, maternal tachycardia, uterine tenderness, maternal fever of > 100.4°F.

6.1.6 Neonatal Information

D1a. Date of birth: ___/___/___
M M/D D/Y Y Y Y

D1b. Time of birth: ___:___ (24 hr )
Hours:Minutes

45
D2. Sex: ____

1 = Male
2 = Female
3 = Ambiguous

D3. If multiple gestation, indicate which baby at delivery ____

1 = A
2 = B
3 = C
4 = D
5 = E

D4. Gestational Age:

Record the best estimate of gestational age using the following hierarchy:
1. Gestational age assessed by IVF when available
2. Gestational age by first trimester (up to 14-0 weeks) assessment
3. Gestational age by second trimester (up to 28-0 weeks) assessment
4. Gestational age by third trimester assessment (after 28-1 weeks)
5. Last Menstrual Period (LMP)
6. Newborn maturational assessment

In instances when the gestational age in days is not recorded, enter 0 in the “days” field.

D4a. # Weeks ____ ____
D4b. # Days ____

D4c. Assessed by: ____

1 = 1st Trimester US (ending at 14-0 weeks)
2 = 2nd Trimester US (14-1 weeks to 28-0 weeks)
3 = 3rd Trimester US (from 28-1 weeks)
4 = by IVF
5 = LMP
6 = Newborn maturational assessment

D5. Birth Weight (grams): ____ ____ ____

D6. Length (cm): ____ ____

D7. Head Circumference (cm): ____ ____

D8. Infant died in ≤ 12 hours  Y  N
D9. Ethnicity: 
   1 = Hispanic or Latino
   2 = Not Hispanic or Latino

D10. Race: 
   1 = American Indian or Alaskan Native
   2 = Asian
   3 = Native Hawaiian or Other Pacific Islander
   4 = Black
   5 = White
   6 = More Than one race
   7 = Unknown

D11. Apgar Score - 1 minute: 

D12. Apgar Score - 5 minutes: 

D13. Apgar Score - 10 minutes: 

What should you do if you do not have a 10 minute Apgar Score?

If there is no 10 minute Apgar Score, Question D13 may be left blank and still submitted.

D14. Birth resuscitation/stabilization: CHECK LIST (Please check all that apply.)

D14a. Oxygen Y N
D14b. Bag and mask Y N
D14c. CPAP Y N
D14d. Intubation Y N
D14e. Chest compression Y N
D14f. Epinephrine Y N
D14g. Volume Y N
If more than one form of birth resuscitation/stabilization is used, please check all that apply.

If a NeoPuff is used for resuscitation should that be coded as CPAP?
The NeoPuff can be used for face mask CPAP, bag and mask ventilation, as well as be attached to an endotracheal tube if the infant is intubated. Therefore the response depends on how the device is used. If it is used for CPAP ventilation, 14c should be coded as “Y;” if it is used for bag and mask, D14b should be coded as “Y,” and if it is attached to an endotracheal tube with intubation, D14d should be coded as “Y.”

D15. Cord blood obtained for blood gas analysis

Y N

Record “Y” if a cord gas was obtained at the time of delivery. Do not report cord gas that was obtained following admission to the NICU. Record pH and base deficit values as documented on the delivery room record in the maternal and/or infant chart. If more than one vessel was sampled, record results from umbilical artery sample.

D15a. If YES, vessel type ____

1 = Arterial
2 = Venous
3 = UNK

D15b. If YES, Cord pH: ____ . ____

D15c. If YES, Base deficit: ____ . ____

6.1.7 Verification of Form Completion

E1. Person completing this form STAFF ID: ____ ____ ____

E2. Date completed ____ / ____ / ____ ____ (mm/dd/yyyy)

Entry of the individual’s Staff ID number at the end of each form will serve as certification to the CORE that every variable has been checked for accuracy.
6.2 Neonatal Data Form

The Neonatal Data Form is a multiple page form used to collect information about the newborn’s pulmonary, cardiac and gastrointestinal status **DURING THE FIRST 28 DAYS OF LIFE, and neurological status during the first 35 days of life.** Information regarding infections the infant has contracted, surgeries, SNAP Scores, and family history is also collected. While we recognize that important information that takes place after this time period will not be captured in this form, we ask that sites only include events that occur during the stipulated time frames. In situations where conditions were diagnosed in the first 28 or 35 days, but interventions were not implemented until after day 28 or 35, code only the diagnosis and code “N” for questions relating to interventions. There is a comment box available in the on-line data forms that may be used for documenting events that are not directly queried in this form.

6.2.1 Heading

Subject ID: ___ ___ ___ ___ ___

**Subject ID:** The subject ID number is made up of a two letter code identifying the site and a 3 digit sequential pre-assigned number. Therefore the Subject ID will be 5 characters.

<table>
<thead>
<tr>
<th>Site</th>
<th>Site Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baylor College of Medicine</td>
<td>BA</td>
</tr>
<tr>
<td>Brown University</td>
<td>BR</td>
</tr>
<tr>
<td>Karolinska University School of Medicine</td>
<td>KA</td>
</tr>
<tr>
<td>East Carolina University</td>
<td>EC</td>
</tr>
<tr>
<td>Indiana University</td>
<td>IU</td>
</tr>
<tr>
<td>Loma Linda University School of Medicine</td>
<td>LL</td>
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<tr>
<td>Queen Silvia Children’s Hospital</td>
<td>QS</td>
</tr>
<tr>
<td>University of Alabama School of Medicine</td>
<td>AL</td>
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<tr>
<td>University of Arkansas for Medical Sciences</td>
<td>AR</td>
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<td>University of Kentucky School of Medicine</td>
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<td>Washington University in Saint Louis School of Medicine</td>
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<td>WS</td>
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<tr>
<td>Yale University School of Medicine</td>
<td>YA</td>
</tr>
</tbody>
</table>
Mother's D.O.B.: ___/___/_____  
M M D D Y Y Y Y

Mother's D.O.B.: The mother's date of birth is used for verification of subject.

Status: 
1 = IVH Gr 2 - 4  
2 = IVH NEG Control

If control, this infant matched to Subject ID: ___ ___ ___ ___

For controls – Code the study number of the infant with Gr. 2 – 4 IVH to whom they are matched. Controls must be enrolled following the enrollment of a case and must be matched for gender and birth weight group. However, they may be born prior to the case.

Infant expired ≤ 12 hours  
Y N

In situations where the infant died less than 12 hours after birth, leave all of the following fields with missing information blank, instead of coding “N.”

6.2.2 Neurologic

A1. Indomethacin was given within the first 6 – 12 hours following birth  
Y N

If YES,

A1a. Date of first dose ___/___/____  
M M / D D / Y Y Y Y

A1b. Total number of doses given in first three days ___ ___

A2. Head ultrasound (HUS) – Local Reading

A2a1. HUS # 1: Date ___/___/____  
M M / D D / Y Y Y Y
For purposes of this study the ultrasound done closest to DOL 7 should be considered as HUS # 1.

A2a2. Blood/echo-density in germinal matrix/sub-ependymal area  

Y  N

A2a3. Highest Grade IVH on LEFT (0 - 1 - 2 - 3 - 4)  

A2a4. Highest Grade IVH on RIGHT (0 - 1 - 2 - 3 - 4)  

A2b. Baby died before second HUS  

Y  N

**IF NO,**

A2b1. HUS # 2: Date ____/____/____ (only required if control)  

M M / D D / Y Y Y Y

A2b2. Blood/echo-density in germinal matrix/sub-ependymal area  

Y  N

A2b3. Highest Grade IVH on LEFT (0 - 1 - 2 - 3 - 4)  

A2b4. Highest Grade IVH on RIGHT (0 - 1 - 2 - 3 - 4)  

Please note that a second ultrasound is only required for controls. In situations where multiple ultrasound have been completed prior to day 35 of life, the HUS completed closest to DOL 28 should be considered as “HUS #2.”

A2c1. If available, HUS # 3: Date ____/____/____  

M M / D D / Y Y Y Y

If more than two HUS are available from the first 35 days of life, please choose the HUS with the most significant findings for HUS #3.

A2c2. Blood/echo-density in germinal matrix/sub-ependymal area  

Y  N

A2c3. Highest Grade IVH on LEFT (0 - 1 - 2 - 3 - 4)  

51
A2c4. Highest Grade IVH on RIGHT (0 - 1 - 2 - 3 - 4) ____

A3. Cystic periventricular leukomalacia within 35 days  Y  N

*IF YES,*

A3a. Left  Y  N

A3b. Right  Y  N

A4. Porencephalic cyst within 35 days  Y  N

*IF YES,*

A4a. Left  Y  N

A4b. Right  Y  N

A5. Ventriculomegaly within 35 days of birth  Y  N  UNK

**Ventricular size is made at the mid-body of the lateral ventricle on the sagittal scan. Make the measurement as shown by the large arrows using the centimeter marks along the side of the scan.**

**Ventriculomegaly will be graded as follows:**

VM = 0: < 0.5 cm at midbody on sagittal scan
VM = 1: 0.5-1.0 cm at midbody on sagittal scan
VM = 2: 1.1-1.5 cm at midbody on sagittal scan
VM = 3: > 1.5 cm at midbody on sagittal scan

*For the data forms, if VM stage 1 or greater is reported, please indicate Y.*
A6. Seizures in first 28 days?

Y  N

"A seizure is defined clinically as a paroxysmal alteration in neurologic function (i.e., behavioral, motor and/or autonomic function)." Clinical seizure types in infants include the following: subtle, clonic (focal, multifocal), tonic (focal, generalized), and myoclonic (focal, multifocal or generalized). Subtle seizures require EEG confirmation, but infants with the other types of seizures need not have EEG confirmation to receive a "Y" code.


If YES,

A6a. Seizures were treated for >72 hours with an anticonvulsant in the first 28 days

Y  N

If YES,

A6a1. Date medication begun

M M D D Y Y Y

6.2.3 Pulmonary

B1. Respiratory Distress Syndrome:

B1a. Clinical features of respiratory distress demonstrated within the first 24 hrs

Y  N

Record "Y" if the infant showed signs of grunting, flaring, retracting, paradoxical breathing, cyanosis and/or supplemental oxygen was required within the first hours

B1b. Required oxygen or positive pressure support for more than 6 of the first 24 hours

Y  N

Record "Y" if infant required supplemental oxygen (FiO₂ > .21) and/or positive pressure support continuously for more than 6 hours within the first 24 hours.
B2. Baby received surfactant

If YES,

B2a. Type of surfactant
1 = Curasurf
2 = Survanta
3 = Infrasurf
4 = Surfaxin
5 = Other
6 = More than one type of surfactant

B2b. Total number of doses ___

B3. Baby received endotracheal PPV in the first 7 days Y N

B4. Baby received nasal ventilation in the first 7 days Y N

**Does nasal ventilation refer to NCPAP with IMV or nasal cannula or something entirely different?**

Nasal ventilation refers to ventilation through NCPAP prongs. The ventilator is providing mechanical breaths with nasal ventilation, as opposed to NCPAP (question B6 below), where the infant breathes entirely on his or her own.

B5. Baby receive HFOV during the first 7 days Y N

B6. Baby received NCPAP in the first 7 days Y N

**Code “Y” for NCPAP is ventilator-generated or bubble CPAP.**

B7. Pneumothorax in the first 28 days Y N

Record “Y” if pneumothorax is documented in the infant’s chart. Pneumothorax is a collection of air in the pleural space where a lucency is identified with displacement of the lung away from the chest wall on CXR. Do not include pneumothorax resulting from a thoracotomy during surgery (e.g. PDA ligation) or pneumomediastinum.
If YES:

B7a. Episode 1

M M / D D / Y Y Y Y Y

B7b. Episode 2

M M / D D / Y Y Y Y Y

B7c. Episode 3

M M / D D / Y Y Y Y Y

B8. Pulmonary hemorrhage in the first 28 days

Y N

Record ‘Y’ if there was bright red blood per the ET tube associated with clinical deterioration.

B8a. If YES, date

M M / D D / Y Y Y Y Y

B9. Infant received inhaled nitric oxide within the first 28 days

Y N

B9a. If YES, date of first exposure:

M M / D D / Y Y Y Y Y

B10. Infant received methylxanthines within the first 28 days

Y N

If you have answered “N” to Question B10, please leave Questions B10a – B10c blank and skip to Question B11. Do not code other types of medication in this section.

B10a. If YES, start date

M M / D D / Y Y Y Y Y

Type of Methylxanthine(s):

B10b. ___ B10c. ___ (Please refer to Appendix – F, on page 94)
B11. pCO₂ checked in the first 24 hours

When there is more than one source of pCO₂ the following guidelines should be followed: If levels for arterial and capillary pCO₂ are available, report the highest and lowest values, regardless of their source. Venous values should only be reported when these are the only samples available on a given day. In all other cases, disregard venous results.

In the event that only one pCO₂ reading is obtained each day, please record this reading as both the highest and lowest pCO₂ for each 24 hour period (Questions B11–B14).

If YES,

B11a. Highest pCO₂ in first 24 hrs

B11b. Source of pCO₂
   1 = arterial
   2 = capillary
   3 = venous

B11c. Lowest pCO₂ in first 24 hours

B11d. Source of pCO₂
   1 = arterial
   2 = capillary
   3 = venous

B12. pCO₂ checked in the second 24 hours

B12a. Highest pCO₂ in second 24 hrs

B12b. Source of pCO₂
   1 = arterial
   2 = capillary
   3 = venous

B12c. Lowest pCO₂ in second 24 hours
B12d. Source of pCO₂
  1 = arterial
  2 = capillary
  3 = venous

B13. pCO₂ checked in the third 24 hours
     Y     N

B13a. Highest pCO₂ in third 24 hrs

B13b. Source of pCO₂
  1 = arterial
  2 = capillary
  3 = venous

B13c. Lowest pCO₂ in third 24 hours

B13d. Source of pCO₂
  1 = arterial
  2 = capillary
  3 = venous

B14. pCO₂ checked in the fourth 24 hours
     Y     N

B14a. Highest pCO₂ in fourth 24 hrs

B14b. Source of pCO₂
  1 = arterial
  2 = capillary
  3 = venous

B14c. Lowest pCO₂ in fourth 24 hours

B14d. Source of pCO₂
  1 = arterial
  2 = capillary
  3 = venous
6.2.4 Cardiac – Within the first 28 days following birth

C1. Patent ductus arteriosus (PDA)  

Y  N

Record "Y" for Question C1 if clinical evidence of left to right PDA shunt is documented by any of the following: continuous murmur, hyperdynamic precordium, bounding pulses, wide pulse pressure, congestive heart failure, increased pulmonary vasculature or cardiomegaly by CXR, and/or increased oxygen requirement or ECHO evidence of PDA with documentation of left to right ductal shunting.

C1a. If YES, PDA was pharmacologically treated  

Y  N

Code "Y" for C1a only if pharmacological treatment was initiated by Day 28. In situations where PDA was diagnosed by day 28 but pharmacologic treatment was not initiated until day 29 or later, code "N" for Question C1a and proceed to C1b.

C1a1. Drug the infant received ____

1 = Indomethacin
2 = Ibuprofen
3 = Both Ibuprofen and Indomethacin

C1a2. Date of first dose of first drug: ___/___/___  

M  M  D  Y  Y  Y  Y

C1a3. First course completed  

Y  N

A complete course of indomethacin or ibuprofen is 3 doses. If an infant received a partial course and then a second partial course or complete course, this should be counted as 2 courses in question C1a4.

C1a4. Total number of courses ____
C1b. If YES, surgery for PDA

C1b1. If YES, date of Surgery

Y N

MM/DD/YY

Code “Y” for C1b only if surgery for PDA was performed by Day 28. In situations where PDA was diagnosed by day 28 but surgery did not occur until day 29 or later, code “N” for Question C1b and proceed to C2.

C2. Lowest Mean Arterial Blood Pressure prior to US #1

C2a. Date

MM/DD/YY

The subject never had an umbilical arterial catheter, but I can provide a mean non-invasive blood pressure (NIBP). How should I code this?

If there is no information regarding arterial blood pressure, please leave questions C2 and C3 blank. If you wish to add information regarding the NIBP, you may do so in the comment section provided in the on-line data entry forms.

C3. Lowest Mean Arterial Blood Pressure in interval between

US #1 and US #2

C3a. Date

MM/DD/YY

C4. Highest systolic BP prior to US #1

C4a. Date

MM/DD/YY

C5. Highest systolic BP between and US#1 and US#2

Record Highest BP inclusive of the days on which US #1 and US #2 were obtained.

C5a. Date

MM/DD/YY

59
6.2.5 Infection - Within the first 28 days following birth

D1. Early onset septicemia/bacteremia (< 72 hrs) Y N

Record "Y" if there was a positive blood culture drawn within the first 72 hours.

If YES, organism codes of first episode:
D1a. ___ ___ ___ D1b. ___ ___ ___

(Please Refer to Appendix – G, on page 97, for Organism Codes)

Record the organism codes from positive blood culture for which the infant was treated, or where there was intent to treat, for > 5 days. If more than 2 organisms are identified, code for the 2 organisms felt to be the most important.

D2. Infant receive antibiotics for ≥ 5 days, starting within the first 72 hrs of life? Y N

D3. Number of episodes of late onset culture negative clinical infection (>72 hours of age) treated with antibiotics for 5 days: ___ ___

An episode is defined as a blood culture obtained and antibiotics started. Record the number of culture negative episodes, occurring after 72 hours, treated with antibiotics for five or more days. Include cases where the infant died before an intended therapy of five or more days was completed.

D4. Late onset culture positive septicemia/bacteremia (>72 hours of age) Y N

Code "Y" if there was a positive culture of blood, obtained in the presence of compatible clinical signs of septicemia, occurring after 72 hours.

If YES, organism codes of first episode:
D4a. ___ ___ ___ D4b. ___ ___ ___

(Please Refer to Appendix – G on page 97 for Organism Codes)
D5. Infection of meninges/brain

Y N

Code “Y” if the infant was diagnosed with meningitis, brain abscess(es), and/or encephalitis.

If YES, organism codes of first episode:

D5a. _____ D5b. _____

(Please Refer to Appendix – G on page 97 for Organism Codes)

6.2.6 Gastrointestinal/Metabolic – Within first 28 days following birth

E1. Baby had Na value > 150 during the first 7 days

Y N UNK

E2. Proven NEC

Y N

Code “Y” for “Proven NEC” if the criteria for Bell’s Stage IIA or greater are met.
Please refer to Appendix – K, on page 108 of this manual for further information about Bell’s Staging Criteria.

E2a. If YES,:

1 = No surgery

2 = Surgery

Drain insertion is considered to be surgery and should be coded as “2”

E2b. Date of first episode

/ / Y Y Y

M M/ D/ Y

E3. Spontaneous gastrointestinal perforation without NEC

Y N

Record “Y” if the infant has a spontaneous gastrointestinal perforation separate from necrotizing enterocolitis.
E3 a. **If YES**, date of the first spontaneous gastrointestinal perforation

\[
\text{M} \quad \text{M/ D/ Y Y Y Y}
\]

E4. Highest blood glucose in first 72 hours: ___  ___  ___

E5. Lowest blood glucose in first 72 hours: ___  ___  ___

6.2.7. **Hematologic**

F1. Thrombocytopenia in first 7 days

**Thrombocytopenia is defined as a platelet count < 100,000/mm³.**

F2. Coagulopathy in first 7 days

**Coagulopathy is defined as an abnormal coagulation screening test in the presence of clinical bleeding. Gestational age-specific values for the lower and upper boundaries of coagulation screening tests found for 95% of the population are found in the table below. If test results fall within the boundaries given, code “N.” Code “Y”, if coagulation screening test results fall below or above the values provided in the following table.**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>19 – 23 weeks</th>
<th>24 – 29 weeks</th>
<th>30 – 38 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prottime (PT, seconds)</td>
<td>19 - 23</td>
<td>19 – 44</td>
<td>16 – 30</td>
</tr>
<tr>
<td>Prottime (INR)</td>
<td>1.7 - 11.1</td>
<td>2.1 - 10.6</td>
<td>1.5 – 5.0</td>
</tr>
<tr>
<td>Activated Prothrombin Time (APTT, seconds)</td>
<td>83 – 250</td>
<td>87 – 210</td>
<td>76 – 128</td>
</tr>
<tr>
<td>Total Clotting Time (seconds)</td>
<td>24 – 44</td>
<td>24 – 28</td>
<td>17.0 – 23.3</td>
</tr>
<tr>
<td>Fibrinogen (g/L, Von Clauss Method)</td>
<td>0.57 – 1.50</td>
<td>0.65 – 1.65</td>
<td>1.25 -1.65</td>
</tr>
</tbody>
</table>


**If YES**, the following treatments were used
6.2.8 **SNAP Score** – Data collected within the first 12 hours following birth

*The SNAP Score is an index of mortality risk and illness severity used by many hospitals for neonates receiving NICU care. It is based on data collected during the first 12 hours of postnatal life.*


G1. Child is eligible for SNAP Score _____

1 = Yes  
2 = No, moribund  
3 = No, missing/lost data

**Infants are not eligible for SNAP Scoring under the following circumstances:**

- Infant dies before admission to the NICU (In this situation, the infant would not be enrolled in the study.)
- Moribund infants who are admitted to the NICU for pre-terminal comfort care only, and who do not receive intubation, mechanical ventilation, vasopressors or chest compressions (Code 2 for Question G1)
- Infants whose medical records are lost (including the relevant flow sheets or specific laboratory results) (Code 3 for Question G1)

*If the infant does not fall into one of the three criteria listed above, please code as “1” (Yes) and consider this infant eligible for SNAP Scoring even if some of the following data is not available.*

*If the infant is not eligible for SNAP Scoring, Questions G2 through G10 may be left blank. However, Question G11 should be answered regardless of whether the infant is eligible for SNAP Scoring.*
G2a. Date when admission vital signs taken
   __ / ___ / ___
   M M / D D / Y Y Y Y

G2b. Time when admission vital signs taken
   ___ : ___
   (24 hr clock)

G3a. Date of death if < 12 hours after admission
   __ / ___ / ___
   M M / D D / Y Y Y Y

G3b. Time of death/discharge if < 12 hours after admission
   ___ : ___
   (24 hr clock)

G4. Lowest mean blood pressure (mm Hg)
   ___ ___

G5. Lowest temperature:
   G5a. (F) ___ ___ ___ OR
   G5b. (C) ___ ___ ___

How should lowest temperature be coded if the infant’s body temperature is lower than the lowest measurement available on the NICU’s thermometers?

If the infant’s body temperature is too low to measure, code one degree lower than the lowest temperature available. For example, if the lowest temperature on the electronic thermometer is 28 degrees Celsius, code 27 degrees C.

G6. Temperature measured
   1 = axillary
   2 = rectal

G7. Lowest serum pH:
   G7a. arterial ___ . ___ ___ OR
   G7b. capillary ___ . ___ ___ OR
   G7c. venous ___ ___ ___

G8. Multiple seizures
   Y   N
G9. Total urine output in first 12 hours (ml) __ __ __

**How should urine output in the first 12 hours be measured when wet diapers also contained stool?**

*If there is nothing listed in the nurses’ notes for urine output, leave this item blank.*

G10. Arterial blood gases: FiO2 (%) pO2 (mm Hg)

**If only venous gases are available, leave Question G10 blank.**

G10a. With lowest pO2 __ __ __

G10b. With highest Mean Airway Pressure __ __ __

**There are several blood gases with the same MAP, which should I choose to record?**

*Please use the one with the lowest PO2 to reflect the worst oxygenation status*

G10c. With highest FiO2 __ __ __

**When recording the highest FiO2, please use the highest pO2 value**

G11. Early onset sepsis: __

1=no
2=culture negative
3=culture positive
Some institutions consider all babies <1250 g to be at risk for sepsis and automatically culture and administer antibiotics prophylactically as standard of care practice. Would this practice affect the culture results and if so how should Question G11 be coded?

- Code 1 (No) if the culture is negative and antibiotics are discontinued within 2 – 4 days.
- Code 2 (Culture Negative) if the culture is negative and antibiotics are continued for at least 5 days.
- Code 3 for culture positive if the blood culture is positive despite the early introduction of antibiotics.

6.2.9 Family History

Please ask parent(s) if the infant has any biological relatives who have experienced the events listed below. Family History Interview Guidelines are available in Appendix – H, on page 101 of this manual. Code the relationship to the infant NOT the relationship to informant. In cases where the infant is adopted, only record history of biological parents. Similarly, in situations where a sperm donor or egg donor was involved, history of known biological parent only should be included. Family Relationship Codes are listed in Appendix – I on page 108 of this manual.

Event

H1. Heart attack at any age                        Y  N  UNK
   If YES: H1a. ___ ___  H1b. ___ ___  H1c. ___ ___  H1d. ___ ___

H2. Heart attack prior to age 55 for women/50 for men Y  N  UNK
   If YES: H2a. ___ ___  H2b. ___ ___  H2c. ___ ___  H2d. ___ ___

H3. Stroke                                         Y  N  UNK
   If YES: H3a. ___ ___  H3b. ___ ___  H3c. ___ ___  H3d. ___ ___
One of the babies enrolled in the study has a great uncle who died at age 33 of hemorrhagic stroke. Should we code this as death due to stroke (H3), history of bleeding in the brain (H4), or history of sudden, nonaccidental death after age 15 (H5)?

Hemorrhagic Stroke may be coded in both H3 and H4. Since the cause of death in this situation is known, it is not necessary to code it as sudden, nonaccidental death after age 15 (H5), this question is designed to capture undiagnosed causes of death that may be relevant to IVH.

<table>
<thead>
<tr>
<th></th>
<th>History of bleeding in the brain</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES: H4a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H4b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H4c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H4d.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>History of sudden, non-accidental death after age 15 not due to suicide, chronic illness or cancer</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES: H5a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H5b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H5c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H5d.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Blood clots in the brain</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES: H6a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H6b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H6c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H6d.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Blood clots in the arms and/or legs</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES: H7a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H7b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H7c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H7d.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>History of another infant with IVH</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>

If the infant's twin has IVH, how should this be coded?

Code Yes.

<table>
<thead>
<tr>
<th></th>
<th>If YES: H8a.</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H8b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H8c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H8d.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>History of prior child with developmental delay or Cerebral Palsy</th>
<th>Y</th>
<th>N</th>
<th>UNK</th>
</tr>
</thead>
</table>
H10. Previous child enrolled in this study

   Y   N

H10a. If YES, __

   1 = Case
   2 = Control

6.2.10 Verification of Form Completion

I1. Person completing this form STAFF ID ___ ___ ___ ___

I2. Date completed ___/___/____ (MM/DD/YYYY)

Entry of the individual's Staff ID number at the end of each form will serve as certification to the CORE that every variable has been checked for accuracy.
6.3 **Last Follow-Up Data Form:**

### 6.3.1 Heading

**Subject ID:**

*Subject ID:* The subject ID number is made up of a two letter code identifying the site and a 3 digit sequential pre-assigned number. Therefore the Subject ID will be 5 characters.

<table>
<thead>
<tr>
<th>Site</th>
<th>Site Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baylor College of Medicine</td>
<td>BA</td>
</tr>
<tr>
<td>Brown University</td>
<td>BR</td>
</tr>
<tr>
<td>Karolinska University School of Medicine</td>
<td>KA</td>
</tr>
<tr>
<td>East Carolina University</td>
<td>EC</td>
</tr>
<tr>
<td>Indiana University</td>
<td>IU</td>
</tr>
<tr>
<td>Loma Linda University School of Medicine</td>
<td>LL</td>
</tr>
<tr>
<td>Queen Silvia Children's Hospital</td>
<td>QS</td>
</tr>
<tr>
<td>University of Alabama School of Medicine</td>
<td>AL</td>
</tr>
<tr>
<td>University of Arkansas for Medical Sciences</td>
<td>AR</td>
</tr>
<tr>
<td>University of Kentucky School of Medicine</td>
<td>KY</td>
</tr>
<tr>
<td>University of Miami School of Medicine</td>
<td>MI</td>
</tr>
<tr>
<td>University of Michigan Medical School</td>
<td>UM</td>
</tr>
<tr>
<td>University of New Mexico School of Medicine</td>
<td>NM</td>
</tr>
<tr>
<td>University of South Alabama</td>
<td>SA</td>
</tr>
<tr>
<td>University of Tennessee School of Medicine</td>
<td>TN</td>
</tr>
<tr>
<td>University of Utah</td>
<td>UU</td>
</tr>
<tr>
<td>Wake Forest University School of Medicine</td>
<td>WF</td>
</tr>
<tr>
<td>Washington University in Saint Louis School of Medicine</td>
<td>WU</td>
</tr>
<tr>
<td>Wayne State University School of Medicine</td>
<td>WS</td>
</tr>
<tr>
<td>Yale University School of Medicine</td>
<td>YA</td>
</tr>
</tbody>
</table>

**Mother's Date of Birth:**

- **Mother's D.O.B.:** The mother's date of birth is used for verification of subject.
6.3.2 36 - 44 Week PMA Neurological Data

The 36 – 44 Week Neurological Data Form is to be completed for all infants enrolled in the study, regardless of whether they have died, been discharged home or transferred to another facility. In the event of transfer, please obtain follow-up information needed from the new facility.

A1. Died <36 weeks PMA

A2. Head ultrasounds (HUS) – Local Reading

A2a. HUS: Date _____ / _____ / _____
     M M D DYYYY Y

Please record data from the first HUS conducted during the 36 to 44 week PMA time frame. If there are no HUS results from his period, leave Question A2 blank. Do not include information prior to 36 weeks PMA even if it was only a few days prior to this cut-off.

A2b. Blood/echodensity in germinal matrix/subependymal area

Record "Y" if blood/echodensity in the germinal matrix/subependymal area is documented. When blood echodensity is seen in the ventricle but NOT in the germinal matrix, record "N" for germinal matrix hemorrhage.

A2c. Highest Grade IVH on LEFT (0 – 1 – 2 – 3 – 4) [______]

A2d. Highest Grade IVH on RIGHT (0 – 1 – 2 – 3 – 4) [______]

If an infant had a previous hemorrhage that is resolving or has resolved, code the highest grade of the previous hemorrhage. If a new hemorrhage is evident, code the highest level of IVH.
A2e. Cystic Periventricular Leukomalacia (cPVL) Y N

Record "Y" when this diagnosis is used. In the absence of cystic PVL on sonographic reports, use cPVL when cysts (echo-lucencies) are described in the white matter around the ventricle. These cysts are most commonly dorsal and lateral to the external angle of the lateral ventricle. Echolucencies may be single or multiple, may be bilateral or unilateral, may vary in size, and may be diffuse or focal in distribution along the front to back axis of the head. If PVL is reported and cysts or echolucencies within the brain parenchyma are not specified, review the scan with the site ultrasonographer to verify the presence of this finding.

If YES,

A2e1. Left Y N
A2e2. Right Y N

A2f. Porencephalic cyst Y N

Porencephalic cyst will be used to categorize all cystic disease other than cystic PVL. In the absence of a diagnosis on sonographic reports, use porencephalic cyst when there is a single unitary cyst within the cerebral hemisphere that may or may not communicate with the lateral ventricle. These cysts may be congenital and can be present on sonograms shortly after birth, or may evolve over time at the site of a previous parenchymal blood/echodensity (3g from above). These cysts may also be termed post-hemorrhagic cysts, or if more than one, multi-cystic encephalomalacia. Do not include subependymal cysts or choroid plexus cysts as part of this category.

A2f1. Left Y N
A2f2. Right Y N

A2g. Ventriculomegaly Y N
Ventricular size is made at the mid-body of the lateral ventricle on the sagittal scan. Make the measurement as shown by the large arrows using the centimeter marks along the side of the scan. Ventriculomegaly (VM) will be graded by the Core Ultrasonographers as follows:
VM = 0: < 0.5 cm at midbody on sagittal scan
VM = 1: 0.5-1.0 cm at midbody on sagittal scan
VM = 2: 1.1-1.5 cm at midbody on sagittal scanVM = 3: > 1.5 cm at midbody on sagittal scan

For the data forms, if VM stage 1 or greater is reported, please indicate Y.

A3. MRI (When available, use 36 – 44 week PMA MRI results) Y N
   A3a. Date of MRI ___/___/___
        M M D D Y Y Y Y
   A3b. Hemorrhage noted on MRI Y N

   If YES, hemorrhage occurred in:
   A3b1. White matter Y N UNK
   A3b2. Parenchyma Y N UNK
   A3b3. Cerebellum Y N UNK
   A3b4. Deep nuclear gray matter Y N UNK
A3c. Abnormalities noted on MRI scan

If YES, abnormalities occurred in:

A3c1. White matter

A3c2. Parenchyma

A3c3. Cerebellum

A3c4. Deep nuclear gray matter

A4. Infant developed post hemorrhagic hydrocephalus

If YES, the following treatments were used

A4a. Lumbar puncture(s)

A4b. Ventriculostomy/drain

A4c. Third ventriculostomy

A4d. Reservoir

A4e. VP shunt

6.3.3 Ophthalmology

B.1. Exam performed for ROP

Review the medical record to determine if an examination was performed for ROP and flag all examinations found in order to answer the remaining questions. Record “Y” if an ophthalmologist examined the infant’s eyes for ROP. The exams usually begin at 4 to 6 weeks and continue until the retina’s vasculature is mature.

B1a. IF YES, ROP diagnosed

B1b. IF YES, eye(s) in which ROP was diagnosed

Left  Right  Both
B1c. **If ROP diagnosed**, surgical intervention was needed  

Y  N

Record "Y" for all surgical interventions for ROP, including laser and cryo.

B2. Discharge included follow-up exams for ROP  Y  N  UNK

6.3.4 **Pulmonary**

C1. BPD  Y  N

**Severity-Based Diagnostic Criteria for BPD:**

- **Time point of assessment:** 36 wk PMA or discharge home, whichever comes first
- **Therapy with oxygen > 21% for at least 28 d plus:**

  Mild  
  Breathing room air

  Moderate  
  Need for < 30% oxygen

  Severe  
  Need for ≥ 30% oxygen and/or positive pressure (i.e. PPV or nasal CPAP)


C1a. **If YES,**

1 = Mild  
2 = Moderate  
3 = Severe

C1b. **If YES,** given steroids for BPD  Y  N

Code "Y" if any steroids were administered in any form for the treatment of BPD. **If steroids were administered for other reason, for example, hypotension, code “N.”**

C1c. **If YES,** date of first steroid dose:

M  M/  D  D/  Y  Y  Y  Y
C1d. Infant still receiving oxygen at 36 weeks Y N

**Code “N” if the only oxygen received at 36 weeks PMA is for feedings.**

C1e. **If YES**, oxygen challenge test performed to document need for treatment with oxygen Y N

6.3.5 Discharge or Death

D1. Date of discharge or death ___/___/___ M M/ D D/ Y Y Y Y Y

In the event of multiple discharges or transfers to a different facility, please enter the date of the first discharge.

D2. Discharged Y N

**D2a. IF YES**, discharged to____

1 = home
2 = foster care
3 = another hospital
4 = rehab facility

D3. Death prior to discharge Y N

**IF YES,**

D3a. Autopsy performed Y N

*In situations where an autopsy was performed the cause of death should not be coded until the results of the autopsy are known. In the absence of an autopsy, the clinical evidence will be used to determine cause of death.*
D3b. Contributory causes to death

(Please refer to Appendix – J, found on page 105 for Death Codes)

Code the underlying, proximate disease(s) which initiated the train of events leading to the cause of death. This underlying cause(s) should be etiologically specific and an antecedent to all other causes with respect to time and pathologic relationship. Without the underlying cause, death would not have occurred. The cause of death should be based on both clinical evidence and autopsy findings.

D3b1. ___  D3b2. ___  D3b3. ___  D3b4. ___

6.3.6 Verification of Form Completion

D15. Person completing this form STAFF ID ___ ___ ___

D15a. Date Form completed ___ / ___ / ___  M M / D D / Y Y Y Y

Entry of the individual's Staff ID number at the end of each form will serve as certification to the CORE that every variable has been checked for accuracy.