

Neonatal Encephalopathy Registry

Manual of Operations

2010

Version 4.0

Revisions Section

- A. New Data Items: There are no new data items for 2010. Continue to use the NER Manual of Operations, version 2.1, and collect data items described in that version of the Manual for infants born prior to 2009.

- B. Discontinued Data Items: There are no discontinued NER data items for 2010.

Contents

Neonatal Encephalopathy Registry

Revisions Section	i
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CHAPTER 1 Neonatal Encephalopathy Registry Purpose, Background and Methods	1
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Introduction	1
Specific Aims	2
Background.....	2
Methods	2
Personnel.....	5
References.....	5

CHAPTER 2 Determining Eligibility for the Neonatal Encephalopathy Registry	7
---	----------

Steps for Determining Eligibility for the Registry	8
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CHAPTER 3	Completing Registry Forms	9
<hr/>		
CHAPTER 4	Eligibility Form Definitions	13
<hr/>		
CHAPTER 5	OB/Initial Status Form Definitions	17
<hr/>		
CHAPTER 6	Neurological Form Definitions	29
<hr/>		
CHAPTER 7	Diagnoses and Discharge Form Definitions	49
<hr/>		
CHAPTER 8	Hypothermic Therapy Form Definitions	65
<hr/>		
APPENDIX A	Modified Sarnat Stage	81
<hr/>		
APPENDIX B	NER Booklet for 2009	83
<hr/>		
APPENDIX C	NER DRD Booklet for 2009	103
<hr/>		
APPENDIX D	Anticonvulsant Drugs: Generic and Trade Names	113
<hr/>		

CHAPTER 1

Neonatal Encephalopathy Registry Purpose, Background and Methods

Introduction

The Vermont Oxford Network has established a Registry for Neonatal Encephalopathy. The Registry enrolls newborn infants with documented encephalopathy to identify their demographic characteristics, associated perinatal factors, medical treatments, co-morbidities and outcomes. The Registry allows us to characterize the population of infants with encephalopathy, evaluate variations in current practice, identify opportunities for improvement in the quality and safety of care for infants with encephalopathy, monitor the introduction and dissemination of new neuroprotective therapies such as hypothermia, assess selection criteria for neuroprotective therapy, define important questions for clinical research, and plan prospective research and randomized trials.

Participation in the Registry is open to all member hospitals in the Vermont Oxford Network. Data will be managed and submitted using the Network's **eNICQ** user software. The Registry will be supported by an optional module within the eNICQ software. No protected healthcare information will be submitted to the Vermont Oxford Network for the Registry. There is no additional fee for participation or for the use of the software.

Hospitals participating in the Registry will receive confidential reports characterizing infants at their center with encephalopathy and comparing them to all participating hospitals. These reports are intended for use in local quality improvement efforts.

Because the data in the Registry may be used as the basis for publications and presentations about neonatal encephalopathy, all participating units must submit the project to their local IRB for review and approval. A letter of IRB approval from your center is required before your center can participate in the Registry.

Specific Aims

- Identify opportunities to improve the quality and safety of care.
- Conduct observational research and disseminate the findings.
- Monitor the dissemination of hypothermia and other neuroprotective therapies.
- Conduct research on neonatal encephalopathy.

Background

Neonatal encephalopathy has been defined as a “syndrome of disturbed neurological function in the earliest days of life in the term infant, manifested by difficulty with initiating and maintaining respiration, depression of tone and reflexes, subnormal level of consciousness, and often by seizures.”¹

The prevalence of neonatal encephalopathy has been estimated to be 3.8 per 1000 live term births.^{2,3} In the past it was accepted that fetal asphyxia during labor and delivery was the predominant cause of neonatal encephalopathy and cerebral palsy, leading to the diagnosis of hypoxic-ischemic encephalopathy (HIE) for most infants presenting with encephalopathy soon after birth. More recently, it has been recognized that there may be multiple etiologies for neonatal encephalopathy, that the proportion of cases attributable to perinatal hypoxic-ischemic injury is unclear, and that the significant predisposing factors and those contributing to unfavorable long-term outcome are for the most part unknown.⁴ Data from a large multicenter registry will be needed to address these critical questions.

Two additional arguments support the need for a registry of neonatal encephalopathy. First, given the paucity of scientific data, variation in routine practice for the diagnosis and management of neonatal encephalopathy is likely to be great leading to deficiencies in the quality and safety of medical care for these high risk infants.⁵ Second, if new therapies such as hypothermia and neuroprotective agents are to be tested appropriately and used effectively, selection criteria for treatment must be developed and assessed, and prospective studies planned and designed.⁶ The Vermont Oxford Network Registry for Neonatal Encephalopathy will provide data which describes treatment variation and efficacy and which will suggest hypotheses for future study.

Methods

The Registry will be maintained at the Vermont Oxford Network in Burlington, VT. The Network will provide the necessary staff, space and support services to operate the Registry.

Hospital Eligibility: In the pilot years, 2006 and 2007, all hospitals in the Vermont Oxford Network Expanded Database will be eligible. We anticipate 125 eligible hospitals of which we plan to recruit 50. In subsequent years, all hospitals participating in the Vermont Oxford Network will be eligible.

Infant Eligibility: 36 weeks gestation or more with evidence of neonatal encephalopathy within 3 days of birth defined as presence of seizures and/or altered consciousness (lethargy, stupor, and coma). All infants treated with hypothermic therapy will also be eligible. Infants with central nervous system birth defects will be excluded. The eligibility criteria are described in detail in Chapter 2.

Data Collection and Monitoring: Data will be collected and submitted using the Vermont Oxford Network **eNICQ** software. A special data module for the **eNICQ** application has been created to support collection, editing, and electronic submission of data to the Registry. The software is available at no additional charge to participating units. The data submitted will become the property of the Vermont Oxford Network. The Network may use these data for research and reporting, but will maintain the confidentiality of individual hospital data.

Patient Confidentiality and Human Subjects: The confidentiality of individual patients will be protected. No protected healthcare information will be submitted to Vermont Oxford Network for the Registry. Although some patient identifiers are maintained locally at participating units using the **eNICQ** software, no protected healthcare information is transmitted or submitted to the Vermont Oxford Network. Only de-identified data are submitted. All patients will receive the current standard of care at their institution. The Registry does not require any interventions, or protocols for treatment. The Registry will be reviewed by the IRB at the University of Vermont and by the IRBs at the participating hospitals. Because the Registry data are expected to be used to perform observational research, participating units will be required to submit the project to their local IRBs for review. Since there is no expected risk for individual patients, and only de-identified data are submitted to the Registry, we anticipate that individual patient consent will not be required. However, the conditions for approval of Registry participation are the responsibility of each participating site. If a hospital chooses to participate in the optional follow-up of infants treated with hypothermia, this must also be reviewed and approved by the local hospital IRB. A letter of IRB approval from your center is required before your center can participate in the Registry and follow-up.

Routine Reporting to Participating Hospitals: Participating hospitals will receive confidential reports comparing their own data with those of all hospitals participating in the Registry.

Quality Improvement Opportunities: Data from the Registry will be used to identify opportunities for improvements in the quality and safety of the diagnosis, care and follow-up of infants with neonatal encephalopathy. These opportunities will be explored through the Vermont Oxford Network NICQ Quality Improvement Collaboratives, and Registry Internet sessions. Case studies of improvements will be disseminated at the Network's Annual Quality Congress for Neonatology and through interactive Internet conferences.

Observational Research: The Registry may be used to perform observational research including describing the population of infants with encephalopathy, associated perinatal factors, medical treatments, co-morbidities and outcomes. A planned focus of observational research will be to monitor the introduction and dissemination of new neuroprotective therapies such as hypothermia, assess selection criteria for neuroprotective therapy, and to identify variations in routine

practices and outcomes. Each observational study will require approval by the Steering Committee. Data from individual hospitals would not be identifiable in these study reports, although hospitals participating in the Registry would be identified in an Appendix to the manuscripts. No personal patient identifiers or protected healthcare information would be included in any study reports.

Planning for Prospective Research: Individual hospitals care for relatively few infants each year with neonatal encephalopathy. Many of these infants are born at outlying hospitals and often there is significant delay between birth and transfer to a referral center. These factors present challenges to the design and performance of prospective multi-center studies of interventions for neonatal encephalopathy. The Registry will provide valuable information for generating hypotheses for prospective studies and randomized trials, and for estimating the sample sizes and feasibility of such studies.

Other reporting: The Vermont Oxford Network has contracted with Olympic Medical to provide reports based on the Registry related to the post marketing surveillance of their head cooling equipment. Olympic Medical may at their discretion submit information to the FDA that uses information from these reports. Vermont Oxford Network will not have any responsibility for reporting to the FDA. Any reports provided by Vermont Oxford Network to Olympic Medical or to other parties will include aggregate data only and will not identify data from individual hospitals or patients.

Personnel

Registry Director: Jeffrey D. Horbar, MD
Co-Directors: Jerold F. Lucey, MD, Roger F. Soll, MD
Statistician: Joseph H. Carpenter, MS
Steering Committee: Peter Bingham, MD, Univ. of VT College of Medicine
Terrie Inder, MD, Washington University
Karin B. Nelson, MD, Senior Investigator, NIH
Tonse Raju, MD, NICHD

References

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- 2) Badawi N, Kurinczuk JJ, Keogh JM, et al. Antepartum risk factors for newborn encephalopathy: the Western Australian case-control study. *BMJ* 1998;317:1549-53.
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- 4) Edwards AD, Nelson KB. Neonatal encephalopathies: Time to reconsider the causes of encephalopathies. *BMJ* 1998;317:1537-8.
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CHAPTER 2

Determining Eligibility for the Neonatal Encephalopathy Registry

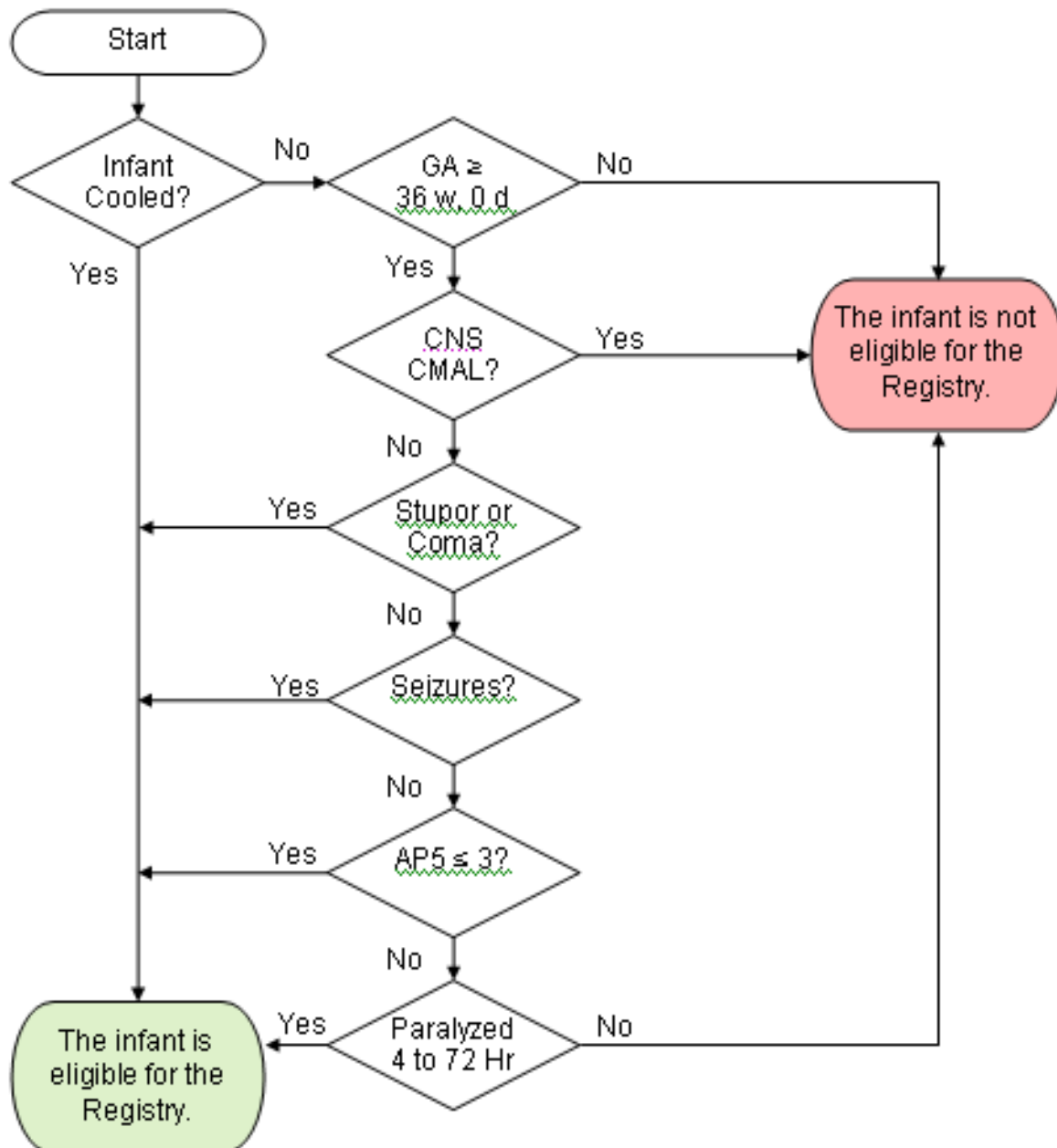


Figure 2.1. Determining Eligibility for Neonatal Encephalopathy Registry

Steps for Determining Eligibility for the Registry

NOTE: Infants who meet delivery room death criteria may be eligible for the Registry if their gestational age is \geq 36 weeks, 0 days and one or more of the conditions in paragraph 3 below is met. See the Vermont Oxford Network Manual of Operations, Version 14.0, for these criteria.

NOTE: Unless hypothermic therapy is performed, an infant can only be eligible based on events occurring prior to initial disposition at your hospital.

- 1) Determine if the infant is eligible for the VLBW or Expanded Database. Please refer to the 2010 Manual of Operations, version 14.0, for eligibility criteria. If the infant is not eligible for the VLBW or Expanded Database, stop here. If the infant is eligible for the VLBW or Expanded Databases, go to Step 2.
- 2) If the infant receives hypothermic therapy prior to discharge home or death, the infant is eligible for the Registry. Complete all NER forms, including all items on the Eligibility Form. Hypothermic therapy is defined as treatment with head or whole body cooling. This includes hypothermic therapy at another hospital prior to admission to your hospital or following transfer, hypothermic therapy in your center, or hypothermic therapy while in transit to or from your center. If the infant does not receive hypothermic therapy, go to step 3.
- 3) Determine if the infant's gestational age is 36 weeks or greater (completed weeks). If less than 36 weeks and the infant did not receive hypothermic therapy, the infant is not eligible for the Registry – stop here. If 36 weeks or greater, or the infant received hypothermic therapy, go to step 3a.
 - a) If the infant has a major CNS congenital malformation, the infant is not eligible for the Registry – stop here. If the infant does not have a major CNS congenital malformation, go to step 3b.
 - b) Infants whose gestational age is 36 weeks or more and who have no major CNS malformation are eligible for the Registry if one or more of the following conditions is present prior to initial disposition from your center (discharge home, death or transfer). For outborn infants, this includes conditions present at the hospital from which the infant transferred.
 - (1) Stupor or coma within 72 hours of birth, and the stupor or coma lasts continuously for at least six hours. Stupor is defined as “no spontaneous eye opening, and tactile stimulation elicits poorly sustained eye opening”. Coma is defined as “no eye opening to vigorous tactile stimulation”.
 - (2) One or more seizures within 72 hours of birth. Seizures may be either clinical or electro-encephalographic (EEG). Clinical seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia, hypertension or pupillary dilation).
 - (3) Paralysis with pancuronium or other muscle relaxant within 4 hours of birth and continuing until 72 hours after birth.
 - (4) APGAR score at five minutes of 3 or less.

CHAPTER 3

Completing Registry Forms

The Neonatal Encephalopathy Registry includes five forms:

Eligibility Form: determination of eligibility for the Registry. Other Registry forms are not applicable if the infant is not eligible.

OB/Initial Status Form: obstetric history and initial clinical status. Complete for all infants who are eligible for the Registry.

Neurological Form: neurological indicators, electrophysiology, seizures, anticonvulsants and neuroimaging. Complete for all infants who are eligible for the Registry.

Diagnoses and Discharge Form: outcomes relevant to conditions diagnosed prior to discharge from your center, as well as indicators of the infant's status at discharge. Complete for all infants who are eligible for the Registry.

Hypothermic Therapy Form: methods of hypothermic therapy used and adverse events, as well as the dates and times of cooling. Complete only for infants who receive hypothermic therapy (Item EL1 on the Eligibility Form is YES).

Completing the Eligibility Form

Use the data definitions in chapter 4 when completing this form.

If an infant receives hypothermic therapy, item EL1 on the Eligibility Form must be answered YES and items EL2 through EL8 must be completed. Since all infants receiving hypothermic therapy are eligible for the Registry, the other applicable Registry forms must be completed as well.

The forms in Appendix B show which forms and items are applicable for all other eligible infants. The forms in Appendix C show the applicable forms and items for infants who meet the delivery room death criteria.

For infants whose gestational age is 36 weeks or greater, use the following guidelines depending on whether your center participates in the VLBW Database or the Expanded Database.

- If your center participates in the Expanded Database, complete the Eligibility Form for all infants who are eligible for the Expanded Database.

<p>NOTE: If the infant's gestational age is less than 36 weeks according to the 28 Day Form, the eNICQ software will automatically set items on the Eligibility Form to "No" or "N/A". If the infant receives hypothermic therapy and is less than 36 weeks, you should answer "Yes" to Item EL1 on the Eligibility Form. This will override the default "No" value for eligibility and allow the NER forms to be completed.</p>

After the Eligibility Form is completed, the eNICQ software automatically calculates whether the infant is eligible for the Registry based on your responses on the Eligibility Form. If the infant is eligible for the Registry, complete the other applicable forms. These forms are in Appendix B and Appendix C.

If the infant is not eligible for the Registry, the eNICQ software will automatically set the items on other Registry forms to N/A.

- If your center participates in the VLBW Database, you should first determine whether the infant is eligible for the Registry based on the guidelines in Figure 2.1. Only complete the Eligibility Form and other applicable forms for infants that you have determined are eligible for the Registry.

NOTE: Centers participating in the VLBW Database and in the Registry must complete the Supplemental Data Form for infants who are eligible for the Registry. See the Vermont Oxford Network Manual of Operations for instructions on completing the Supplemental Data Form.

Completing the OB/Initial Status Form, Neurological Form, and Diagnoses and Discharge Form

Complete these forms for all infants who are eligible for the Registry using the following guidelines:

- Complete the forms in Appendix C for eligible infants who meet the delivery room death criteria. Complete the forms in Appendix B for all other eligible infants.
- Use the data definitions in Chapters 5, 6 and 7 when completing these forms.
- For infants who did not transfer from your center to another hospital, consider all events recorded in the medical record which occurred prior to death, discharge home or first birthday, whichever comes first. For outborn infants, this includes events which occurred in the hospital from which transferred.
- For infants who transferred to another hospital prior to discharge home or first birthday:
 - If the infant was not readmitted to your hospital prior to discharge home or first birthday, consider events which occurred in your hospital prior to transfer. For outborn infants, this includes events which occurred in the hospital from which transferred. Do not consider events which occurred following transfer from your hospital.
 - If the infant was readmitted to your hospital prior to discharge home or first birthday, consider events which occurred prior to transfer, events which occurred in the hospital to which transferred, and events which occurred in your hospital following readmission, until the time the infant was

transferred again, died, reached his or her first birthday or was discharged home, whichever was soonest.

Completing the Hypothermic Therapy Form

Use the data definitions in chapter 8 when completing this form.

- Only complete the Hypothermic Therapy Form if item EL1 on the Eligibility Form is answered YES and if the infant does not meet the delivery room death criteria.
- This form is only completed if the infant received active cooling.
- Complete the Hypothermic Therapy Form for infants who receive hypothermic therapy prior to discharge home, first birthday or death, whichever is soonest, regardless of where hypothermic therapy was received. This includes,
 - Outborn infants who receive hypothermic therapy prior to admission to your center. Record events which occur at the hospital from which the infant was transferred or which occurred during transport to your center.
 - Infants who receive hypothermic therapy at your center. Record events which occur at your hospital.
 - Infants who transferred from your center to another hospital. Record events which occur during transport to and at the hospital to which the infant was transferred.

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CHAPTER 4

Eligibility Form Definitions

ITEM EL1: Hypothermic Therapy Received?

NOTE: Selective head cooling is active cooling restricted to the head and brain; it is an intervention to reduce the temperature of the head and brain by exposing the head to lower than environmental temperature. Specially designed head cooling devices, other cooling devices and ice packs applied to the head would be considered active cooling of the head and brain. Passive exposure to environmental temperature or cooling of the face for the treatment of supraventricular tachycardia is not considered active cooling of the head and brain.

Whole body cooling is active cooling of the body that is not restricted to the head and brain; it is an intervention to reduce the core body temperature and temperature of the brain by exposing the body to lower than environmental temperature. Whole body cooling may include cooling of the head in addition to the rest of the body. Cooling blankets, other cooling devices and ice packs applied to the body would be considered active cooling of the whole body. Passive exposure to environmental temperature is not considered active cooling of the whole body.

Select **“Yes”** if the infant was treated with selective head and/or whole body cooling prior to discharge home or death. If an eligible outborn infant was cooled at another hospital or during transport prior to admission to your center, select **“Yes”**. If, prior to discharge home or death, the infant received hypothermic therapy at your center or was transferred to another hospital and received hypothermic therapy during transport to or at the other hospital, select **“Yes”**.

Select **“No”** if the infant was not treated with head and/or whole body cooling at any time prior to discharge home or death.

Select **“Unknown”** if it is not known whether or not the infant was treated with head and/or whole body cooling at any time prior to discharge home or death.

ITEM EL2: Gestational Age ≥ 36 Weeks, 0 Days or More?

NOTE: The answer to this item should be consistent with the Gestational Age item on the 28 Day Form and is calculated automatically by the **eNICQ** software.

Select “**Yes**” if the infant’s gestational age in completed weeks is 36 weeks, 0 days or more.

Select “**No**” if the infant’s gestational age in completed weeks is less than 36 weeks, 0 days.

Select “**Unknown**” if the infant’s gestational age is not known.

NOTE: Only answer questions EL3 to EL8 on the NER Eligibility Form if the answer to question EL1 or EL2 above is “Yes”.

ITEM EL3: Major CNS Congenital Malformation?

Lethal or life threatening central nervous system (CNS) congenital malformations include birth defect codes 101 through 105 and code 901 in Appendix C of the 2009 Vermont Oxford Network Manual of Operations. The code 901, other lethal or life threatening CNS defects, means that the defect is either the primary cause of death or is treated prior to discharge with specific surgical or medical therapy to correct a major anatomic defect or a life threatening physiologic dysfunction.

Select “**Yes**” if the infant has a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

Select “**No**” if the infant does not have a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

Select “**Unknown**” if it is not known whether the infant has a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

ITEM EL4: Stupor or Coma within 72 Hours?

Stupor is defined as “no spontaneous eye opening, and tactile stimulation elicits poorly sustained eye opening” Coma is defined as “no eye opening to vigorous tactile stimulation”.

Select “**Yes**” if the infant had stupor or coma within 72 hours of birth, and the stupor or coma lasts continuously for at least six hours.

Select “**No**” if the infant did not have stupor or coma lasting continuously for at least six hours within 72 hours of birth.

Select “**Unknown**” if it is not known whether the infant had stupor or coma lasting continuously for at least six hours within 72 hours of birth.

ITEM EL5: Seizures within 72 Hours?

Clinical seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation).

Select “**Yes**” if the infant had at least one clinical or electroencephalographic (EEG) seizure at any time within 72 hours of birth.

Select “**No**” if the infant did not have any clinical or EEG seizures at any time within 72 hours of birth.

Select “**Unknown**” if it is not known whether the infant had any clinical or EEG seizures within 72 hours of birth.

ITEM EL6: Paralysis Induced for First 72 Hours?

Select “**Yes**” if the infant was paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

Select “**No**” if the infant was not paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

Select “**Unknown**” if it is not known whether the infant was paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

ITEM EL7: APGAR Score at 5 Minutes of 3 or Less?

NOTE: The answer to this item should be consistent with the response to the APGAR score at 5 minutes on the 28 Day Form and is automatically calculated by the **eNICQ** software.

Select **“Yes”** if the value of the APGAR score at 5 minutes was between 0 and 3.

Select **“No”** if the value of the APGAR score at 5 minutes was between 4 and 10.

Select **“Unknown”** if the value of the APGAR score at 5 minutes is not known.

ITEM EL8: Eligible for NER?

NOTE: This item is automatically calculated by the **eNICQ** software. If the infant is eligible for the Registry, complete all applicable Registry forms. The OB/Initial Status Form, Neurological Form and Diagnoses and Discharge Form are completed for all eligible infants. The Hypothermic Therapy Form is completed only for eligible infants who received hypothermic therapy (Item EL1 above is answered “Yes”).

If the infant is eligible for the Registry based on the eligibility criteria described above, this item is answered **“Yes”**.

If the infant is not eligible for the Registry based on the eligibility criteria described above, or if the infant’s eligibility is indeterminate, this item is answered **“No”**.

CHAPTER 5

OB/Initial Status Form Definitions

The OB/Initial Status Form includes data items for the obstetric history of the infant and the infant's initial clinical status and is completed for all infants who are eligible for the registry.

For infants who did not transfer to another hospital, consider all events recorded in the medical record which occur prior to death, discharge home or first birthday, whichever is soonest. For outborn infants, this includes events which occurred in the hospital from which the infant transferred.

OB/INITIAL STATUS FORM PART A, OBSTETRIC-PERINATAL HISTORY

ITEM OB1: Mode of Delivery

Select one of the following which best describes the mode of delivery as recorded in the maternal or infant medical record.

- Vaginal without Vacuum or Forceps**
- Vacuum and/or Forceps Assisted Vaginal**
- C-Section before Labor Started**
- C-Section after Labor Started**
- C-Section after Failed Vacuum or Forceps Delivery**

Select “**Unknown**” if both the maternal and infant records are missing and not available for review, or if the mode of delivery is not noted in these records.

ITEM OB2: Presentation

Select one of the following to indicate the infant's presentation as recorded in the maternal or infant medical record.

- Vertex**
- Breech**
- Transverse**
- Other**

Select “**Unknown**” if both the maternal and infant records are missing and not available for review, or if the infant's presentation is not noted in these records.

ITEM OB3: Ruptured Membranes 24 Hours or More Prior to Delivery?

Select “**Yes**” if the mother’s membranes ruptured either spontaneously or artificially 24 hours or more before the infant was delivered, as recorded in either the maternal or infant medical record.

Select “**No**” if the mother’s membranes were not ruptured either spontaneously or artificially 24 hours or more before the infant was delivered, as recorded in either the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB4: Cord Prolapse?

Select “**Yes**” if there was a record of umbilical cord prolapse in either the maternal or infant medical record.

Select “**No**” if there was no record of cord prolapse in either the maternal or infant record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB5: Uterine Rupture?

Select “**Yes**” if there was a record of uterine rupture in either the maternal or infant medical record.

Select “**No**” if there was no record of uterine rupture in either the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB6: Antepartum Hemorrhage?

Select “**Yes**” if placenta previa, abruption or threatened abortion resulting in bleeding that can be external (vaginal bleeding in the absence of a vaginal or cervical source) or occult (retroplacental clot) other than bloody show was documented after 20 weeks of pregnancy in the maternal or infant medical record.

Select “**No**” if placenta previa, abruption or threatened abortion resulting in bleeding that can be external (vaginal bleeding in the absence of a vaginal or cervical source)

or occult (retroplacental clot) other than bloody show was not documented after 20 weeks of pregnancy in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB7: Chorioamnionitis?

Select “**Yes**” if a diagnosis of chorioamnionitis was recorded in the maternal or infant medical record.

Select “**No**” if a diagnosis of chorioamnionitis was not recorded in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB8: Maternal Temperature during Labor and Delivery

a. Maternal Temperature Recorded?

Select “**Yes**” if a maternal temperature obtained during labor and delivery was recorded in the maternal or infant record.

Select “**No**” if a maternal temperature obtained during labor and delivery was not recorded in the maternal or infant record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

If “Yes” to a., answer question b. below.

b. Temperature of Mother

If maternal temperature was recorded during labor and delivery, enter the highest maternal temperature recorded during labor in degrees Centigrade, as documented during labor in the maternal or infant medical record. Use a single decimal place, e.g. 36.7° C.

ITEM OB9: Antenatal Magnesium Exposure?

Select “**Yes**” if it is noted in the infant or maternal record that magnesium was administered to the mother prior to delivery for any indication.

Select “**No**” if it is not noted in the infant or maternal record that magnesium was administered to the mother prior to delivery for any indication.

Select “**Unknown**” if both the infant or maternal records are missing and not available for review.

ITEM OB10: Maternal Hypertension, Pre-eclampsia, or Eclampsia?

Select “**Yes**” if maternal hypertension, chronic or pregnancy induced, with or without edema and proteinuria, was recorded in the maternal or infant medical record, or if a maternal blood pressure above 140 systolic or 90 diastolic was recorded prior to or during the present pregnancy.

Select “**No**” if maternal hypertension, chronic or pregnancy induced, with or without edema and proteinuria, was not recorded in the maternal or infant medical record, and if a maternal blood pressure above 140 systolic or 90 diastolic was not recorded prior to or during the present pregnancy.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB11: Maternal Diabetes?

Select “**Yes**” if maternal diabetes mellitus treated with insulin and/or an oral hypoglycemic agent during or prior to the present pregnancy was recorded in the maternal or infant medical record.

Select “**No**” if maternal diabetes mellitus treated with insulin and/or an oral hypoglycemic agent during or prior to the present pregnancy was not recorded in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB12: Maternal Hypothyroidism?

Select “**Yes**” if a diagnosis of maternal hypothyroidism during or prior to the present pregnancy was recorded in the maternal or infant medical record.

Select “**No**” if a diagnosis of maternal hypothyroidism during or prior to the present pregnancy was not recorded in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB13: Non-Reassuring Fetal Assessment

Record any abnormalities noted in the maternal or infant medical record based on fetal heart rate monitoring prior to delivery. Select all that apply.

a. Bradycardia Prior to Delivery?

Select “**Yes**” if a baseline fetal heart rate < 110 beats per minute on fetal heart rate monitoring (electronic or auscultation) prior to delivery was noted in the maternal or infant medical record.

Select “**No**” if a baseline fetal heart rate < 110 beats per minute on fetal heart rate monitoring (electronic or auscultation) prior to delivery was not noted in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

b. Tachycardia Prior to Delivery?

Select “**Yes**” if a baseline fetal heart rate >160 beats per minute on fetal heart rate monitoring prior to delivery (electronic or auscultation) was noted in the maternal or infant medical record.

Select “**No**” if a baseline fetal heart rate >160 beats per minute on fetal heart rate monitoring prior to delivery (electronic or auscultation) was not noted in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

c. Decreased FHR Variability Prior to Delivery?

Select “**Yes**” if minimal (amplitude range detectable but less than 5 beats per minute or fewer) or absent (amplitude range undetectable) fetal heart rate variability on electronic fetal heart rate monitoring prior to delivery was noted in the maternal or infant medical record.

Select “**No**” if minimal (amplitude range detectable but less than 5 beats per minute or fewer) or absent (amplitude range undetectable) fetal heart rate variability on electronic fetal heart rate monitoring prior to delivery was not noted in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

d. Prolonged or Recurrent Decelerations Prior to Delivery?

Select “**Yes**” if either prolonged or recurrent decelerations on electronic fetal heart monitoring prior to delivery was noted in the maternal or infant medical record.

Select “**No**” if neither prolonged nor recurrent decelerations on electronic fetal heart monitoring prior to delivery was noted in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB14: Umbilical Cord Blood Sampling

a. Umbilical Cord Blood Sampling Performed?

Select “**Yes**” if the performance of either arterial or venous umbilical cord blood sampling was noted in the maternal or infant medical record.

Select “**No**” if the performance of either arterial or venous umbilical cord blood sampling was not noted in the maternal or infant medical record.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

NOTE: If multiple cord blood samples were obtained, the lowest pH and worse base deficit values, defined below, may be from different cord blood specimens.

If “Yes” to a., answer questions b. and c. below.

b. pH from Cord Blood Sample

If either arterial or venous umbilical cord blood sampling was performed, record the pH observed to two decimal places. If multiple umbilical cord samples were obtained, record the lowest pH observed to two decimal places.

c. Base Deficit from Cord Blood Sample

If either arterial or venous umbilical cord blood sampling was performed, record the base deficit observed in mmoles/liter. If multiple umbilical cord samples were obtained, record the worst (highest) base deficit measured or calculated in mmoles/liter.

NOTE: We are asking you to record the Base Deficit. Some laboratories report Base Excess rather than Base Deficit. This can be confusing. Please take the following steps when recording Base Deficit for the Registry:

- 1) Determine whether your laboratory is reporting results to you as Base Excess or Base Deficit.
- 2) If the laboratory is reporting Base Deficit, record the value exactly as reported by the laboratory.
- 3) If your laboratory is reporting Base Excess, you must change the sign in front of the number before recording it for the Registry. For example, if your laboratory reports a Base Excess of -6 (negative 6), the Base Deficit would be +6 (positive 6). You would enter 6 in eNICQ. If your laboratory reports a Base Excess of +3 (positive 3), the Base Deficit would be -3 (negative 3). You would enter -3 in eNICQ. The number stays the same; only the sign in front of the number changes.

Please also note that infants with acidosis usually have a positive Base Deficit. That means that they have a deficit of Base. The same infant would have a negative Base Excess meaning that there is a negative excess or a deficit! Confusing but important.

ITEM OB15: Assisted Reproduction?

Select “**Yes**” if it is documented in the maternal or infant medical record that this pregnancy was the product of artificial or assisted reproductive technology. This may include medications to induce ovulation (clomid) and/or procedures to assist fertilization (artificial insemination, in vitro fertilization).

Select “**No**” if it is not documented in the maternal or infant medical record that this pregnancy was the product of artificial or assisted reproductive technology.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

ITEM OB16: Placenta Sent for Pathology?

Select “**Yes**” if it is recorded in the maternal or infant medical record that the placenta was sent for pathological examination.

Select “**No**” if it is not recorded in the maternal or infant medical record that the placenta was sent for pathological examination.

Select “**Unknown**” if both the maternal and infant records are missing and not available for review.

OB/INITIAL STATUS FORM PART B, INFANT’S INITIAL CLINICAL STATUS

ITEM OB17: Infant Admitted to you NICU?

a. Infant Admitted to your NICU?

NOTE: The date and time of birth and date and time of admission are protected health care data items. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer.

Select “**Yes**” if the infant was admitted to your NICU.

Select “**No**” if the infant was not admitted to your NICU.

If “Yes” to a., answer questions b., c., and d. below. If the date is known but the time is uncertain, enter the best estimate for time.

b. Age at Admission, Days

Age at Admission, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time of admission to your NICU. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

c. Age at Admission, Hours

Age at Admission, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time of admission to your NICU. The number of hours can vary between 0 and 23.

d. Age at Admission, Minutes

Age at Admission, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time of admission to your NICU. The number of minutes can vary between 0 and 59.

ITEM OB18: APGAR Score at 10 Minutes

Enter the **10 minute APGAR** score if the score was recorded in either the maternal or infant medical record.

Enter “**Unknown**” if the APGAR score at 10 minutes was not recorded in either the maternal or infant medical record.

ITEM OB19: Assisted Ventilation at 10 Minutes?

Select “**Yes**” if it is documented in the infant’s record that assisted ventilation by either bag-mask or endotracheal tube was provided to the infant at 10 minutes of life.

Select “**No**” if it is not documented in the infant’s record that assisted ventilation by either bag-mask or endotracheal tube was provided to the infant at 10 minutes of life.

Select “**Unknown**” if the infant record is missing and not available for review.

ITEM OB20: Arterial, Venous, or Capillary Blood Gas

a. Arterial, Venous, or Capillary Blood Gas Obtained during First Hour of Life?

Select “**Yes**” if it is documented in the infant record that an arterial, venous, or capillary blood gas was obtained within the first hour after birth.

Select “**No**” if it is not documented in the infant record that an arterial, venous, or capillary blood gas was obtained within the first hour after birth.

Select “**Unknown**” if the infant record is missing and not available for review.

NOTE: If multiple blood gases were obtained, the lowest pH and worst base deficit values, defined below, may be from different blood gas specimens.

b. pH from Arterial, Venous, or Capillary Blood Gas

Enter the lowest pH from an arterial, venous, or capillary blood gas obtained within the first hour after birth to two decimal places. If multiple capillary cord samples were obtained, record the lowest pH observed to two decimal places.

c. Base Deficit from Arterial Venous, or Capillary Blood Gas

Enter the worst base deficit in mmoles/liter from an arterial, venous, or capillary blood gas obtained within the first hour after birth.

Example 1: Base Deficit of 6.4 should be rounded to 6.

Example 2: Base Deficit of 6.5 should be rounded to 7.

Example 3: Base Deficit of – 6.4 should be rounded to -6.

Example 4: Base Deficit of – 6.5 should be rounded to -7.

NOTE: We are asking you to record the Base Deficit. Some laboratories report Base Excess rather than Base Deficit. This can be confusing. Please take the following steps when recording Base Deficit for the Registry:

- 1) Determine whether your laboratory is reporting results to you as Base Excess or Base Deficit.
- 2) If the laboratory is reporting Base Deficit, record the value exactly as reported by the laboratory.
- 3) If your laboratory is reporting Base Excess, you must change the sign in front of the number before recording it for the Registry. For example, if your laboratory reports a Base Excess of -6 (negative 6), the Base Deficit would be +6 (positive 6). You would enter 6 in eNICQ. If your laboratory reports a Base Excess of +3 (positive 3), the Base Deficit would be -3 (negative 3). You would enter -3 in eNICQ. The number stays the same; only the sign in front of the number changes.

Please also note that infants with acidosis usually have a positive Base Deficit. That means that they have a deficit of Base. The same infant would have a negative Base Excess meaning that there is a negative excess or a deficit! Confusing but important.

ITEM OB21: Infant Temperature Recorded?

a. Infant Temperature Recorded within 72 Hours of Birth?

Select “**Yes**” if at least one measurement of the infant’s temperature obtained within the first 72 hours of birth was recorded in the infant record.

Select “**No**” if no measurement of the infant’s temperature obtained within the first 72 hours of birth was recorded in the infant record.

Select “**Unknown**” if the infant records are missing and not available for review.

If “Yes” to Item a, answer question b and c below.

b. Highest Temperature of Infant

If the infant body temperature was recorded during the first 72 hours after birth (rectal, esophageal, tympanic, or axillary), enter the highest temperature recorded during this period in degrees Centigrade. In recording the temperature, use a single decimal place and indicate that the temperature is in degrees Centigrade, e.g. 36.7° C.

c. Lowest Temperature of Infant

If the infant body temperature was recorded during the first 72 hours after birth (rectal, esophageal, tympanic, or axillary), enter the lowest temperature recorded during this period in degrees Centigrade. In recording the temperature, use a single decimal place and indicate that the temperature is in degrees Centigrade, e.g. 36.7° C.

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CHAPTER 6

Neurological Form Definitions

The Neurological Form includes data items for neurological indicators, electrophysiology, seizures, anticonvulsants and neuroimaging. The form includes three parts:

Part A: Neurological Examination (Day 1 \leq 6 Hours, Day 1 > 6 to 24 Hours, Day 3 and Day 7 \pm 1 day)

Part B: Electrophysiology, Seizures and Anticonvulsants

Part C: Neuroimaging

NEUROLOGICAL FORM PART A

Answer the items in Part A of the Neurological Form for each examination period (Day 1 (\leq 6 Hours), Day 1 (> 6 to 24 Hours), Day 3 and Day 7 of life). Two examination periods are reported for Day 1 as indicated; Day 3 includes the period 48 to 72 hours of age; Day 7 \pm 1 day includes the period of day 7 of life plus or minus 1 day (120 to 192 hours of age).

ITEM NU1: Infant Alive During Examination Period?

For the applicable examination period (Day 1 \leq 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 \pm 1 day),

Select “**Yes**” if the infant was alive in your hospital or, if outborn, was in the hospital from which the infant was transferred for some or all of the applicable examination period. If the infant was transferred and readmitted to your hospital, and the infant was in your hospital or in the “transferred to” hospital during the examination period, answer “**Yes**”.

Select “**No**” if the infant was not alive in your hospital and, if outborn, was not alive in the hospital from which the infant was transferred, at any time during the applicable examination period. If the infant was transferred prior to an examination period and not readmitted, answer “**No**”.

NOTE: If the answer to Item NU1 above is “**No**”, do not answer the other questions in Part A of the Neurological Form for the applicable examination period. If the answer to Item NU1 is “**Yes**”, answer Item NU2 below for the applicable examination period.

ITEM NU2: Paralysis for the Entire Examination Period?

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Select **“Yes”** if Paralysis with pancuronium or other muscle relaxant was pharmacologically induced during the entire period for which the examination is applicable (0 to 24 hours for Day 1, 48 to 72 hours for Day 3 and 120 to 192 hours for Day 7 ± 1 day).

Select **“No”** if Paralysis with pancuronium or other muscle relaxant was not pharmacologically induced during the entire period for which the examination is applicable.

NOTE: If the answer to Item NU2 above is **“Yes”**, do not answer the other questions in Part A of the Neurological Form for the applicable examination period. If the answer to Item NU2 is **“No”**, answer all the other questions in Part A of the Neurological Form for the applicable examination period.

ITEM NU3: Conscious State

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day), select the worst conscious state during the period (from best to worst, states are normal, irritability, lethargy, stupor and coma):

Select **“Normal”** if the infant is in the normal conscious state during the entire examination period.

Select **“Irritability”** if there is excessive, often high-pitched cry with little sustained quiet (which may be associated with spontaneous tremors).

Select **“Lethargy”** if the infant sleeps excessively with occasional spontaneous eye opening.

Select **“Stupor”** if there is no spontaneous eye opening, and tactile stimulation elicits poorly sustained eye opening.

Select **“Coma”** if there is no eye opening with vigorous tactile stimulation.

Select **“Unknown”** if the conscious state was not known.

ITEM NU4: Brainstem Function

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Select “**Normal**” if brainstem function was normal during the entire examination period.

Select “**Abnormal**” if any of the following abnormalities were observed at any time during the examination period: decreased facial movements; eyes not normally aligned or incomplete eye movements to Doll’s eye maneuver; poor suck, excess drooling, decreased swallow, or depressed gag reflex; depressed corneal reflex; sustained periodic hyperventilation or ‘gaspings’ patterns.

Select “**Unknown**” if it is not known whether brainstem function was normal or abnormal.

ITEM NU5: Movements

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Select “**Normal**” if the infant’s movements were normal in frequency and amplitude throughout the examination period.

Select “**Abnormal**” if the infant’s movements were decreased in frequency or amplitude at any time during the examination period.

Select “**Unknown**” if it is not known whether the infant’s movements were normal or abnormal.

ITEM NU6: Posturing

Posturing is sustained abnormal position such as tonic extension or flexion of limbs or trunk, e.g., opisthotonus (extension of neck and trunk); retrocollis (extension of neck); decerebrate posturing (extension of arms and legs); decorticate posturing (extension of legs/ flexion of elbows).

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**Present**” if posturing was observed at any time during the examination period.

Select “**Absent**” if posturing was not observed during the examination period.

Select “**Unknown**” if it is not known whether posturing was present or absent.

ITEM NU7: Tone

Tone is abnormal if it is either increased (shows increased resistance to passive movement) or decreased (shows decreased resistance to passive movement, which may be associated with frog-leg posturing with arms and legs lying flaccid in abduction).

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**Normal**” if the tone was normal during the entire examination period.

Select “**Abnormal**” if the infant’s tone was observed to be abnormal at any time during the examination period.

Select “**Unknown**” if it is not known whether tone was normal or abnormal.

ITEM NU8: Reflexes

Reflexes are abnormal if they (1) are hyperactive e.g., exaggerated response to tendon tap (which may be associated with sustained clonus of > 5 beats at the ankles) or (2) show crossed adductor response of opposite knee when tapping medial aspect of knee or (3) are hypoactive, e.g., when there is reduced or absent response to tendon tap.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**Normal**” if the infant’s deep tendon reflexes were normal during the entire examination period.

Select “**Abnormal**” if the infant’s deep tendon reflexes are observed to be abnormal at any time during the examination period.

Select “**Unknown**” if it is not known whether reflexes were normal or abnormal.

ITEM NU9: Feeding

NOTE: Feedings by mouth include nipple feeding from the breast, nipple feeding from a bottle of human or formula milk, and feedings of human or formula milk by mouth using a feeding cup or spoon.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**No Enteral Feedings**” if there are no enteral feedings at all, including feedings by mouth or tube feedings. The infant may receive feedings by parenteral routes.

Select “**Enteral Feedings, No Feedings by Mouth**” if the infant is receiving enteral feedings but none of the enteral feedings are by mouth as defined above. All enteral feedings are by tube.

Select “**Enteral Feedings, Some Feedings by Mouth**” if the infant is receiving enteral feedings, and some of the enteral feedings are by mouth as defined above, with supplementation by enteral tube feedings and/or parenteral nutrition.

Select “**Enteral Feedings, All Feedings by Mouth**” if all feedings are by mouth as defined above. There are no supplemental tube feedings or supplemental parenteral nutrition. Infant may receive IV fluids for medications but not for parenteral nutrition or supplemental hydration.

Select “**Unknown**” if the feeding method is not known.

ITEM NU10: Assisted Ventilation?

NOTE: Intermittent positive pressure ventilation via nasal prongs and synchronized intermittent positive pressure ventilation via nasal prongs are not considered assisted ventilation.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**Yes**” if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a ventilator (conventional or high frequency) at any time on the applicable day of life.

Select “**No**” if the infant was not given intermittent positive pressure ventilation through an endotracheal tube with a ventilator (conventional or high frequency) at any time on the applicable day of life.

Select “**Unknown**” if it is not known whether the infant received assisted ventilation during the examination period.

ITEM NU11: Clinical Seizures?

A clinical seizure is defined as “paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/papillary dilation)”.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Select “**Yes**” if one or more clinical seizures as defined above were recorded in the infant medical record on the applicable day of life.

Select “**No**” if no clinical seizure as defined above was recorded in the infant medical record during the examination period.

Select “**Unknown**” if the infant medical record is missing and unavailable.

NEUROLOGICAL FORM PART B

NOTE: When answering questions for Part B of the Neurological Form, “prior to discharge from your hospital” includes diagnoses made prior to admission to your hospital if the infant was outborn. If the infant transfers to another hospital and is readmitted to your center without having gone home, include diagnoses following transfer until the infant is discharged home, died or transfers again, whichever is soonest.

ITEM NU12: Full Channel EEG

a. Full Channel EEG Performed?

Select “**Yes**” if a full channel electroencephalogram (EEG) was performed at any time prior to discharge from your hospital.

Select “**No**” if a full channel EEG was not performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it is not known whether a full channel EEG was performed at any time prior to discharge from your hospital.

b. EEG Background Pattern

If a full channel EEG was performed at any time prior to discharge from your hospital, select the one category that most closely describes the worst EEG background pattern observed on any full channel EEG prior to discharge from your hospital, including EEGs performed prior to admission for outborn infants (from best to worst, patterns are normal, excessively discontinuous, depressed amplitude, burst suppression and background iso-electric).

Select “**Normal**” if the background pattern is normal in continuity, amplitude and frequency for gestational age.

Select “**Excessively Discontinuous**” if the background pattern is excessively discontinuous (‘dysmature’) for gestational age.

Select “**Depressed Amplitude**” if the background pattern shows depressed amplitude and/or slowing.

Select “**Burst Suppression Pattern**” if a burst suppression pattern is present or a severely depressed background is present.

Select “**Background Iso-Electric**” if the background pattern shows no recognizable electro-cortical activity.

Select “**Unknown**” if the worst background pattern is not known.

ITEM NU13: Bedside aEEG

a. Bedside aEEG Performed

Select “**Yes**” if a bedside amplitude integrated EEG (aEEG) monitor was used at any time prior to discharge from your hospital.

Select “**No**” if a bedside aEEG monitor was not used at any time prior to discharge from your hospital.

Select “**Unknown**” if it is not known whether a bedside aEEG monitor was used at any time prior to discharge from your hospital.

b. Bedside aEEG Background Pattern

If a bedside aEEG was performed at any time prior to discharge from your hospital, select the one category that most closely describes the worst background pattern observed at any time prior to discharge from your hospital, including bedside monitor

tracings performed prior to admission for outborn infants (from best to worst, patterns are normal, moderately abnormal or discontinuous, and severely abnormal).

NOTE: A minimum of one hour recording with low electrode impedance and the absence of continuous EEG seizures should be available in order to classify the worst background. The output appears as a thick dense band on the chart. The lower margin of the dense band represents the minimum degree of cerebral activity and the upper margin represents the maximum cerebral activity.¹ A line is drawn through the upper margin and the lower margin of the dense band of the aEEG and the voltage measured from these marked lines with the scale on the printed record.²

1 Bjerre I, Hellstrom-Westas L, Rosen I, Svenningsen N. Monitoring of cerebral function after severe asphyxia in infancy. Archives of Disease in Childhood 2002; 58(12):997-1002.)

2 (Thornberg E, Thiringer K. Normal pattern of the cerebral function monitor trace in term and preterm neonates. Acta Paediatrica Scandinavica 1990; 79(1):20-5.)

Select “**Normal**” if the upper margin of the dense aEEG band is greater than 10 μ v and the lower margin is greater than 5 μ v.

Select “**Moderately Abnormal or Discontinuous**” if the upper margin of the dense aEEG band is greater than 10 μ v and the lower margin is less than 5 μ v.

Select “**Severely Abnormal**” if the upper margin of the dense aEEG band is less than 10 μ v and the lower margin is less than 5 μ v.

Select “**Unknown**” if the worst aEEG background pattern is not known. If there is less than one hour of recording with low electrode impedance and absence of continuous EEG seizures is available, the worst background cannot be determined and “Unknown” should be selected.

ITEM NU14: Seizures Prior to Discharge

a. Seizures Occurred Prior to Discharge?

Select “**Yes**” if one or more seizures were documented in the infant medical record at any time prior to discharge from your hospital. The diagnosis may be made by clinical observation, full channel EEG or bedside aEEG monitor.

Select “**No**” if one or more seizures were not documented in the infant medical record at any time prior to discharge from your hospital.

Select “**Unknown**” if the infant medical record is missing and unavailable for review.

NOTE: If seizures were documented at any time prior to discharge from your hospital, indicate in b. through d. below the evidence used to determine that seizures occurred; record the date that seizures first occurred in e. below.

b. Evidence of Clinical Seizure?

A clinical seizure is defined as “paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/papillary dilation)”.

Select “**Yes**” if one or more clinical seizures as defined above were recorded in the infant medical record at any time prior to discharge from your hospital.

Select “**No**” if clinical signs of seizures as defined above were not recorded in the infant medical record at any time prior to discharge from your hospital.

c. Full Channel EEG Evidence of Seizure?

Select “**Yes**” if electroencephalographic evidence of seizures was detected on a full channel EEG performed at any time prior to discharge from your hospital.

Select “**No**” if electroencephalographic evidence of seizures was not detected on a full channel EEG performed at any time prior to discharge from your hospital.

d. Bedside aEEG evidence of seizure?

Select “**Yes**” if electroencephalographic evidence of seizures was detected on a bedside aEEG recording performed at any time prior to discharge from your hospital.

Select “**No**” if electroencephalographic evidence of seizures was not detected on a bedside aEEG recording performed at any time prior to discharge from your hospital.

e. Age Seizures First Observed

If seizures were documented at any time from birth until discharge from your hospital, enter the date and time that seizures were first observed by any method (clinically, full channel EEG, or bedside EEG).

NOTE: The date and time seizures were first observed is protected health care information. This item will not be exported to the Vermont Oxford Network. It will be stored on your local computer. Only the age of the infant when seizures were first observed will be exported to VON. The infant’s age in days, hours and minutes is automatically calculated by the eNICQ software.

If the date is known but the time is uncertain, enter the best estimate for time.

Date Seizures First Observed (mm/dd/yyyy).

Use the mm/dd/yyyy format (for example 06/06/2006 for June 6, 2006).

Time First Observed (hh:mm AM/PM).

Use the hh:mm AM/PM format (for example 11:22 AM for 11:22 AM).

(1) Age Seizures First Observed, Days

The age seizures were first observed, days, is automatically calculated by eNICQ by subtracting the date and time of birth from the date and time seizures were first observed. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

(2) Age Seizures First Observed, Hours

The age seizures were first observed, hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time that seizures were first observed. The number of hours can vary between 0 and 23.

(3) Age Seizures First Observed, Minutes

The age seizures were first observed, minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time seizures were first observed. The number of minutes can vary between 0 and 5.

ITEM NU15: Anticonvulsants Prior to Discharge

NOTE: See Appendix D for complete list of anticonvulsant generic and trade names. If anticonvulsants were documented at any time prior to discharge from your hospital, indicate in b. through h. below all of the anticonvulsants that were received.

a. Anticonvulsants Received Prior to Discharge?

Select **“Yes”** if the infant received anticonvulsant treatment at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“No”** if the infant did not receive anticonvulsant treatment at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“Unknown”** if the infant medical record is missing and unavailable for review.

If Item a is answered “Yes”, answer questions b through h below.

b. Phenobarbital Prior to Discharge?

Select **“Yes”** if the infant received Phenobarbital at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“No”** if the infant did not receive Phenobarbital at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“Unknown”** if it cannot be determined whether Phenobarbital was received prior to discharge.

c. Phenytoin or Fosphenytoin Prior to Discharge?

Select **“Yes”** if the infant received Phenytoin or Fosphenytoin at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“No”** if the infant did not receive Phenytoin or Fosphenytoin at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select **“Unknown”** if it cannot be determined whether Phenytoin or Fosphenytoin was received prior to discharge.

d. Lorazepam Prior to Discharge?

Select “**Yes**” if the infant received Lorazepam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant did not receive Lorazepam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Unknown**” if it cannot be determined whether Lorazepam was received prior to discharge.

e. Diazepam Prior to Discharge?

Select “**Yes**” if the infant was receiving Diazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Diazepam at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Diazepam at discharge.

f. Midazolam Prior to Discharge?

Select “**Yes**” if the infant received Midazolam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant did not receive Midazolam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Unknown**” if it cannot be determined whether Midazolam was received prior to discharge.

g. Topiramate Prior to Discharge?

Select “**Yes**” if the infant received Topiramate at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant did not receive Topiramate at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Unknown**” if it cannot be determined whether Topiramate was received prior to discharge.

h. Other Anticonvulsant Prior to Discharge?

Select **“Yes”** if the infant was receiving any other anticonvulsant not mentioned above at the time of discharge from your hospital, as recorded in the infant medical record. If **“Yes”**, record the name of the other anticonvulsant received in the space provided.

Select **“No”** if the infant was not receiving any other anticonvulsant at the time of discharge from your hospital.

Select **“Unknown”** if it cannot be determined whether the infant was receiving other anticonvulsants at discharge.

If **“Yes”** to this item, specify which other anticonvulsants were received at discharge (see Appendix D).

NEUROLOGICAL FORM PART C, NEUROIMAGING

NOTE: Prior to completing Part C of the Neurological Form, please first review all reports of neuroimaging studies (Cranial Ultrasounds, CT Scans, and MRI Scans) performed prior to discharge from your hospital, including studies performed prior to admission for outborn infants. Refer to the actual neuroimaging reports when completing these items. It would be advantageous to share Part C of the Neurological Form and review cases with your local neuro-radiologist/ radiologist who reports most of the neuroimaging for your NICU. This will assist you as the radiologist will understand what codings are being used and you may find it easier to approach them for any assistance in recording the findings of neuroimaging studies. Abbreviations for the studies used below are US for cranial ultrasound, CT for CT scan and MRI for MRI scan.

NOTE: When answering questions for Part C of the Neurological Form, “prior to discharge from your hospital” includes diagnoses made prior to admission if the infant was outborn.

ITEM NU16: Exam or Scan Performed?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if one or more exams/scans were performed prior to discharge from your hospital.

Select “**No**” if one or more exams/scans were not performed prior to discharge from your hospital.

Select “**Unknown**” if the maternal and infant records and the neuroimaging reports are missing and not available for review.

NOTE: If the answer to Item NU16 above is “No”, do not answer the other questions in Part C of the Neurological Form for the applicable exam or scan. If the answer to Item NU16 is “Yes”, complete all of the other questions in Part C of the Neurological Form for the applicable exam or scan.

ITEM NU17: Day of First Exam/Scan

NOTE: The dates of the first cranial ultrasound exam, CT scan and MRI scan are protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. The eNICQ software will automatically calculate the day of first exam in days, and this data item will be exported to VON.

For each type of exam performed (US, CT or MRI), enter the day of life that the first exam/scan of that type was performed.

ITEM NU18: Day of Last Exam/Scan

NOTE: The dates of the last cranial ultrasound exam, CT scan and MRI scan are protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. The eNICQ software will automatically calculate the day of first exam in days, and this data item will be exported to VON.

For each type of exam performed (US, CT or MRI), enter the day of life that the last exam/scan of that type was performed.

ITEM NU19: Intraventricular Hemorrhage?

For each type of exam performed (US, CT or MRI),

Select **“Yes”** if intraventricular hemorrhage was recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“No”** if intraventricular hemorrhage was not recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“Unknown”** if it cannot be determined whether an intraventricular hemorrhage was recorded for the type of exam/scan.

ITEM NU20: Extra-Axial, Subdural or Subarachnoid Hemorrhage?

For each type of exam performed (US, CT or MRI),

Select **“Yes”** if extra-axial, subdural or subarachnoid hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“No”** if extra-axial, subdural or subarachnoid hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“Unknown”** if it cannot be determined whether extra-axial, subdural or subarachnoid hemorrhage was recorded for the type of exam/scan.

ITEM NU21: Intraparenchymal Hemorrhage?

For each type of exam performed (US, CT or MRI),

Select **“Yes”** if intraparenchymal hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“No”** if intraparenchymal hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“Unknown”** if it cannot be determined whether an intraparenchymal hemorrhage was recorded for the infant for the type of exam/scan.

ITEM NU22: Subependymal Hemorrhage?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if subependymal hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if subependymal hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether a subependymal hemorrhage was recorded for the infant for the type of exam/scan.

ITEM NU23: Abnormality in Deep Nuclear Gray Matter?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if an abnormality in the deep nuclear gray matter was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if an abnormality in the deep nuclear gray matter was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether an abnormality in deep nuclear gray matter was recorded for the type of exam/scan.

ITEM NU24: Cystic White Matter Injury?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if a cystic white matter injury was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital. Cystic white matter injury may be focal, multifocal or diffuse but must include the presence of cysts.

Select “**No**” if a cystic white matter injury was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether a cystic white matter injury was recorded for the type of exam/scan.

ITEM NU25: Diffuse White Matter Injury?

Note: this item only applies to MRI scans.

Select “**Yes**” if diffuse white matter injury was indicated in a MRI scan performed at any time prior to discharge from your hospital. This form of white matter injury should have no cystic changes.

Select “**No**” if diffuse white matter injury was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether a diffuse white matter injury was recorded on an MRI scan.

ITEM NU26: Ventriculomegaly?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if ventriculomegaly was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if ventriculomegaly was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether ventriculomegaly was recorded for the type of exam/scan.

ITEM NU27: Venocclusion?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if venocclusion was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if venocclusion was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether veno-occlusion was recorded for the type of exam/scan.

ITEM NU28: Arterial Occlusion?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if arterial occlusion was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if arterial occlusion was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether arterial occlusion was recorded for the type of exam/scan.

ITEM NU29: Brainstem Injury?

Note: This item only applies to CT scans and MRI scans.

Select “**Yes**” if brainstem injury was indicated in one or more CT or MRI scans performed at any time prior to discharge from your hospital.

Select “**No**” if brainstem injury was not indicated in one or more CT or MRI scans performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether brainstem injury was recorded for the type of scan.

ITEM NU30: Cerebellar Injury?

For each type of exam performed (US, CT or MRI),

Select “**Yes**” if cerebellar injury was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**No**” if cerebellar injury was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether cerebellar injury was recorded for the type of exam/scan.

ITEM NU31: Diffuse Cortical Signal Abnormality?

Note: this item only applies to MRI scans.

Select “**Yes**” if diffuse cortical signal abnormality was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**No**” if diffuse cortical signal abnormality was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether diffuse cortical signal abnormality was recorded on an MRI scan.

ITEM NU32: Parasagittal Watershed Cortical Gray Matter Injury?

Note: this item only applies to MRI scans.

Select “**Yes**” if parasagittal watershed cortical gray matter injury was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**No**” if parasagittal watershed cortical gray matter injury was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether parasagittal watershed cortical gray matter injury was recorded on an MRI scan.

ITEM NU33: Absence of Posterior Limb of the Internal Capsule?

Note: This item only applies to MRI scans.

Select “**Yes**” if absence of the posterior limb of the internal capsule was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**No**” if absence of the posterior limb of the internal capsule was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether absence of posterior limb of the internal capsule was recorded on an MRI scan.

ITEM NU34: Other Intracranial Abnormalities?

For each type of exam performed (US, CT or MRI),

Select **“Yes”** if any other intracranial abnormalities are recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital. If **“Yes”**, describe the other abnormalities in the space provided.

Select **“No”** if any other intracranial abnormalities are not recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Select **“Unknown”** if it cannot be determined whether other intracranial abnormalities were recorded for this type of exam/scan.

CHAPTER 7

Diagnoses and Discharge Form Definitions

The Diagnoses and Discharge Form includes data items which identify infant outcomes relevant to conditions diagnosed prior to discharge from your center, as well as indicators of the infant's status at discharge. The form includes two parts:

Part A: Diagnoses

Part B: Discharge Status

DIAGNOSES AND DISCHARGE FORM PART A, DIAGNOSES

ITEM DD1: Persistent Pulmonary Hypertension of the Newborn, PPHN?

Select **“Yes”** if a diagnosis of Persistent Pulmonary Hypertension of the Newborn (PPHN), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Select **“No”** if the infant medical record did not include documentation that a diagnosis of PPHN occurred prior to discharge from your hospital.

Select **“Unknown”** if the infant medical record was missing and unavailable for review.

ITEM DD2: Renal Failure?

Select **“Yes”** if a diagnosis of renal failure (acute or chronic), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Select **“No”** if the infant medical record did not include documentation that a diagnosis of renal failure (acute or chronic) occurred prior to discharge from your hospital.

Select **“Unknown”** if the infant medical record was missing and unavailable for review.

ITEM DD3: Syndrome of Inappropriate Secretion of Antidiuretic Hormone SIADH?

Select “**Yes**” if a diagnosis of Syndrome of Inappropriate Secretion of Antidiuretic Hormone (SIADH), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Select “**No**” if the infant medical record did not include documentation that a diagnosis of SIADH occurred prior to discharge from your hospital.

Select “**Unknown**” if the infant medical record was missing and unavailable for review.

ITEM DD4: Disseminated Intravascular Coagulation, DIC?

Select “**Yes**” if a diagnosis of Disseminated Intravascular Coagulation (DIC), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Select “**No**” if the infant medical record did not include documentation that a diagnosis of DIC occurred prior to discharge from your hospital.

Select “**Unknown**” if the infant medical record was missing and unavailable for review.

ITEM DD5: Hepatic Dysfunction?

NOTE: Aspartate aminotransferase (AST) was formerly called serum glutamic oxaloacetic transaminase (SGOT). Alanine aminotransferase (ALT) was formerly called serum glutamic pyruvic transaminase (SGPT).

Select “**Yes**” if serum AST (SGOT) and/or ALT (SGPT) were obtained prior to discharge from your hospital and one or both values were elevated above local normal laboratory values.

Select “**No**” if serum AST (SGOT) and/or ALT (SGPT) were obtained prior to discharge from your hospital and the values were not elevated above local normal laboratory values.

Select “**Unknown**” if neither serum AST (SGOT) nor ALT (SGPT) were measured, or if the results are unknown.

ITEM DD6: Hyperbilirubinemia within 7 Days of Birth?

NOTE: The date of birth counts as Day 1 regardless of the time of birth. For example, if an infant is born at 11:59PM on September 1, then Day 7 would be September 7 - all bilirubin values from September 1 to 7 would be evaluated in answering this question.

Select **“Yes”** if a serum indirect bilirubin level ≥ 20 mg/dl (342 micromoles/L) was recorded in the infant medical record for a specimen obtained at any time within 7 days of birth.

Select **“No”** if a serum indirect bilirubin level ≥ 20 mg/dl (342 micromoles/L) was not recorded in the infant medical record for a specimen obtained at any time within 7 days of birth.

Select **“Unknown”** if the infant medical record is missing or not available for review.

ITEM DD7: Cardiac Dysfunction?

Evidence of cardiac dysfunction includes myocardial dysfunction and/or tricuspid insufficiency on physical exam, echocardiogram, or cardiac catheterization. Arrhythmias do not count as evidence of cardiac dysfunction for this question.

Select **“Yes”** if a diagnosis of cardiac dysfunction, occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Select **“No”** if the infant medical record did not include documentation that a diagnosis of cardiac dysfunction occurred prior to discharge from your hospital.

Select **“Unknown”** if the infant medical record was missing and unavailable for review.

ITEM DD8: Prenatal TORCH Infection

a. Prenatal TORCH Infection Present?

Select **“Yes”** if a diagnosis of prenatal infection with toxoplasmosis, rubella, syphilis, cytomegalovirus, or Herpes Simplex was documented in either the infant or maternal medical record.

Select **“No”** if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with toxoplasmosis, rubella, syphilis, cytomegalovirus, or Herpes Simplex.

Select “**Unknown**” if the infant and maternal medical records were missing and unavailable for review.

NOTE: If a prenatal TORCH infection was present, answer questions b. through f. below. Do not answer these questions if a prenatal TORCH infection was not present.

b. Toxoplasmosis?

Select “**Yes**” if a diagnosis of a prenatal infection with toxoplasmosis was documented in either the infant or maternal medical record.

Select “**No**” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with toxoplasmosis.

Select “**Unknown**” if it cannot be determined whether toxoplasmosis was present.

c. Rubella?

Select “**Yes**” if a diagnosis of a prenatal infection with rubella was documented in either the infant or maternal medical record.

Select “**No**” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with rubella.

Select “**Unknown**” if it cannot be determined whether rubella was present.

d. Syphilis?

Select “**Yes**” if a diagnosis of a prenatal infection with syphilis was documented in either the infant or maternal medical record.

Select “**No**” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with syphilis.

Select “**Unknown**” if it cannot be determined whether syphilis was present.

e. Cytomegalovirus?

Select “**Yes**” if a diagnosis of a prenatal infection with cytomegalovirus was documented in either the infant or maternal medical record.

Select “**No**” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with cytomegalovirus.

Select “**Unknown**” if it cannot be determined whether cytomegalovirus was present.

f. Herpes Simplex?

Select “**Yes**” if a diagnosis of a prenatal infection with herpes simplex was documented in either the infant or maternal medical record.

Select “**No**” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with herpes simplex.

Select “**Unknown**” if it cannot be determined whether herpes simplex was present.

ITEM DD9: Congenital Neuromuscular Disorder?

Select “**Yes**” if a diagnosis of congenital neuromuscular disorder was documented in the infant medical record. If a diagnosis of congenital neuromuscular disorder was made, describe the specific disorder in the space provided.

Select “**No**” if the infant medical record did not include documentation of a diagnosis of congenital neuromuscular disorder.

Select “**Unknown**” if the infant medical record was missing and unavailable for review.

ITEM DD10: Birth Trauma

a. Traumatic Birth Injury?

Select “**Yes**” if one or more of the injuries in questions b. through h. below were diagnosed and documented in the maternal or infant record.

Select “**No**” if the infant and maternal medical records did not include documentation of any of the injuries in questions b. through h. below.

Select “**Unknown**” if the maternal and infant medical records were missing and unavailable for review.

NOTE: If a traumatic birth injury occurred, answer questions b. through h. below. Do not answer these questions if no traumatic birth injury occurred.

b. Spinal Cord Injury?

Select “**Yes**” if a spinal cord injury was present at birth.

Select “**No**” if a spinal cord injury was not present at birth.

Select “**Unknown**” if it cannot be determined whether spinal cord injury occurred.

c. Brachial Plexus Injury?

Select “**Yes**” if a brachial plexus injury was present at birth.

Select “**No**” if a brachial plexus injury was not present at birth.

Select “**Unknown**” if it cannot be determined whether brachial plexus injury occurred.

d. Skull Fracture?

Select “**Yes**” if a skull fracture was present at birth.

Select “**No**” if a skull fracture was not present at birth.

Select “**Unknown**” if it cannot be determined whether skull fracture occurred.

e. Long Bone Fracture?

Select “**Yes**” if a long bone fracture was present at birth.

Select “**No**” if a long bone fracture was not present at birth.

Select “**Unknown**” if it cannot be determined whether long bone fracture occurred.

f. Clavicle Fracture?

Select “**Yes**” if a clavicle fracture was present at birth.

Select “**No**” if a clavicle fracture was not present at birth.

Select “**Unknown**” if it cannot be determined whether clavicle fracture occurred.

g. Cephalhematoma?

Select “**Yes**” if a cephalhematoma was present at birth.

Select “**No**” if a cephalhematoma was not present at birth.

Select “**Unknown**” if it cannot be determined whether cephalhematoma occurred.

h. Other Traumatic Birth Injury?

Select “**Yes**” if any traumatic birth injury was present at birth which is not listed in questions b. through g. above. Do not record lacerations. Describe the injuries in the space provided.

Select “**No**” if no other traumatic birth injury was present at birth.

ITEM DD11: Meningitis or Encephalitis

a. Meningitis or Encephalitis Suspected or Proven?

Select “**Yes**” if the infant was suspected or proven to have bacterial, fungal or viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record. Suspected meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest meningitis or encephalitis.

Select “**No**” if the infant was not suspected or proven to have bacterial, fungal or viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Unknown**” if the infant medical record was missing and unavailable for review.

NOTE: If meningitis or encephalitis was suspected or proven, answer questions b. through d. below. Do not answer these questions if meningitis or encephalitis was not suspected or proven.

b. Bacterial Meningitis or Encephalitis

Select “**None**” if the infant did not have suspected or proven bacterial meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Suspected**” if the infant had suspected bacterial meningitis or encephalitis recorded in the infant medical record at any time prior to discharge from your hospital. Suspected bacterial meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest bacterial meningitis or encephalitis.

Select “**Proven**” if the infant had bacterial meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

NOTE: If bacterial meningitis or encephalitis was suspected, only answer question (1) below. If bacterial meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if bacterial meningitis or encephalitis was not suspected or proven.

(1) Onset of Bacterial Meningitis or Encephalitis

NOTE: Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2006, Day 3 will be September 3, 2006. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Select “**Early**” if the onset of bacterial meningitis or encephalitis was within 3 days of birth.

Select “**Late**” if the onset of bacterial meningitis or encephalitis was more than 3 days after birth.

Select “**Unknown**” if the onset of bacterial meningitis or encephalitis was unknown.

(2) Name of Bacterial Meningitis or Encephalitis Organism

If a proven bacterial meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.

c. Fungal Meningitis or Encephalitis

Select “**None**” if the infant did not have suspected or proven fungal meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Suspected**” if the infant had suspected fungal meningitis or encephalitis recorded in the infant medical record at any time prior to discharge from your hospital. Suspected fungal meningitis or the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest fungal meningitis or encephalitis.

Select “**Proven**” if the infant had fungal meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

NOTE: If fungal meningitis or encephalitis was suspected, only answer question (1) below. If fungal meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if fungal meningitis or encephalitis was not suspected or proven.

(1) Onset of Fungal Meningitis or Encephalitis

NOTE: Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2006, Day 3 will be September 3, 2006. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Select “**Early**” if the onset of fungal meningitis or encephalitis was within 3 days of birth.

Select “**Late**” if the onset of fungal meningitis or encephalitis was more than 3 days after birth.

Select “**Unknown**” if the onset of fungal meningitis or encephalitis was unknown.

(2) Name of Fungal Meningitis or Encephalitis Organism

If a proven fungal meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.

d. Viral Meningitis or Encephalitis

Select “**None**” if the infant did not have suspected or proven viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.

Select “**Suspected**” if the infant had suspected viral meningitis or encephalitis recorded in the infant medical record at any time prior to discharge from your hospital. Suspected viral meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest viral meningitis or encephalitis.

Select “**Proven**” if the infant had viral meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

NOTE: If viral meningitis or encephalitis was suspected, only answer question (1) below. If viral meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if viral meningitis or encephalitis was not suspected or proven.

(1) Onset of Viral Meningitis or Encephalitis

NOTE: Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2006, Day 3 will be September 3, 2006. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Select “**Early**” if the onset of viral meningitis or encephalitis was within 3 days of birth.

Select “**Late**” if the onset of viral meningitis or encephalitis was more than 3 days after birth.

Select “**Unknown**” if the onset of viral meningitis or encephalitis was unknown.

(2) Name of Viral Meningitis or Encephalitis

If a proven viral meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.

DIAGNOSES AND DISCHARGE FORM PART B, DISCHARGE STATUS

ITEM DD12: Hearing Screen

a. Hearing Screen Exam Performed?

Select “**Yes**” if one or more hearing screen exams, either otoacoustic emissions (OAE) or auditory brainstem response (ABR), were recorded in the infant medical record as having been performed prior to discharge from your hospital.

Select “**No**” if no hearing screen exam (otoacoustic emissions, OAE, or auditory brainstem response, ABR) was recorded in the infant medical record as having been performed prior to discharge from your hospital.

Select “**Unknown**” if the infant medical record was missing and unavailable for review.

NOTE: If a hearing screen exam was performed, answer question b. below. Do not answer question b. if no hearing screen exam was performed.

b. Hearing Screen Passed?

If one or more hearing screen exams were performed prior to discharge from your hospital, enter the results of the last exam before discharge. Consider all hearing assessments documented in the infant medical record performed prior to discharge from your hospital.

Select “**Yes**” if the infant passed the last hearing screen exam administered prior to discharge from your hospital.

Select “**No**” if the infant did not pass the last hearing screen exam administered prior to discharge from your hospital.

Select “**Unknown**” if it is not known whether the infant passed the last hearing screen exam administered prior to discharge from your hospital.

ITEM DD13: Feeding at Discharge

NOTE: Feedings by mouth include nipple feeding from the breast, nipple feeding from a bottle of human or formula milk, and feedings of human or formula milk by mouth using a feeding cup or spoon.

Select “**No Enteral Feedings**” if there are no enteral feedings at all when the infant is discharged, including feedings by mouth or tube feedings. The infant may receive feedings by parenteral routes.

Select “**Enteral Feedings, No Feedings by Mouth**” if the infant is receiving enteral feedings at discharge but none of the enteral feedings are by mouth as defined above. All enteral feedings at discharge are by tube.

Select “**Enteral Feedings, Some Feedings by Mouth**”, if the infant is receiving enteral feedings at discharge, and some of the enteral feedings are by mouth as defined above, with supplementation by enteral tube feedings and/or parenteral nutrition.

Select “**Enteral Feedings, All Feedings by Mouth**” if all feedings at discharge are by mouth, i.e., there are no supplemental tube feedings or supplemental parenteral nutrition. Infant may receive IV fluids for medications but not for parenteral nutrition or supplemental hydration.

Select “**Unknown**” if the method of feeding at discharge is unknown.

ITEM DD14: Tracheotomy at Discharge?

Select “**Yes**” if the infant was discharged from your hospital with a tracheotomy in place.

Select “**No**” if the infant was not discharged from your hospital with a tracheotomy in place.

Select “**Unknown**” if it is not known whether or not the infant was discharged with a tracheotomy in place.

ITEM DD15: Discharged with Ventilator?

Select “**Yes**” if the infant was discharged with either a conventional or high frequency ventilator, with the expectation that assisted ventilation would be provided at least intermittently after discharge.

Select “**No**” if the infant was not discharged with either a conventional or high frequency ventilator and with the expectation that assisted ventilation would be provided at least intermittently after discharge.

Select “**No**” if the infant’s discharge status was “Died”.

Select “**Unknown**” if it is not known whether or not the infant was discharged with a conventional or high frequency ventilator, with the expectation that assisted ventilation would be provided at least intermittently after discharge.

ITEM DD16: Anticonvulsant Medication at Discharge?

a. Anticonvulsant Medication at Discharge?

Select “**Yes**” if the infant was receiving anticonvulsant medication at the time of discharge from your hospital, with the expectation that anticonvulsant therapy would continue after discharge.

Select “**No**” if the infant was not receiving anticonvulsant medication at the time of discharge from your hospital and there was not the expectation that anticonvulsant therapy would continue after discharge.

Select “**No**” if the infant’s discharge status was “Died”.

Select “**Unknown**” if it is not known whether or not the infant was discharged on anticonvulsant medication, with the expectation that anticonvulsant therapy would continue after discharge.

NOTE: If the infant was receiving anticonvulsant medication at the time of discharge, answer questions b. through h. below.

b. Phenobarbital at Discharge?

Select “**Yes**” if the infant was receiving Phenobarbital at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Phenobarbital at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Phenobarbital at discharge.

c. Phenytoin or Fosphenytoin at Discharge?

Select “**Yes**” if the infant was receiving Phenytoin or Fosphenytoin at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Phenytoin or Fosphenytoin at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Phenytoin or Fosphenytoin at discharge.

d. Lorazepam at Discharge?

Select “**Yes**” if the infant was receiving Lorazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Lorazepam at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Lorazepam at discharge.

e. Diazepam at Discharge?

Select “**Yes**” if the infant was receiving Diazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Diazepam at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Diazepam at discharge.

f. Midazolam at Discharge?

Select “**Yes**” if the infant was receiving Midazolam at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Midazolam at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Midazolam at discharge.

g. Topiramate at Discharge?

Select “**Yes**” if the infant was receiving Topiramate at the time of discharge from your hospital, as recorded in the infant medical record.

Select “**No**” if the infant was not receiving Topiramate at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving Topiramate at discharge.

h. Other Anticonvulsant at Discharge?

Select “**Yes**” if the infant was receiving any other anticonvulsant not mentioned above at the time of discharge from your hospital, as recorded in the infant medical record. If “Yes”, record the name of the other anticonvulsant received in the space provided.

Select “**No**” if the infant was not receiving any other anticonvulsant at the time of discharge from your hospital.

Select “**Unknown**” if it cannot be determined whether the infant was receiving other anticonvulsants at discharge.

If “Yes” to this item, specify which other anticonvulsants were received at discharge (see Appendix D).

ITEM DD17: Autopsy Status

Select one response regarding autopsy status.

Select “**N/A**” if the infant was discharged home from your hospital, was transferred to another hospital or was still in your hospital at one year of age.

Select “**Autopsy Performed**” if the infant died in your hospital prior to discharge home or first birthday and an autopsy was performed.

Select “**Autopsy Permission Requested and Denied**” if the infant died in your hospital prior to discharge home or first birthday, and an autopsy was requested but parental permission for the autopsy was denied.

Select “**Autopsy Permission Not Requested**” if the infant died in your hospital prior to discharge home or first birthday and no autopsy was requested.

Select “**Unknown**” if it is not known whether the infant died, or if it is not known whether an autopsy was requested or performed.

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CHAPTER 8

Hypothermic Therapy Form Definitions

The Hypothermic Therapy Form includes data items related to methods of hypothermic therapy used, adverse events and the locations, dates and times of cooling. Complete this form for infants who receive hypothermic therapy prior to discharge home, first birthday or death, whichever is soonest, regardless of where hypothermic therapy was received. This form is only completed if the infant received hypothermic therapy and did not meet the delivery room death criteria.

ITEM HT1: Cooling Location and Method

Indicate whether cooling occurred at the hospital from which the infant transferred (outborn infants only), during transport (outborn infants only), at your hospital (all infants), during transport to another hospital (only infants who transferred from your center to another hospital without having gone home) and at the hospital to which the center transferred (only infants who transferred from your center to another hospital without having gone home). If cooling was performed at the hospital from which the infant was transferred, during transport to your hospital, or at the hospital to which the infant was transferred from your center, record the name and location of the hospital from or to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

For each site at which hypothermic therapy was performed, indicate the method of cooling used. If no cooling at that site, indicate “None”. The following definitions of the types of hypothermic therapy apply to the selection categories for each site (questions a. through e. below).

“Selective Head” Cooling: Active cooling restricted to the head and brain. An intervention to reduce the temperature of the head and brain by exposing the head to lower than environmental temperature. Specially designed head cooling devices, other cooling devices and ice packs applied to the head would be considered active cooling. Passive exposure to environmental temperature and cooling of the face for treatment of supraventricular tachycardia are not considered active cooling of the head and brain.

“Whole Body” Cooling: Active cooling of the body not restricted to the head and brain. An intervention to reduce the core body temperature and temperature of the brain by exposing the body to lower than environmental temperature. Cooling

blankets, other cooling devices and ice packs applied to the body would be considered active cooling. Passive exposure to environmental temperature would not be considered active cooling. Whole body cooling may include cooling of the head in addition to the rest of the body.

“Unknown”: It is not known whether active selective head or whole body cooling was performed.

a. Cooling at Hospital from which Infant Transferred (outborn infants only)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy at the Hospital from which Tranferred?

Select **“Not Outborn”** if the infant is inborn.

Select **“Yes”** if the infant is outborn and either selective head or whole body cooling was provided at the hospital from which the infant was transferred.

Select **“No”** if the infant is outborn and neither selective head nor whole body cooling was provided at the hospital from which the infant was transferred.

Select **“Unknown”** if the infant is outborn and it is not known whether selective head or whole body cooling was provided at the hospital from which the infant was transferred.

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method at the Hospital from which Transferred

Choose the method of cooling at the hospital from which the infant was transferred to your center. Choose **“Selective Head”** cooling, **“Whole Body”** cooling or **“Unknown”** using the above definitions.

(3) Hospital from which Infant Transferred

Enter the name and location of the hospital from which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

b. Cooling During Transport to Your Hospital (outborn infants only)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy during Transport to Your Hospital?

Select “**Not Outborn**” if the infant is inborn.

Select “**Yes**” if the infant is outborn and received either selective head or whole body cooling during transport to your hospital.

Select “**No**” if the infant is outborn and neither selective head nor whole body cooling was provided during transport to your hospital.

Select “**Unknown**” if the infant is outborn and it is not known whether the infant received either selective head or whole body cooling during transport to your hospital.

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method during Transport to Your Hospital

Choose the method of cooling during transport to your hospital. Choose “**Selective Head**” cooling, “**Whole Body**” cooling or “**Unknown**” using the above definitions.

(3) Hospital from which Infant Transferred

Enter the name and location of the hospital from which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

c. Cooling at Your Hospital

(1) Hypothermic Therapy at Your Hospital?

Select **“Yes”** if either selective head or whole body cooling was provided at your hospital.

Select **“No”** if neither selective head nor whole body cooling was provided at your hospital.

Select **“Unknown”** if it is not known whether selective head or whole body cooling was provided at your hospital.

If “Yes” to (1), answer question (2).

(2) Cooling Method at Your Hospital

Choose the method of cooling at your hospital. Choose **“Selective Head”** cooling, **“Whole Body”** cooling or **“Unknown”** using the above definitions.

d. Cooling During Transport from Your Hospital (only infants who transfer from you center to another hospital without having gone home)

<p>NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.</p>
--

(1) Hypothermic Therapy during Transport from Your Hospital?

Select **“Not Transferred”** if the infant is not transferred from your center to another hospital.

Select **“Yes”** if the infant was transferred from your center to another hospital and received either selective head or whole body cooling during transport to the other hospital.

Select **“No”** if the infant was transferred from your center to another hospital and did not receive either selective head or whole body cooling during transport to the other hospital.

Select **“Unknown”** if the infant was transferred from your center to another hospital and it is not known whether the infant received either selective head or whole body cooling during transport to the other hospital.

If “Yes” to (1), answer question (2) below.

(2) Cooling Method during Transport from Your Hospital

Choose the method of cooling during transport from your hospital. Choose “**Selective Head**” cooling, “**Whole Body**” cooling, “**None**” or “**Unknown**” using the above definitions.

(3) Hospital to which Infant Transferred

Enter the name and location of the hospital to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

e. Cooling at Hospital to which Infant Transferred (only infants who transfer from your center to another hospital without having gone home)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy at the Hospital to which Transferred?

Select “**Not Transferred**” if the infant did not transfer to another hospital.

Select “**Yes**” if the infant was transferred from your center to another hospital and either selective head or whole body cooling was provided at the hospital to which the infant was transferred.

Select “**No**” if the infant was transferred from your center to another hospital and neither selective head nor whole body cooling was provided at the hospital to which the infant was transferred.

Select “**Unknown**” if the infant was transferred from your center to another hospital and it is not known whether selective head or whole body cooling was provided at the hospital to which the infant was transferred.

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method at the Hospital to which Transferred

Choose the method of cooling at the hospital to which the infant was transferred from your center. Choose “**Selective Head**” cooling, “**Whole Body**” cooling or “**Unknown**” using the above definitions.

(3) Hospital to which Infant Transferred

Enter the name and location of the hospital to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

ITEM HT2: Age Hypothermic Therapy Began

NOTE: The date and time that hypothermic therapy began is protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. Only the age that hypothermic therapy began will be exported to VON.

If the date is known but the time is uncertain, enter the best estimate for time.

Date Began (mm/dd/yyyy):

Enter the date that hypothermic therapy first began, as recorded in the infant medical record. Use the mm/dd/yyyy format (for example 06/06/2006 for June 6, 2006).

Time Began (hh:mm AM/PM):

Enter the time that hypothermic therapy first began, as recorded in the infant medical record. Use AM or PM and hh:mm format (for example 10:15 AM for 10:15 in the morning).

a. Age Hypothermic Therapy Began, Days

The Age Hypothermic Therapy Began, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

b. Age Hypothermic Therapy Began, Hours

The Age Hypothermic Therapy Began, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. The number of hours can vary between 0 and 23.

c. Age Hypothermic Therapy Began, Minutes

The Age Hypothermic Therapy Began, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. The number of minutes can vary between 0 and 59.

ITEM HT3: Age Hypothermic Therapy Stopped

NOTE: The date and time that hypothermic therapy stopped is protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. Only the age that hypothermic therapy began will be exported to VON.

Hypothermic therapy is considered stopped when all active cooling is stopped. This occurs when cooling devices are turned off, removed or set to ambient temperature. At this point the process of re-warming is considered to begin, even if no additional heating is provided. If cooling is interrupted and is re-started, record the last date and time that hypothermic therapy stops. If the date is known but the time is uncertain, enter the best estimate for time.

Date Hypothermic Therapy Stopped (mm/dd/yyyy):

Enter the date that hypothermic therapy was stopped, as recorded in the infant medical record. Use the mm/dd/yyyy format (for example 06/06/2006 for June 6, 2006).

Time Hypothermic Therapy Stopped (hh:mm AM/PM):

Enter the time that hypothermic therapy was stopped, as recorded in the infant medical record. Use AM or PM and hh:mm format (for example 10:15 AM for 10:15 in the morning).

a. Age Hypothermic Therapy Stopped, Days

The Age Hypothermic Therapy Stopped, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

b. Age Hypothermic Therapy Stopped, Hours

The Age Hypothermic Therapy Stopped, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. The number of hours can vary between 0 and 23.

c. Age Hypothermic Therapy Stopped, Minutes

The Age Hypothermic Therapy Stopped, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. The number of minutes can vary between 0 and 59.

ITEM HT4: Core Body Temperature when Hypothermic Therapy Stopped

Hypothermic therapy is considered stopped when all active cooling is stopped. This occurs when cooling devices are turned off, removed or set to ambient temperature. At this point the process of re-warming is considered to begin, even if no additional heating is provided.

a. Temperature Measured when Hypothermic Therapy Stopped

Select “**Yes**” if the core body temperature was recorded in the infant medical record at the time active cooling was stopped and re-warming began (\pm 10 minutes). If “**Yes**”, answer question b. below. Core body temperature can be measured as rectal, esophageal, tympanic, or axillary temperature.

Select “**No**” if the core body temperature was not recorded in the infant medical record at the time active cooling was stopped and re-warming began (\pm 10 minutes). If “**No**”, do not answer question b. below.

Select “**Unknown**” if the core body temperature when hypothermic therapy stopped cannot be determined.

b. Temperature when Hypothermic Therapy Stopped

If “Yes” to question a. above, record the core body temperature measured closest in time to when hypothermic therapy stopped and the units in which it was recorded (Centigrade). Record rectal, esophageal, tympanic or axillary temperature using a single decimal place, e.g. 36.7° C. If cooling is interrupted and is re-started, record the temperature when hypothermic therapy was finally stopped.

ITEM HT5: Age Re-Warming Completed

NOTE: The date and time that re-warming was completed is protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. Only the age that re-warming was completed will be exported to VON.

Enter the date and time that re-warming was completed. This is defined as the time at which a core body temperature of 36.5 degrees Centigrade (97.7 degrees F) or greater was first reached during re-warming. If the date is known but the time is uncertain, enter the best estimate for time.

Date Completed (mm/dd/yyyy):

Enter the date that re-warming was completed, as recorded in the infant medical record. Use the mm/dd/yyyy format (for example 07/06/2006 for July 6, 2006).

Time Completed (hh:mm AM/PM):

Enter the time that re-warming was completed, as recorded in the infant medical record. Use AM or PM and hh:mm format (for example 10:15 AM for 10:15 in the morning).

a. Age Re-Warming Completed, Days

The Age Hypothermic Re-Warming Completed, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

b. Age Re-Warming Completed, Hours

The Age Re-Warming Completed, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. The number of hours can vary between 0 and 23.

c. Age Re-Warming Completed, Minutes

The Age Re-Warming Completed, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. The number of minutes can vary between 0 and 59.

ITEM HT6: Cooling Interruptions

a. Was Cooling Interrupted for More than 30 Minutes?

Select “**Yes**” if, after cooling was started, it was interrupted for more than 30 consecutive minutes for any reason and then restarted. If “**Yes**”, answer question b. below.

Select “**No**” if, after cooling was started, it was never interrupted for more than 30 consecutive minutes for any reason and then restarted. If “**No**”, do not answer question b. below.

Select “**Unknown**” if, after cooling was started, it is not known whether cooling was ever interrupted for more than 30 consecutive minutes for any reason and then restarted. If “**Unknown**”, do not answer question b. below.

b. Number of Cooling Interruptions

If “**Yes**” to question a. above, record the number of times cooling was interrupted for more than 30 minutes in the space provided.

ITEM HT7: Cooling as Part of a Randomized Controlled Trial?

Select “**Yes**” if the infant was enrolled in a randomized controlled trial (RCT), in which random assignment determined the details of the cooling treatment. The RCT could compare cooling to no treatment or placebo, or could compare different methods, protocols or devices for cooling.

Select “**No**” if the infant was not enrolled in a RCT in which random assignment determined the details of the cooling treatment. The RCT could compare cooling to no treatment or placebo, or could compare different methods, protocols or devices for cooling.

Select “**Unknown**” if it is not known whether or not the infant was enrolled in an RCT that determined the details of the cooling treatment.

ITEM HT8: Adverse Events within 7 Days of Birth

NOTE: The date of birth counts as Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, then Day 7 would be September 7 – the period from September 1 to 7 would be evaluated in answering the questions for this item.

a. Cardiac Arrhythmia within 7 Days of Birth?

Select “**Yes**” if a cardiac arrhythmia occurred at any time within seven days of birth. If “**Yes**”, answer questions (1) through (7) below. For each question, answer “**Yes**” if the adverse event occurred or “**No**” if the adverse event did not occur.

Select “**No**” if a cardiac arrhythmia did not occur at any time within seven days of birth. If “**No**”, do not answer questions (1) through (7) below.

Select “**Unknown**” if it cannot be determined whether the adverse event(s) occurred.

- 1) Sinus Bradycardia?
- 2) Sinus Tachycardia?
- 3) Ventricular Tachycardia?
- 4) Ventricular Fibrillation?
- 5) Conduction Block?
- 6) Prolonged QT Interval?
- 7) Other Arrhythmia? If “Yes”, describe the adverse event in the space provided.

b. Thrombosis within 7 Days of Birth?

Select “**Yes**” if thrombosis not related to an infusion line occurred at any time within seven days of birth.

Select “**No**” if thrombosis not related to an infusion line did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether thrombosis occurred within 7 days of birth.

c. Severe Hypotension within 7 Days of Birth?

Select “**Yes**” if severe hypotension requiring treatment with pressors or hydrocortisone occurred at any time within seven days of birth.

Select “**No**” if severe hypotension requiring treatment with pressors or hydrocortisone did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether severe hypotension occurred within 7 days of birth.

d. Seizure during Re-Warming within 7 Days of Birth?

Clinical seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation). Electroencephalographic (EEG) seizures may be diagnosed by full channel EEG or bedside aEEG.

Select “**Yes**” if clinical or EEG seizures during re-warming occurred at any time within seven days of birth.

Select “**No**” if clinical or EEG seizures during re-warming did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether seizure during re-Warming occurred within 7 days of birth.

e. Scalp Edema within 7 Days of Birth?

Select “**Yes**” if scalp edema occurred at any time within seven days of birth.

Select “**No**” if scalp edema did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether scalp edema occurred within 7 days of birth.

f. Skin Breakdown within 7 Days of Birth?

Select “**Yes**” if skin breakdown occurred at any time within seven days of birth.

Select “**No**” if skin breakdown did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether skin breakdown occurred within 7 days of birth.

g. Sclerema Neonatorum within 7 Days of Birth?

Select “**Yes**” if sclerema neonatorum occurred at any time within seven days of birth.

Select “**No**” if sclerema neonatorum did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether sclerema neonatorum occurred within 7 days of birth.

h. Thrombocytopenia within 7 Days of Birth?

Select “**Yes**” if thrombocytopenia occurred at any time within seven days of birth.

Select “**No**” if thrombocytopenia did not occur at any time within seven days of birth.

Select “**Unknown**” if it cannot be determined whether thrombocytopenia occurred within 7 days of birth.

ITEM HT9: Seizures Prior to Cooling?

a. Were seizures noted prior to cooling?

Select **“Yes”** if clinical, aEEG, or EEG seizures were present prior to the beginning of cooling.

Select **“No”** if clinical, aEEG, or EEG seizures were not present prior to the beginning of cooling.

Select **“Unknown”** if it cannot be determined whether seizures occurred prior to cooling.

b. Diagnosis of Seizures Prior to Cooling

Seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation). Electroencephalo-graphic (EEG) seizures may be diagnosed by full channel EEG or bedside aEEG.

(1) Clinical Diagnosis of Seizures Prior to Cooling

Select **“Yes”** if seizures were clinically diagnosed prior to the beginning of cooling.

Select **“No”** if seizures were not clinically diagnosed prior to the beginning of cooling.

Select **“Unknown”** if it is not known whether seizures were clinically diagnosed prior to the beginning of cooling.

(2) aEEG Diagnosis of Seizures Prior to Cooling

Select **“Yes”** if seizures were diagnosed by bedside aEEG prior to the beginning of cooling.

Select **“No”** if seizures were not diagnosed by bedside aEEG prior to the beginning of cooling.

Select **“Unknown”** if it is not known whether seizures were diagnosed by bedside aEEG prior to the beginning of cooling.

(3) EEG Diagnosis of Seizures Prior to Cooling

Select **“Yes”** if seizures were diagnosed by full channel EEG prior to the beginning of cooling.

Select **“No”** if seizures were not diagnosed by bedside full channel EEG prior to the beginning of cooling.

Select **“Unknown”** if it is not known whether seizures were diagnosed by full channel EEG prior to the beginning of cooling.

ITEM HT10: Modified SARNAT Stage Prior to Cooling

Record the modified SARNAT Stage obtained before active cooling started. Use the table in Appendix A to determine the Modified SARNAT Stage. Record the modified SARNAT Stage as “0”, “1”, “2” or “3” based on the category that fits most closely. Normal is scored as “0”. If the score was not determined or is unknown, record “9”.

ITEM HT11: Full channel EEG Prior to Cooling

a. Full channel EEG performed Prior to Cooling?

Select **“Yes”** if a full channel electroencephalogram (EEG) was performed prior to cooling.

Select **“No”** if a full channel electroencephalogram (EEG) was not performed prior to cooling.

Select **“Unknown”** if it is not known whether a full channel EEG was performed prior to cooling.

b. Full channel EEG performed Prior to Cooling Background Pattern

If a full channel EEG was performed at your hospital prior to cooling, select the one category that most closely describes the worst EEG background pattern observed on any EEG prior to the application of any cooling therapy.

Select **“Normal”** if the background pattern is normal in continuity, amplitude, and frequency for gestational age.

Select **“Excessively Discontinuous”** if the background pattern is excessively discontinuous (‘dysmature’) for gestational age.

Select **“Burst Suppression Pattern”** if a burst suppression pattern is present or a severely depressed background is present.

Select “**Background Iso-Electric**” if the background pattern shows no recognizable electro-cortical activity.

Select “**Unknown**” if the worst background pattern is not known.

ITEM HT12: Bedside aEEG Prior to Cooling

a. Bedside aEEG prior to cooling

Select “**Yes**” if a bedside amplitude integrated EEG (aEEG) was performed prior to cooling.

Select “**No**” if a bedside amplitude integrated EEG (aEEG) was not performed prior to cooling.

Select “**Unknown**” if it is not known whether a bedside amplitude integrated EEG (aEEG) was performed prior to cooling.

b. Bedside aEEG Background Pattern

If a bedside aEEG was performed at your hospital prior to cooling, select the one category that most closely describes the worst EEG background pattern observed on any aEEG prior to the application of any cooling therapy.

NOTE: A minimum of one hour recording with low electrode impedance and the absence of continuous seizures should be available in order to classify the worst background. The output appears as a thick dense band on the chart. The lower margin of the dense band represents the minimum degree of cerebral activity. A line is drawn through the upper margin and the lower margin of the dense band of the aEEG and the voltage measured from these marked lines with the scale on the printed record.

Select “**Normal**” if the upper margin of the dense EEG band is greater than 10 μ V and the lower margin is greater than 5 μ V.

Select “**Moderately Abnormal or Discontinuous**” if the upper margin of the dense aEEG band is greater than 10 μ V and the lower margin is less than 5 μ V.

Select “**Severely Abnormal**” if the upper margin of the dense aEEG band is less than 10 μ V and the lower margin is less than 5 μ V.

Select “**Unknown**” if the worst aEEG background pattern is not known. If there is less than one hour of recording with low electrode impedance and absence of continuous EEG seizures is available, the worst background cannot be determined and “Unknown” should be selected.

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APPENDIX A

Modified Sarnat Stage

Modified Sarnat Stage *			
STAGE **	Stage 1	Stage 2	Stage 3
Level of Consciousness	Hyperalert	Lethargic or obtunded	Stupor or coma
Activity	Normal	Decreased	Absent
Neuromuscular Control			
Muscle Tone	Normal	Mild hypotonia	Flaccid
Posture	Mild distal flexion	Strong distal flexion	Intermittent decerebration (extension)
Stretch Reflexes	Overactive	Overactive	Decreased or absent
Complex / Primitive Reflexes			
Suck	Weak	Weak or absent	Absent
Moro (startle)	Strong; low threshold	Weak; incomplete; high threshold	Absent
Tonic Neck	Slight	Strong	Absent
Autonomic Function			
Pupils	Mydriasis	Miosis	Variable; often unequal; poor light reflex; fixed; dilated
Heart Rate	Tachycardia	Bradycardia	Variable
Seizures	None	Common; focal or multifocal	Uncommon (excluding decerebration)

* Sarnat H.B., Sarnat M.S.: Neonatal encephalopathy following fetal distress. Arch Neurol. 33:698-705. 1976.

** STAGE 0 = Normal

APPENDIX B

NER Booklet for 2009

VERMONT OXFORD NETWORK NER Booklet for 2010

Center Number: _____

Network ID Number:

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The Neonatal Encephalopathy Registry (NER) forms are provided to aid Registry participants in collecting and organizing NER patient data. **Since data on some of the forms include patient identifiers, do not submit this booklet or any of the paper forms to the Vermont Oxford Network.** All Registry data collected should be submitted to the Vermont Oxford Network as electronic files using the Network's *eNICQ* software. Data files submitted using the *eNICQ* software do not include any protected health care information, as defined by the U.S. Health Insurance Portability and Accountability Act of 1996. No dates or times will be exported to the Vermont Oxford Network. The Vermont Oxford Network does not accept protected health care information.

Contents:

- I: Eligibility Form
- II: OB/Initial Status Form
- III: Neurological Form
- IV: Diagnoses and Discharge Form
- V: Hypothermic Therapy Form (only for infants who received hypothermic therapy.)

I. ELIGIBILITY FORM

(Expanded centers complete this form for all infants eligible for the Expanded Database; VLBW centers verify eligibility for all eligible NICU infants and complete this form for all infants eligible for the Registry).

EL1. Hypothermic Therapy Received?

Yes No Unknown

EL2. Gestational Age \geq 36 Weeks 0 Days or More?

Yes No Unknown

If yes to EL2, answer items EL3 through EL 8 below.

EL3. Major CNS Congenital Malformation?

Yes No Unknown

EL4. Stupor or Coma within 72 Hours?

Yes No Unknown

EL5. Seizures within 72 Hours?

Yes No Unknown

EL6. Paralysis Induced for First 72 Hours?

Yes No Unknown

EL7. APGAR Score at 5 Minutes of 3 or Less?

Yes No Unknown

EL8. Eligible for NER?

Yes No



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1

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

II. OB/INITIAL STATUS FORM (complete this form for all infants who are eligible for the Registry and who did not die in the delivery room/initial resuscitation area).

PART A. OBSTETRIC-PERINATAL HISTORY

OB1. Mode of Delivery (select one):

- Vaginal without Vacuum or Forceps
- Vacuum and/or Forceps Assisted Vaginal
- C Section before Labor Started
- C Section after Labor Started
- C Section after Failed Vacuum or Forceps Delivery
- Unknown

OB2. Presentation (select one):

- Vertex
- Breech
- Transverse
- Other
- Unknown

OB3. Ruptured Membranes 24 Hours or More Prior to Delivery?

- Yes
- No
- Unknown

OB4. Cord Prolapse?

- Yes
- No
- Unknown

OB5. Uterine Rupture?

- Yes
- No
- Unknown

OB6. Antepartum Hemorrhage?

- Yes
- No
- Unknown

OB7. Chorioamnionitis?

- Yes
- No
- Unknown

OB8. Maternal Temperature during Labor and Delivery:

a. Maternal Temperature Recorded?

- Yes
- No
- Unknown

b. Temperature of Mother: Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown

Record the highest intrapartum maternal temperature and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: ° C ° F

OB9. Antenatal Magnesium Exposure:

- Yes
- No
- Unknown



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01/06/2010 2

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

OB10. Maternal Hypertension, Pre-eclampsia, or Eclampsia?

Yes No Unknown

OB11. Maternal Diabetes?

Yes No Unknown

OB12. Maternal Hypothyroidism?

Yes No Unknown

OB13. Non-Reassuring Fetal Assessment:

a. Bradycardia Prior to Delivery?

Yes No Unknown

b. Tachycardia Prior to Delivery?

Yes No Unknown

c. Decreased FHR Variability Prior to Delivery?

Yes No Unknown

d. Prolonged or Recurrent Decelerations Prior to Delivery?

Yes No Unknown

OB14. Umbilical Cord Blood Sampling:

a. Cord Blood Sampling Performed?

Yes No Unknown

If "Yes" to a, answer questions b and c below.

b. pH from Cord Blood Sample: Range: 5.00-8.00, 77.77=N/A, 99.9=Unknown

Record the lowest cord blood pH to 2 decimal places: .

c. Base Deficit from Cord Blood Sample: Range: -20.0 to 40.0, 77.7=N/A, 99.9=Unknown

Record the worst cord blood base deficit (mmoles/liter) to the nearest tenth (base deficit is normally a positive number): +/- .

OB15. Assisted Reproduction?

Yes No Unknown

OB16. Placenta Sent for Pathology?

Yes No Unknown



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3

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

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PART B, INFANT'S INITIAL CLINICAL STATUS

Date and Time of Birth:

****Date of Birth (mm/dd/yyyy):** ____/____/____

****Time of Birth (hh/mm AM/PM):** ____:____ AM PM

OB17a. Infant Admitted to your NICU?

Yes No

If Yes to a, enter **Age at Admission:**

Date of Admission: ____/____/____ Time of Admission: ____:____ AM PM

b. Age, Days: ____ **c. Age, Hours:** ____ **d. Age, Minutes:** ____

OB18. APGAR Score at 10 Minutes: Range: 0-10, 99=Unknown _____

OB19. Assisted Ventilation at 10 Minutes?

Yes No Unknown

OB20. Infant Arterial, Venous, or Capillary Blood Gas:

a. Arterial, Venous, or Capillary Blood Gas Obtained During First Hour of Life?

Yes No Unknown

If "Yes" to a, answer questions b and c below.

b. pH from Arterial, Venous, or Capillary Blood Gas: Range: 5.00-8.00, 77.77=N/A, 99.99=Unknown

Record the lowest arterial, venous, or capillary pH obtained within the first hour of

life to 2 decimal places: .

c. Base Deficit from Arterial, Venous, or Capillary Blood Gas:

Range: -20.0 to 40.0, 77.7=N/A, 99.9=Unknown

Record the worst arterial, venous, or capillary base deficit obtained within the first hour

of life to the nearest tenth (base deficit is normally a positive number): +/- .



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4

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

OB21. Temperature of Infant:

a. Infant Temperature Recorded within 72 Hours of Birth?

Yes No Unknown

If "Yes" to a, answer questions b and c below.

b. Highest Temperature of Infant: Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown
Record the highest temperature within 72 hours of birth and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: . ° C ° F

c. Lowest Temperature of Infant: Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown
Record the lowest temperature within 72 hours of birth and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: . ° C ° F



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5

VERMONT OXFORD NETWORK NER Booklet for 2010

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Center Number: _____ Network ID Number: _____

III. NEUROLOGICAL FORM

PART A, NEUROLOGICAL INDICATORS ON DAY 1 (≤ 6 HOURS AND 6 TO 24 HOURS)

	A Neuro Status Day 1 (≤ 6 Hours)	B Neuro Status Day 1 (>6-24 Hours)
NU1. Infant Alive During Examination Period? See Manual of Operations	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
NU2. Paralysis for the Entire Examination Period?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
If infant was alive and not paralyzed during the examination period, complete item NU3 through NU11 below based on the <u>worst</u> state during the examination period.		
NU3. Conscious State: (Select the worst)	<input type="checkbox"/> Normal <input type="checkbox"/> Irritability <input type="checkbox"/> Lethargy <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Stupor <input type="checkbox"/> Coma <input type="checkbox"/> Normal <input type="checkbox"/> Irritability <input type="checkbox"/> Lethargy <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU4. Brainstem Function:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A
NU5. Movements:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A
NU6. Posturing:	<input type="checkbox"/> Present <input type="checkbox"/> Unknown <input type="checkbox"/> Absent <input type="checkbox"/> N/A	<input type="checkbox"/> Present <input type="checkbox"/> Unknown <input type="checkbox"/> Absent <input type="checkbox"/> N/A
NU7. Tone:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A
NU8. Reflexes:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> Abnormal <input type="checkbox"/> N/A
NU9. Feeding:	<input type="checkbox"/> No enteral feedings <input type="checkbox"/> No feedings by mouth <input type="checkbox"/> Some feedings by mouth <input type="checkbox"/> All feedings by mouth <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> No enteral feedings <input type="checkbox"/> No feedings by mouth <input type="checkbox"/> Some feedings by mouth <input type="checkbox"/> All feedings by mouth <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU10. Assisted Ventilation?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU11. Clinical Seizures?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A



VERMONT OXFORD NETWORK NER Booklet for 2010

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Center Number: _____ Network ID Number: _____

III. NEUROLOGICAL FORM

PART A CONTINUED, NEUROLOGICAL INDICATORS ON DAY 3 AND DAY 7 (± 1 DAY)

	C Neuro Status Day 3	D Neuro Status Day 7 (± 1 Day)
NU1. Infant Alive During Examination Period? <small>See Manual of Operations</small>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
NU2. Paralysis for the Entire Examination Period?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
If infant was alive and not paralyzed during the examination period, complete item NU3 through NU11 below based on the <u>worst</u> state during the examination period.		
NU3. Conscious State: <small>(Select the worst)</small>	<input type="checkbox"/> Normal <input type="checkbox"/> Irritability <input type="checkbox"/> Lethargy <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Irritability <input type="checkbox"/> Lethargy <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Stupor <input type="checkbox"/> Coma
NU4. Brainstem Function:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Abnormal
NU5. Movements:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Abnormal
NU6. Posturing:	<input type="checkbox"/> Present <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Present <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Absent
NU7. Tone:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Abnormal
NU8. Reflexes:	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Normal <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> Abnormal
NU9. Feeding:	<input type="checkbox"/> No enteral feedings <input type="checkbox"/> No feedings by mouth <input type="checkbox"/> Some feedings by mouth <input type="checkbox"/> All feedings by mouth <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> No enteral feedings <input type="checkbox"/> No feedings by mouth <input type="checkbox"/> Some feedings by mouth <input type="checkbox"/> All feedings by mouth <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU10. Assisted Ventilation?	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> No
NU11. Clinical Seizures?	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> N/A <input type="checkbox"/> No



**VERMONT OXFORD NETWORK
NER Booklet for 2010**

Center Number: _____

Network ID Number:

III. NEUROLOGICAL FORM

PART B, ELECTROPHYSIOLOGY, SEIZURES AND ANTICONVULSANTS

NU12. Full Channel EEG:

a. Full Channel EEG Performed?

Yes No Unknown

b. EEG Background Pattern:

If "Yes" to a, select worst observed background pattern (select one):

- Normal
- Excessively Discontinuous
- Depressed Amplitude
- Burst Suppression Pattern
- Background Iso-Electric
- Unknown
- N/A

NU13. Bedside aEEG:

a. Bedside aEEG Performed?

Yes No Unknown

b. Bedside aEEG Background Pattern:

If "Yes" to a, select worst observed background pattern (select one):

- Normal
- Moderately Abnormal or Discontinuous
- Severely Abnormal
- Unknown
- N/A

NU14. Seizures Prior to Discharge:

a. Seizures Occurred Prior to Discharge?

Yes No Unknown

If "Yes" to a, answer questions b through e below.

b. Evidence of Clinical Seizure?

Yes No Unknown N/A

c. Full Channel EEG Evidence of Seizure?

Yes No Unknown N/A



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01/06/2010 8

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

III. NEUROLOGICAL FORM

d. Bedside aEEG Evidence of Seizure?

Yes No Unknown N/A

e. Age Seizures First Observed:

Date First Observed: ___/___/____ Time First Observed: ___ : ___ AM PM

(1) Days: _____ (2) Hours: _____ (3) Minutes: _____

NU15. Anticonvulsants Prior to Discharge:

a. Anticonvulsants Received Prior to Discharge?

Yes No Unknown

If "Yes" to a, answer questions b through h below.

b. Phenobarbital Prior to Discharge?

Yes No Unknown N/A

c. Phenytoin or Fosphenytoin Prior to Discharge?

Yes No Unknown N/A

d. Lorazepam Prior to Discharge?

Yes No Unknown N/A

e. Diazepam Prior to Discharge?

Yes No Unknown N/A

f. Midazolam Prior to Discharge?

Yes No Unknown N/A

g. Topiramate Prior to Discharge?

Yes No Unknown N/A

h. Other Anticonvulsants Prior to Discharge:

(1) Were Other Anticonvulsants Given Prior to Discharge?

Yes No Unknown N/A

(2) If "Yes", specify which other anticonvulsants: _____
(see Appendix D of NER Manual of Operations)



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9

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Center Number: _____

Network ID Number:

III. NEUROLOGICAL FORM

PART C. NEUROIMAGING

	A Cranial US Exam(s)	B CT Scan(s)	C MRI Scan(s)
NU16 Exam or Scan Performed?	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> No
NU17 Day of First Exam/Scan:	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>
NU18 Day of Last Exam/Scan:	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>	Date: ____/____/____ Time: ____:____ AM <input type="checkbox"/> PM <input type="checkbox"/>
NU19 Intraventricular Hemorrhage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU20 Extra-axial, Subdural or Subarachnoid Hemorrhage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU21 Intraparenchymal Hemorrhage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU22 Subependymal Hemorrhage?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU23 Abnormality in Deep Nuclear Gray Matter?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU24 Cystic White Matter Injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU25 Diffuse White Matter Injury?			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU26 Ventriculomegaly?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU27 Veno-Occlusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU28 Arterial Occlusion?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU29 Brainstem Injury?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU30 Cerebellar Injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU31 Diffuse Cortical Signal Abnormality?			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU32 Parasagittal Watershed Cortical Gray Matter Injury?			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU33 Absence of Posterior Limb of Internal Capsule?			<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A
NU34 Other Intracranial Abnormalities If "Yes", describe	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A __	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A __	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A __

Note: Shaded items indicate the item does not apply to this type of exam/scan.



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10

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

IV. DIAGNOSES AND DISCHARGE FORM

PART A. DIAGNOSES

DD1. Persistent Pulmonary Hypertension of the Newborn, PPHN?

Yes No Unknown

DD2. Renal Failure?

Yes No Unknown

DD3. Syndrome of Inappropriate Secretion of Antidiuretic Hormone, SIADH?

Yes No Unknown

DD4. Disseminated Intravascular Coagulation, DIC?

Yes No Unknown

DD5. Hepatic Dysfunction?

Yes No Unknown

DD6. Hyperbilirubinemia within 7 Days of Birth?

Yes No Unknown

DD7. Cardiac Dysfunction?

Yes No Unknown

DD8. Prenatal TORCH Infection:

a. Prenatal TORCH Infection Present?

Yes No Unknown

If "Yes" to a, indicate which of the prenatal infections in b through f below were present.

b. Toxoplasmosis?

Yes No Unknown N/A

c. Rubella?

Yes No Unknown N/A

d. Syphilis?

Yes No Unknown N/A

e. Cytomegalovirus?

Yes No Unknown N/A

f. Herpes Simplex?

Yes No Unknown N/A



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11

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

DD9. Congenital Neuromuscular Disorder?

a. Congenital Neuromuscular Disorder Present?

Yes No Unknown

b. If "Yes", describe: _____

DD10. Birth Trauma?

a. Traumatic Birth Injury?

Yes No Unknown

If "Yes" to a, answer questions b through h below:

b. Spinal Cord Injury?

Yes No Unknown N/A

c. Brachial Plexus Injury?

Yes No Unknown N/A

d. Skull Fracture?

Yes No Unknown N/A

e. Long Bone Fracture?

Yes No Unknown N/A

f. Clavicle Fracture?

Yes No Unknown N/A

g. Cephalhematoma?

Yes No Unknown N/A

h. Other Traumatic Birth Injury?

(1) Other Traumatic Birth Injury Observed?

Yes No Unknown N/A

(2) If "Yes", describe: _____

DD11. Meningitis or Encephalitis:

a. Meningitis or Encephalitis Suspected or Proven?

Yes No Unknown

If "Yes" to a, complete the questions below.

b. Bacterial Meningitis or Encephalitis:

None Suspected Proven

If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.



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12

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

(1) Onset of Bacterial Meningitis or Encephalitis:

Early Late Unknown N/A

(2) Name of Bacterial Meningitis or Encephalitis Organism:

c. Fungal Meningitis or Encephalitis:

None Suspected Proven Unknown N/A

If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.

(1) Onset of Fungal Meningitis or Encephalitis:

Early Late Unknown N/A

(2) Name of Fungal Meningitis or Encephalitis Organism:

d. Viral Meningitis or Encephalitis:

None Suspected Proven Unknown N/A

If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.

(1) Onset of Viral Meningitis or Encephalitis:

Early Late Unknown N/A

(2) Name of Viral Meningitis or Encephalitis Organism:

PART B. DISCHARGE STATUS

DD12. Hearing Screening:

a. Hearing Screen Exam Performed?

Yes No Unknown

If "Yes" to a, enter the results of the last exam before discharge.

b. Hearing Screen Passed?

Yes No Unknown N/A

DD13. Feedings at Discharge:

- No Enteral Feedings
- Enteral Feedings, No Feedings by Mouth
- Enteral Feedings, Some Feedings by Mouth
- Enteral Feedings, All Feedings by Mouth
- Unknown



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13

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

DD14. Tracheotomy at Discharge?

Yes No Unknown

DD15. Discharged with Ventilator?

Yes No Unknown

DD16. Anticonvulsant Medication at Discharge?

a. Anticonvulsant Medication at Discharge?

Yes No Unknown

If "Yes" to a, complete questions b through h below:

b. Phenobarbital at Discharge?

Yes No Unknown N/A

c. Phenytoin or Fosphenytoin at Discharge?

Yes No Unknown N/A

d. Lorazepam at Discharge?

Yes No Unknown N/A

e. Diazepam at Discharge?

Yes No Unknown N/A

f. Midazolam at Discharge?

Yes No Unknown N/A

g. Topiramate at Discharge?

Yes No Unknown N/A

h. Other Anticonvulsant at Discharge?

Yes No Unknown N/A

If "Yes", specify which other anticonvulsant(s) _____
(see Appendix D of NER Manual of Operations)

DD17. Autopsy Status:

- N/A
- Autopsy performed
- Autopsy Permission Requested and Denied
- Autopsy Permission Not Requested
- Unknown



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14

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NER Booklet for 2010**

Center Number: _____

Network ID Number:

V. HYPOTHERMIC THERAPY FORM

Complete this form only for eligible infants who received Hypothermic Therapy and who do not meet the delivery room death criteria.

HT1. Cooling Location and Method:

a. Cooling at Hospital from which Infant Transferred (outborn infants only):

(1) Hypothermic Therapy at Hospital from which Transferred?

Not Outborn Yes No Unknown

If "Yes" to (1), answer questions (2) and (3) below.

(2) Cooling Method at Hospital from which Transferred:

Selective Head Whole Body Unknown N/A

(3) Hospital from which Infant Transferred:

(a) Name of Hospital: _____

(b) City: _____ (c) State/Prov./Country: _____

b. Cooling During Transport to Your Hospital (outborn infants only):

(1) Hypothermic Therapy During Transport to Your Hospital?

Not Outborn Yes No Unknown

If "Yes" to (1), answer questions (2) and (3) below.

(2) Cooling Method during Transport to Your Hospital:

Selective Head Whole Body Unknown N/A

(3) Hospital from which Infant Transferred:

(a) Name of Hospital: _____

(b) City: _____ (c) State/Prov./Country: _____

c. Cooling at Your Hospital:

(1) Hypothermic Therapy at Your Hospital?

Yes No Unknown

If "Yes" to (1), answer question (2) below.

(2) Cooling Method at Your Hospital:

Selective Head Whole Body Unknown N/A



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15

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NER Booklet for 2010**

Center Number: _____ Network ID Number:

d. Cooling During Transport from Your Hospital (transferred infants only):

(1) Hypothermic Therapy During Transport from Your Hospital?

Not Transferred Yes No Unknown

If "Yes" to (1), answer questions (2) and (3) below.

(2) Cooling Method during Transport from Your Hospital:

Selective Head Whole Body Unknown N/A

(3) Hospital to which Infant Transferred:

(a) Name of Hospital: _____

(b) City: _____ (c) State/Prov./Country: _____

e. Cooling at Hospital to which Infant Transferred (transferred infants only)

(1) Hypothermic Therapy at Hospital to which Transferred?

Not Transferred Yes No Unknown

If "Yes" to (1), answer questions (2) and (3) below.

(2) Cooling Method at Hospital to which Transferred:

Selective Head Whole Body Unknown N/A

(3) Hospital to which Infant Transferred:

(a) Name of Hospital: _____

(b) City: _____ (c) State/Prov./Country: _____

HT2. Age Hypothermic Therapy Began:

Date Began: ____ / ____ / _____

Time Began: ____ : ____ AM PM

a. Age, Days: ____ b. Age, Hours: ____ c. Minutes: ____

HT3. Age Hypothermic Therapy Stopped:

Date Stopped: ____ / ____ / _____

Time Stopped: ____ : ____ AM PM

a. Age, Days: ____ b. Age, Hours: ____ c. Age, Minutes: ____



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16

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Center Number: _____

Network ID Number:

HT8. Adverse Events within 7 Days of Birth:

a. Cardiac Arrhythmia within 7 Days of Birth?

Yes No Unknown

If "Yes" to a, indicate in (1) through (6) below, the adverse events from Cardiac Arrhythmia:

(1) Sinus Bradycardia? Yes No Unknown N/A

(2) Sinus Tachycardia? Yes No Unknown N/A

(3) Ventricular Tachycardia? Yes No Unknown N/A

(4) Ventricular Fibrillation? Yes No Unknown N/A

(5) Conduction Block? Yes No Unknown N/A

(6) Prolonged QT interval? Yes No Unknown N/A

(7) Other Arrhythmia:

(1) Other Arrhythmia Present?

Yes No Unknown N/A

(2) If Other Arrhythmia, describe: _____

b. Thrombosis within 7 Days of Birth?

Yes No Unknown

c. Severe Hypotension within 7 Days of Birth?

Yes No Unknown

d. Seizure during Re-Warming within 7 Days of Birth?

Yes No Unknown

e. Scalp Edema within 7 Days of Birth?

Yes No Unknown

f. Skin Breakdown within 7 Days of Birth?

Yes No Unknown

g. Sclerema Neonatorum within 7 Days of Birth?

Yes No Unknown

h. Thrombocytopenia within 7 Days of Birth?

Yes No Unknown

HT9. Seizures Prior to Cooling?

a. Were seizures noted prior to cooling?

Yes No Unknown

If "Yes" to a, complete question b below.



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18

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Center Number: _____

Network ID Number:

b. Diagnosis of Seizures Prior to Cooling:

(1) Clinical Diagnosis of Seizures Prior to Cooling?

Yes No Unknown N/A

(2) aEEG Diagnosis of Seizures Prior to Cooling?

Yes No Unknown N/A

(3) EEG Diagnosis of Seizures Prior to Cooling?

Yes No Unknown N/A

HT10. Modified SARNAT Stage Prior to Cooling: Range: 0 to 3, 7=N/A, 9=Unknown

HT11. Full channel EEG Prior to Cooling:

a. Full Channel EEG Performed Prior to Cooling?

Yes No Unknown

If "Yes" to a, select worst background pattern observed prior to cooling (select one).

b. Background Pattern of Full Channel EEG Prior to Cooling:

- Normal
- Excessively Discontinuous
- Depressed Amplitude
- Burst Suppression Pattern
- Background Iso-Electric
- Unknown
- N/A

HT12. Bedside aEEG Prior to Cooling:

a. Bedside aEEG Prior to Cooling?

Yes No Unknown

If "Yes" to a, select worst background pattern observed prior to cooling (select one).

b. Background Pattern of Bedside aEEG Prior to Cooling:

- Normal
- Moderately Abnormal or Discontinuous
- Severely Abnormal
- Unknown
- N/A



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19

APPENDIX C

NER DRD Booklet for 2009

VERMONT OXFORD NETWORK NER DRD Booklet for 2010

Center Number: _____

Network ID Number:

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The Neonatal Encephalopathy Registry (NER) forms are provided to aid Registry participants in collecting and organizing NER patient data for infants who meet the delivery room death criteria specified in the VON Manual of Operations. **Since data on some of the forms include patient identifiers, do not submit this booklet or any of the paper forms to the Vermont Oxford Network.** All Registry data collected should be submitted to the Vermont Oxford Network as electronic files using the Network's *eNICQ* software. Data files submitted using the *eNICQ* software do not include any protected health care information, as defined by the U.S. Health Insurance Portability and Accountability Act of 1996. No dates or times will be exported to the Vermont Oxford Network. The Vermont Oxford Network does not accept protected health care information.

Contents:

- I: Eligibility Form
- II: OB/Initial Status Form
- III: Neurological Form
- IV: Diagnoses and Discharge Form

I. ELIGIBILITY FORM

EL1. Hypothermic Therapy Received?

Yes No Unknown

EL2. Gestational Age \geq 36 Weeks 0 Days or More?

Yes No Unknown

If yes to EL2, answer items EL3 through EL8 below.

EL3. Major CNS Congenital Malformation?

Yes No Unknown

EL4. Stupor or Coma within 72 Hours?

Yes No Unknown

EL5. Seizures within 72 Hours?

Yes No Unknown

EL6. Paralysis Induced for First 72 Hours?

Yes No Unknown

EL7. APGAR Score at 5 Minutes of 3 or Less?

Yes No Unknown

EL8. Eligible for NER?

Yes No



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01/06/2010 1

**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

II. OB/INITIAL STATUS FORM

PART A. OBSTETRIC-PERINATAL HISTORY

OB1. Mode of Delivery (select one):

- Vaginal without Vacuum or Forceps
- Vacuum and/or Forceps Assisted Vaginal
- C Section before Labor Started
- C Section after Labor Started
- C Section after Failed Vacuum or Forceps Delivery
- Unknown

OB2. Presentation (select one):

- Vertex
- Breech
- Transverse
- Other
- Unknown

OB3. Ruptured Membranes 24 Hours or More Prior to Delivery?

- Yes
- No
- Unknown

OB4. Cord Prolapse?

- Yes
- No
- Unknown

OB5. Uterine Rupture?

- Yes
- No
- Unknown

OB6. Antepartum Hemorrhage?

- Yes
- No
- Unknown

OB7. Chorioamnionitis?

- Yes
- No
- Unknown

OB8. Maternal Temperature during Labor and Delivery:

a. Maternal Temperature Recorded?

- Yes
- No
- Unknown

b. Temperature of Mother:

Record the highest intrapartum maternal temperature and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: . ° C ° F

OB9. Antenatal Magnesium Exposure:

- Yes
- No
- Unknown



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01/06/2010 2

**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

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OB10. Maternal Hypertension, Pre-eclampsia, or Eclampsia?

Yes No Unknown

OB11. Maternal Diabetes?

Yes No Unknown

OB12. Maternal Hypothyroidism?

Yes No Unknown

OB13. Non-Reassuring Fetal Assessment:

a. Bradycardia Prior to Delivery?

Yes No Unknown

b. Tachycardia Prior to Delivery?

Yes No Unknown

c. Decreased FHR Variability Prior to Delivery?

Yes No Unknown

d. Prolonged or Recurrent Decelerations Prior to Delivery?

Yes No Unknown

OB14. Umbilical Cord Blood Sampling:

a. Cord Blood Sampling Performed?

Yes No Unknown

If "Yes" to a, answer questions b and c below

b. pH from Cord Blood Sample:

Record the lowest cord blood pH to 2 decimal places:

		.		
--	--	---	--	--

c. Base Deficit from Cord Blood Sample: Range: -20.0 to 40.0, 99.9

Record the worst cord blood base deficit (mmoles/liter) to the

nearest tenth (base deficit is normally a positive number): + / -

		.	
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**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

OB15. Assisted Reproduction?

Yes No Unknown

OB16. Placenta Sent for Pathology?

Yes No Unknown

PART B. INFANT'S INITIAL CLINICAL STATUS

OB17. Age at Admission: Not Applicable

OB18. APGAR Score at 10 Minutes: _____

OB19. Assisted Ventilation at 10 minutes?

Yes No Unknown

OB20. Infant Arterial, Venous, or Capillary Blood Gas:

a. Arterial, Venous, or Capillary Blood Gas Obtained During First Hour of Life?

Yes No Unknown

If "Yes" to a, answer questions b and c below.

b. pH from Arterial, Venous, or Capillary Blood Gas: Range: 5.00-8.00, 99.99

Record the lowest arterial, venous, or capillary pH obtained within the first hour of life to 2 decimal places: .

c. Base Deficit from Arterial, Venous, or Capillary Blood Gas:

Range: -20.0 to 40.0, 99.9

Record the worst arterial, venous, or capillary base deficit obtained within the first hour of life to the nearest tenth (base deficit is normally a positive number): +/- .



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01/06/2010 4

**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

OB21. Temperature of Infant:

a. Infant Temperature Recorded within 72 Hours of Birth?

Yes No Unknown

If "Yes" to a, answer questions b and c below.

b. Highest Temperature of Infant:

Record the highest temperature within 72 hours of birth and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: . ° C ° F

c. Lowest Temperature of Infant:

Record the lowest temperature within 72 hours of birth and the units in which it was recorded.

Use a single decimal place, e.g. 36.7° C or 98.2° F: . ° C ° F



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01/06/2010 5

VERMONT OXFORD NETWORK NER DRD Booklet for 2010

Center Number: _____

Network ID Number:

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III. NEUROLOGICAL

PART A. NEUROLOGICAL INDICATORS ON DAY 1

	Neuro Status Day 1 (< 6 Hours)
NU1. Infant Alive During Examination Period?	<input type="checkbox"/> Yes
NU2. Paralysis for the Entire Examination Period?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If infant was alive and not paralyzed during the examination period, complete item NU3 through NU11 below based on the <u>worst</u> state during the examination period.	
NU3. Conscious State: (Select the worst)	<input type="checkbox"/> Normal <input type="checkbox"/> Irritability <input type="checkbox"/> Lethargy <input type="checkbox"/> Stupor <input type="checkbox"/> Coma <input type="checkbox"/> Unknown
NU4. Brainstem Function:	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
NU5. Movements:	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
NU6. Posturing:	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Unknown
NU7. Tone:	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
NU8. Reflexes:	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Unknown
NU9. Feeding:	<input type="checkbox"/> No enteral feedings <input type="checkbox"/> No feedings by mouth <input type="checkbox"/> Some feedings by mouth <input type="checkbox"/> All feedings by mouth <input type="checkbox"/> Unknown
NU10. Assisted Ventilation?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
NU11. Clinical Seizures?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown



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01/06/2010 6

**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

All Other Neurological Form Items Not Applicable

IV. DIAGNOSES AND DISCHARGE FORM

PART A, DIAGNOSES

DD1 – DD7 Not Applicable

DD8. Prenatal TORCH Infection:

a. Prenatal TORCH Infection Present?

Yes No Unknown

If "Yes" to a, indicate which of the prenatal infections in b through f below were present.

b. Toxoplasmosis?

Yes No Unknown

c. Rubella?

Yes No Unknown

d. Syphilis?

Yes No Unknown

e. Cytomegalovirus?

Yes No Unknown

f. Herpes Simplex?

Yes No Unknown

DD9. Congenital Neuromuscular Disorder?

Yes No Unknown

If "Yes", describe: _____

DD10. Birth Trauma?

a. Traumatic Birth Injury?

Yes No Unknown

If "Yes" to a, answer questions b through h below.

b. Spinal Cord Injury?

Yes No Unknown

c. Brachial Plexus Injury?

Yes No Unknown



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01/06/2010 7

**VERMONT OXFORD NETWORK
NER DRD Booklet for 2010**

Center Number: _____

Network ID Number:

d. Skull Fracture?

Yes No Unknown

e. Long Bone Fracture?

Yes No Unknown

f. Clavicle Fracture?

Yes No Unknown

g. Cephalhematoma?

Yes No Unknown

h. Other Traumatic Birth Injury?

Yes No Unknown

If "Yes", describe: _____

DD11 – DD16 Not Applicable

DD17. Autopsy Status:

- N/A
- Autopsy performed
- Autopsy Permission Requested and Denied
- Autopsy Permission Not Requested
- Unknown

V. HYPOTHERMIC THERAPY FORM

All Items Not Applicable



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01/06/2010 8

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APPENDIX D

Anticonvulsant Drugs: Generic and Trade Names

Generic Name	Trade Name
Carbamazepine	Tegretol®, Carbatrol®, Equetro®
Clonazepam	Klonopin®
Diazepam	Valium®, Diastat®
Fosphenytoin	Cerebyx®
Lamotrigine	Lamictal®
Levetiracetam	Keppra®
Lidocaine	Xylocaine®, Xylocard®
Lignocaine	Xylocaine®, Xylocard®
Lorazepam	Ativan®, Temesta®
Midazolam	Dormicum®, Flormidal®, Versed®, Hypnovel®, Dormonid®
Oxcarbazepine	Tripleptal®, Trexapin®
Paraldehyde	Paral®
Phenobarbital	Luminal®, Solfoton®
Phenytoin	Dilantin®, Phenytek®, Eptoin®, Epanutin®, Diphenin®, Dipheninum®, Phydum™®, Pyridoxine, Vitamin B6
Topiramate	Topamax®
Thiopental	Sodium Pentothal®, Farmotal®, Intraval®, Nesdonal®, Penthiobarbital®, Pentothiobarbital®, Thiomebumal®, Thionembutal®, Thiopentobarbital®, Thiopentobarbitone®, Thiopentobarbituric Acid®, Thiopentone®, Thiothal®, Tiopentale®, Trapanal®
Valproic Acid	Depakote®, Depakene®, Depacon®