

**NEONATAL ENCEPHALOPATHY REGISTRY
FOLLOW-UP**

MANUAL OF OPERATIONS

THE VERMONT OXFORD NETWORK

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I. INTRODUCTION

The Vermont Oxford Network Registry for Neonatal Encephalopathy enrolls newborn infants with documented encephalopathy to identify demographic characteristics, associated perinatal factors, medical treatment, co-morbidities and outcomes. Follow-up of infants enrolled in the registry who have received hypothermic treatment will describe health and neurodevelopmental outcome of these infants at two years (24 months) of age. Longer term follow-up to school age and beyond to identify neurodevelopmental and behavioral correlates of neuroprotective therapy and their predictors will also be planned.

Participation in Registry Follow-up is open to all Vermont Oxford Network member hospitals that are participating in the Registry for Neonatal Encephalopathy. Data will be submitted on paper forms. No protected health care information will be submitted to the Vermont Oxford Network for the Registry Follow-up. There is no additional fee for participation.

Registry Follow-up data will begin to be collected in 2008 for infants born July 1, 2006 and later. Because follow-up data may be included in publications and presentations about hypothermic therapy for neonatal encephalopathy, all participating hospitals must submit a project addendum to their local Institutional Review Board (IRB) for review. A letter indicating Registry Follow-up has been reviewed by and is acceptable to your IRB is required before your center can participate in the Registry Follow-up.

II. PROJECT OVERVIEW

A. Purpose

The purpose of Registry Follow-up is to describe neurodevelopmental and behavioral outcomes of infants who are enrolled in the Vermont Oxford Network Registry for Neonatal Encephalopathy database **and** have received hypothermic therapy. This purpose will be accomplished through a standardized and systematic collection of health and developmental data at two years.

B. Specific Aims

1. To conduct observational research on the two year health and neurodevelopmental outcomes of infants born on or after July 1, 2006, who received hypothermic therapy. Status indicators include survival, growth, medical re-hospitalizations, surgical procedures, neurologic and developmental outcomes.

2. To explore the impact of neuroprotective therapies on outcomes at two years' of age outcome status.
3. To define research questions relevant to the neurodevelopmental and behavioral outcomes for infants enrolled in trials of neuroprotective therapies.
4. To assemble a cohort of infants treated with hypothermia for follow-up at school age and beyond.

C. Background

The prevalence of neonatal encephalopathy has been estimated to be 3.8 per 1000 live term births. The etiology of neonatal encephalopathy is likely multifactorial; the number of cases uniquely attributable to perinatal hypoxic-ischemic injury is unclear.

The Vermont Oxford Network established the Registry for Neonatal Encephalopathy to describe variation in routine practice for the diagnosis and management of neonatal encephalopathy and to identify opportunities to improve the quality of care and safety for infants with encephalopathy. Two year follow-up of infants enrolled in the registry who have received hypothermic treatment will compliment birth hospitalization outcome data to provide a more precise estimate of the effectiveness of hypothermic therapy and neuroprotective therapies.

D. Methods

Follow-up data will be maintained within the Registry for Neonatal Encephalopathy at the Vermont Oxford Network in Burlington, VT. Vermont Oxford Network will provide the staff, space and support services for data collection and analysis associated with follow-up of enrolled infants.

1. Center Eligibility: All member centers in the Vermont Oxford Network are eligible for participation in the Registry for Neonatal Encephalopathy. Center participation in the Extremely Low Birth Weight Infant Follow-up Project is not required.
2. Infant Eligibility: Infants enrolled in the Registry for Neonatal Encephalopathy and treated with hypothermic therapy are eligible for Registry Follow-up. The confidentiality of individual patients will be protected. No protected health care information will be transmitted or submitted to the Vermont Oxford Network; only de-identified data is acceptable.
3. Follow-up Care: All infants will receive the current standard of follow-up care at their institution. The preferred developmental assessment tool for evaluation of infants is the Bayley

Scales of Infant Development (second or third edition). However, Registry Follow-up does not require the Bayley to be performed if it is not within the institution's standard of care. Other developmental assessments within the institution's standard of care should be performed, and the results reported.

4. Institutional Review Board (IRB) Approval: All centers participating in Registry Follow-up must obtain a letter of review and acceptance from their local IRBs prior to beginning data collection. Since the primary goal of the Registry is quality improvement, no patient identifiers are collected, no new therapies are involved and no new evaluative instruments will be tested. As Registry Follow-up poses no expected risks to patients, it is anticipated that most IRBs will approve an addendum to the Registry project and permit follow-up of infants without the requirement for individual patient consent. However, this is a decision for each local IRB. Should individual patient consent be required by the local IRB, the center will need to decide when the consent form is signed (i.e. at the follow-up visit or at discharge from the hospital). Longer term follow-up (i.e. beyond 2 years of age) will require resubmission of detailed plan to all IRBs.

A letter indicating Registry Follow-up has been reviewed by and is acceptable to your IRB is required before your center can participate in follow-up. Approval for Registry Follow-up will also be obtained from the IRB at the University of Vermont.

5. Data collection: Data will be collected at the two year (24 months') follow-up visit. Data collected before 22 months' or after 26 months' of age is not acceptable for submission. Standardized data collection forms will be provided for this purpose.

6. Data submission: All centers participating in Registry Follow-up are required to have a Coordinator who will be responsible for managing data submission. The Coordinator maintains logs to identify infants eligible for follow up, ensures completeness and accuracy of data collection, submits data forms to VON, and works with VON to reconcile any data errors or omissions or both. The Coordinator may also assist in obtaining IRB approval for project participation.

E. Outcome Measures

The following health and developmental status measures will be collected:

1. Home Living Situation: the type of living situation, educational level and financial resources of the primary care giver.

2. Health Status: survival status, support after discharge, medical re-hospitalizations, and surgical procedures for the infant.
3. Developmental Status: growth parameters, visual and auditory impairments, the presence of cerebral palsy, achievement of gross motor milestones, and results of standardized developmental tests for the infant.

F. Patient and Center Identification Data

There are two Neonatal Encephalopathy Registry Follow-up data forms: the *Health Status Report* and the *Developmental Status Report*. At the top of each *Report* form there are two enclosed areas for patient and center identification. These sections should be completed on both *Report* forms for each infant enrolled in Registry Follow-up data forms.

1. Patient Identification: In the topmost section, which is shaded, the Infant's Name and Medical Record Number (MRN) are recorded. The information in this section is for individual center use in completing the Neonatal Encephalopathy Registry Follow-up data form and facilitating any additional reviews or edits. In order to preserve confidentiality of patient data, this section must be masked when transmitting the form to Vermont Oxford Network. Do not send patient name and medical record number for any infant. These should remain confidential.
2. Center Identification: In the second and lower section, the Center Name, Center Number, Infant Network ID Number, and Infant Year of Birth are recorded. The Center Name is the name of your medical center and the Center Number is the number assigned to your center for the VON Database. These fields will be the same for all infants enrolled in the Neonatal Encephalopathy Registry Follow-up at your center. The Infant Network ID Number is the number assigned to the infant for the VON Database according to the VON Database Manual of Operations. The Infant Year of Birth is recorded using four digits. For example, an infant born in 2006 will have the Infant Year of Birth recorded as "2006".

III. DATA COLLECTION

A. THE HEALTH STATUS REPORT

The *Health Status Report* documents the health status of the infant at the two year (24 months) Health Follow-up visit. To complete the *Health Status Report*, you may need to review patient specific hospital charts or outpatient clinical records to answer some of the data items.

1. Infant Status the two year (24 month) visit

The status of the infant at 2 years of age will determine which sections of the *Health Status Report* should be completed.

- If the infant expired prior to the time of the two year Health Follow-up visit, complete only Section A: Health Status, Item #1 of the *Health Status Report*.
- If the infant was alive but was not seen at the time of the two year Health Follow-up visit, complete only Section A: Health Status, Item #1 of the *Health Status Report*.
- If the infant was alive and was seen at your Center's follow-up clinic at the time of the two year Health Follow-up visit, but the infant's parent(s) or legal guardian(s) did not give consent to participate in the Neonatal Encephalopathy Registry Follow-up, complete only Section A: Health Status, Items #1 and 2 of the *Health Status Report*. If the infant's parent(s) or legal guardian(s) gave consent to participate, complete all sections of the Health Status Report.
- If the infant was alive and was seen at another follow-up clinic, and the infant's parent(s) or legal guardian(s) gave consent to participate, coordinate data collection with the Follow-up clinic at the time of the two year Health Follow-up visit, and complete all sections of the *Health Status Report*.

2. Report Completion

a. Section A: Health Status

ITEM 1: Status at 2 years (24 months) of age

Indicate the infant's status at the time of the Health Follow-up visit.

Check "Alive" if the infant is known to be alive at the two year Health Follow-up visit.

Check "Expired" if the infant died between the ultimate hospital discharge date and the two year Health Follow-up visit.

Check "Unknown" if the status of the infant is unknown at the two year Health Follow-up visit, because the infant was lost to follow-up.

ITEM 2: Consent obtained at the follow-up visit

Indicate whether informed consent was obtained from the infant's parent(s) or legal guardian(s) to collect health and developmental follow-up data. Consent may be obtained at the time of, or any time prior to, the two year Health Follow-up visit.

Check “Yes” if the infant’s parent(s) or legal guardian(s) gave consent to participate in the project.

Check “No” if the infant’s parent(s) or legal guardian(s) did not give consent to participate in the project.

b. Section B: Living Situation

ITEM 3: Maternal Age at Infant Birth

Indicate the age of the mother at the time of the infant’s birth. Enter the age in years.

Check “Unknown” if the age of the mother at the infant’s birth is not known.

ITEM 4: Home Child Resides

Indicate the infant’s home living situation between the ultimate hospital discharge and the Health Follow-up visit. If the infant’s home living situation changed between the ultimate hospital discharge and the Health Follow-up visit, check the category that best describes where the infant lived during the majority of time. Check only one category.

Check “Parent/Family member” if the infant lives with the biological mother or father or other family members, or in the case of adoption, the legal guardian(s) who is/are the primary care giver(s).

Check “Foster Care” if the infant lives with an adult(s) who is/are the primary care giver(s) but who are not the infant’s legal guardians.

Check “Chronic Care Facility” if the infant lives and is cared for in an institution or chronic care facility.

ITEM 5: Caregiver(s)

Indicate the type of social support in the infant’s home living situation between the ultimate hospital discharge and the Health Follow-up visit. If the infant’s caregiver(s) changed between the ultimate hospital discharge and the Health Follow-up visit, check the category that best describes the infant’s caregiver(s) during the majority of time. Check only one category.

Check “Single parent” if the infant lives with a single parent as the primary care giver without other adults in the home.

Check “Single parent extended family” if the infant lives with a single parent as the primary care giver and with other related adults who are not the primary caregiver’s partner in the home.

Check “Two parent” if the infant lives with two parents as the primary care givers without other adults in the home.

Check “Two parent extended family” if the infant lives with two parents as the primary care givers and with other related adults in the home.

Check “Institutional” if the infant lives in a chronic care facility or remains hospitalized.

ITEM 6: Primary Caregiver Education

Indicate the highest level of education of the primary care giver in the home between the ultimate hospital discharge and the Health Follow-up visit. If the caregiver’s level of education changed between the ultimate hospital discharge and the Health Follow-up visit, check the category that best describes the level of education during the majority of time. Check only one category.

Check “Some high school or less” if the primary caregiver has attained grade school education and some high school education, but has not graduated from high school.

Check “High school graduate/GED” if the primary caregiver has graduated from high school or attained the equivalent (GED).

Check “Some college/university” if the primary caregiver has graduated from high school and has attended some college courses, but has not graduated from college.

Check “College/university graduate” if the primary caregiver has graduated from a college or university.

Check “Unknown” if the highest level of education of the primary caregiver is not known or is unclear.

Check “Not applicable” only if the infant lives in a chronic care facility or institution.

FOR USA CENTERS ONLY

ITEM 7: Income Below 2006 HHS Poverty Guideline

Indicate whether the household income for 2006 was below the 2006 HHS Poverty Guideline level for the given number of people currently residing in the infant’s home.

Many caregivers feel uncomfortable asking parents or caregivers a question about their household income. To help ask this question we have provided a script and an income reference table (Appendix C, Sample 3). Please note the question does not ask for a specific income level or range. Rather, the question is phrased so as to be answered in

a “Yes” or “No” format. Interviewers may give the parents or caregivers the income reference table as a tool to facilitate their answer to the question as “Yes”, “No”, or “I don’t know” (“Unknown”).

To use the table, instruct the parent or caregiver to look at the column on the left and find the number of adults and children who lived in the home for part or all of 2006. Next have the parent or caregiver look at the column on the right and answer “Yes” or “No” to the question “Was your household income for the year 2006 below the number in the column?”

Check “Yes” if the 2006 household income for the number of people (adults plus children) residing in the home is less than the dollar amount listed in the corresponding column.

Check “No” if the 2006 household income for the number of people (adults plus children) residing in the home is equal to or more than the dollar amount listed in the corresponding column.

Check “Unknown” if the parent or the caregiver is unsure of the 2006 household income.

ITEM 8: Caregiver(s) Primary Language

Indicate the primary language of the caregiver used in the home in which the child resides. Check “Other” if a language other than English or Spanish is used. The “other” language does not need to be specified.

c. Section C: Support at Follow-up

ITEM 9: Support at follow-up

Indicate whether the infant had any of the listed specific supports or interventions at the time of the Health Follow-up visit. The specific support or interventions may have been in place prior to ultimate hospital discharge or may have been placed between the ultimate hospital discharge and the Health Follow-up visit. Check all supports or interventions that apply.

1. Tracheostomy: Indicate whether the infant had a functional tracheostomy at the time of the Health Follow-up visit.

2. Ventilator: Indicate whether the infant received ventilator support. Ventilator support includes intermittent mandatory ventilation or continuous positive airway pressure at the time of the Health Follow-up visit.
3. Oxygen: Indicate whether the infant received supplemental oxygen. Supplemental oxygen includes oxygen given with a ventilator, as well as free flow oxygen through a nasal cannula or hood.
4. Gastrostomy: Indicate whether the infant had a functional gastrostomy at the time of the Health Follow-up visit.
5. Tube feedings: Indicate whether the infant was receiving tube feedings at the time of the Health Follow-up visit.
6. Apnea or Cardio-Respiratory monitor: Indicate whether the infant was on an Apnea Monitor or a Cardio-Respiratory Monitor at the time of the Health Follow-up visit..
7. Anticonvulsant medications: Indicate whether the infant was on anticonvulsant medications at the time of the Health Follow-up visit.
8. Physical or Occupational therapy: Indicate whether the infant was receiving physical or occupational therapy at the time of the Health Follow-up visit.
9. None: Indicate if the infant was not receiving any of the supports or interventions listed above.

d. Section D: Medical Re-hospitalizations & Surgeries

ITEM 10: Medical Re-hospitalizations

Indicate whether the infant was re-hospitalized at any time between the ultimate hospital discharge and the Health Follow-up visit. Medical re-hospitalizations require an overnight hospital stay. Medical re-hospitalizations exclude visits to a Hospital-based Primary Care Medical or Developmental Follow-up Clinic, or other hospital-based specialty clinic or the Emergency Room.

Check “Yes” if the infant was re-hospitalized.

Check “No” if the infant was not re-hospitalized.

Check “Unsure” if you are not sure if the infant was re-hospitalized.

ITEM 10a: If Yes, Category

If Item #10 “Medical Re-hospitalizations” is checked “Yes”, indicate whether the infant was hospitalized for a specific medical re-hospitalization category as defined below, and check all that apply. Enter the “Number of Admissions” as the number of hospital admissions for each specific medical re-hospitalization category. If you are unsure of the number of admissions for a medical re-hospitalization category, enter “99”.

A hospital admission should be assigned to only one re-hospitalization category.

1. Respiratory Illness

Includes medical re-hospitalizations for the sequelae of respiratory distress syndrome, chronic lung disease, and other conditions. These conditions may require oxygen therapy, mechanical ventilation, or tracheostomy. These conditions include pulmonary disease (due to congenital or inherited anomalies of the airway), pulmonary aspiration (due to neurological or neuromuscular disorders), disorders of the chest wall diaphragm or abdominal wall resulting in hypoventilation, or sequelae arising from surgical problems in the neck or chest. These conditions include hospitalizations as related to pulmonary infections (e.g. “RSV-bronchiolitis”), “Acute Life Threatening Event”, or “Near SIDS”.

2. Nutrition/Failure to Thrive

Includes medical re-hospitalizations for nutritional issues or failure to gain weight. Excludes medical re-hospitalizations for gastrointestinal infections.

3. Seizure Disorder

Includes medical re-hospitalizations for partial, generalized or unclassified seizures and convulsive disorders. The seizures may or may not have documented EEG correlates. Nonepileptic paroxysmal physiologic events which mimic seizures (e.g. migraines) or pseudo seizures should be included in this category. Excludes medical re-hospitalizations related to CNS infections. If the seizure is a sequelae of a specific acute infection of the cerebrum or meninges, the re-hospitalization should be coded under the appropriate category of “Infection”.

4. Shunt Complication

Includes medical re-hospitalizations for complications related to or associated with cerebrospinal fluid shunts and re-hospitalizations as related to shunt infections and malfunctions. The diagnosis of a shunt infection is a clinical diagnosis does not require blood or CSF culture to be positive.

5. Infections (not respiratory or shunt infections)

- a. Meningitis: Includes medical re-hospitalizations for bacterial or aseptic meningitis. The diagnosis of meningitis requires a single CSF culture to be positive. Excludes infections related to or associated with cerebrospinal fluid shunts.
- b. Urinary tract infection: Includes medical re-hospitalizations for infections related to either the upper or lower urinary tracts such as acute pyelonephritis, chronic pyelonephritis, cystitis, and urethritis. Primary or secondary vesicoureteral reflux may or may not be involved. The diagnosis of a urinary tract infection requires a positive quantitative urine culture.
- c. Gastrointestinal infection: Includes medical re-hospitalizations for infectious diarrhea illnesses such as bacterial or viral gastroenteritis, anti-microbial associated diarrhea and diarrhea in immunocompromised hosts. This category also includes re-hospitalizations for excessive fluid and electrolyte losses and subsequent replacement therapies. The diagnosis of a gastrointestinal infection does not require a positive culture.
- d. Other infection (specify): Includes medical re-hospitalizations for infections not meeting the inclusion requirements of one of the above categories. Enter a specific infection.

6. Other Medical Re-hospitalization Category (specify):

Includes medical re-hospitalizations that do not meet the inclusion requirements of one of the above categories. Describe the specific reason for re-hospitalization in the space provided for the description.

ITEM 11: Surgical Procedures After Discharge

Indicate whether the infant required a surgical procedure after discharge. Includes one or more surgical procedures performed at any time between the ultimate hospital discharge date and the time of the Health Follow-up visit. Surgical procedures may be with or without re-hospitalizations (i.e. they may occur as outpatient or day surgeries).

Check "Yes" if the infant required a surgical procedure.

Check "No" if the infant did not require a surgical procedure.

Check "Unsure" if you are not sure if the infant required a surgical procedure.

Enter the three digit "P- Code" from the list of surgical procedures on the back of the Health Status Report; or refer to Appendix B: Surgical Procedure Codes. If the infant had Other neurosurgical procedure (code "P-102"), Other gastrointestinal surgical

procedure (code "P-303"), Other genitourinary surgical procedure (code "P-402"), Other ENT surgical procedure (code "P-503"), or Other ophthalmologic surgical procedure (code "P-604"), enter the code number and describe the specific surgery in the space provided for description. If the infant had a surgical procedure not listed on the back of Health Status Report, or in Appendix B, enter "P-900" (Other Surgical Procedure).

Describe the specific surgical procedure in the space provided for description.

Enter the "Number of Procedures" as the number of surgical procedures performed for each surgical category.

B. THE DEVELOPMENTAL STATUS REPORT

The *Developmental Status Report* documents the developmental status of the infant at the two year (24 months) Developmental Follow-up visit. To complete the *Developmental Status Report*, you may need to review patient specific hospital charts or outpatient clinical records to answer some of the data items.

1. Infant Status the two year (24 month) visit

The status of the infant at 2 years of age will determine which sections of the *Developmental Status Report* should be completed.

- If the infant expired prior to the time of the two year Developmental Follow-up visit, do not complete the *Developmental Status Report*.
- If the infant was alive but was not seen at the time of the two year Developmental Follow-up visit, do not complete the *Developmental Status Report*.
- If the infant was alive and was seen at your Center's follow-up clinic at the time of the two year Developmental Follow-up visit, but the infant's parent(s) or legal guardian(s) did not give consent to participate in the Neonatal Encephalopathy Registry Follow-up, do not complete the *Developmental Status Report*. If the infant's parent(s) or legal guardian(s) gave consent to participate, complete all sections of the *Developmental Status Report*.
- If the infant was alive and was seen at another follow-up clinic, and the infant's parent(s) or legal guardian(s) gave consent to participate, coordinate data collection with the Follow-up clinic at the time of the two year Developmental Follow-up visit, and complete all sections of the *Developmental Status Report*.

2. Report Completion

a. Section A: Growth Parameters

ITEM 1: Weight

Enter the weight recorded at the Developmental Follow-up visit. Enter the weight in kilograms (kg), to the hundredths place. If the weight was not obtained at the Developmental Follow-up visit, enter "99.9". Do not enter a weight obtained at another visit.

ITEM 2: Head Circumference

Enter the head circumference recorded at the Developmental Follow-up visit. Enter the head circumference in centimeters (cm), to the tenths place. If the head circumference

was not obtained at the Developmental Follow-up visit, enter “99.9”. Do not enter a head circumference obtained at another visit.

b. Section B: Vision & Hearing Post Discharge

ITEM 3: Ophthalmologic Exam

Indicate whether the infant received an ophthalmologic exam at any time from hospital discharge to the two year Developmental Follow-up visit. A ophthalmologic exam is an examination by an ophthalmologist.

Check “Yes” if the infant had an ophthalmologic exam.

Check “No” if the infant did not have an ophthalmologic exam, or if you are unsure if the infant had an ophthalmologic exam.

ITEM 4: Blindness

Indicate whether the infant has any loss of vision.

Check “One eye” if the infant has a loss of vision in one eye only (including uncorrectable profound impairment or near blindness), regardless of whether the defect causing the visual loss is in the eye, optic nerve or the brain.

Check “Both eyes” if the infant has a loss of vision in both eyes (including uncorrectable profound impairment or near blindness), regardless of whether the defect causing the visual loss is in the eye, optic nerve or the brain.

Check “Not blind” if the infant does not have loss of vision. Infants “not blind” may have other types of visual impairment such as: glaucoma (cloudy or asymmetrically enlarged cornea), hypermetropia (farsightedness), myopia (nearsightedness), strabismus (squint as elicited by the corneal light reflex or unilateral cover test), or other visual impairment not classified as blindness.

Check “Unsure” if you are unsure of the infant’s visual status.

ITEM 5: Prescription glasses

Indicate whether the infant currently uses prescription glasses.

Check “Yes” if prescription glasses are used some or all of the time.

Check “No” if prescription glasses are never used.

ITEM 6: Hearing Test

Indicate whether the infant had testing at any time from hospital discharge until the day of the two year Developmental Follow-up visit. The testing may be for confirmation of a suspected hearing loss based on a failed hearing screen, observation of problems with the infant’s behavioral response to sound, or a caregiver’s report of emerging communication and auditory behavior difficulties. Testing must include otoacoustic emissions (OAEs) and/or auditory brainstem response (ABR).

Check “Yes” if the infant had formal testing.

Check “No” if the infant did not receive formal testing, or if you are unsure if the infant had formal testing.

ITEM 7: Hearing Impairment

Indicate whether the infant has evidence of any hearing impairment.

Check “One ear” if the infant has any hearing impairment *in one ear only*.

Check “Both ears” if the infant has any hearing impairment *in both ears*.

Check “Not impaired” if the infant does not have any hearing impairment.

Check “Unsure” if you are unsure of the infant’s hearing status.

ITEM 8: Amplification

Indicate whether corrective hearing aid(s) are currently used for amplification.

Check “Yes” if a corrective aid(s) is/are used in one or both ears.

Check “No” if corrective aids are never used.

c. Section C: Cerebral Palsy

ITEM 9: Cerebral Palsy

Indicate whether the infant has cerebral palsy at the Developmental Follow-up visit. Cerebral palsy is a disability of the central nervous system, and is characterized by abnormal control of movement or posture or both. The abnormalities of cerebral palsy are not due to mental retardation, meningomyelocele or other spinal cord lesions, or isolated hypotonia and are not transient, or the result of a progressive disease.

Check “Yes” if the infant has cerebral palsy.

Check “No” if the infant does not have cerebral palsy.

ITEM 9a: If Yes, Impairment

If Item # 9 “Cerebral Palsy” is “Yes” the infant has cerebral palsy, indicate the type of impairment. Check only one type.

Check “Diplegia” if the infant is affected in both lower extremities.

Check “Hemiplegia” if the infant is affected in the upper and lower extremity on only one half of the body.

Check “Quadriplegia” if the infant is affected in all extremities.

ITEM 9b: If No, Muscle Tone

If Item #9 “Cerebral Palsy” is answered “No” and the infant does not have cerebral palsy, indicate whether the infant has an abnormality in muscle tone. Check only one type.

Check “Hypotonia” if the infant had a decrease in muscle tone or resistance to passive movement, including dystonia not associated with or suspect for cerebral palsy.

Check “Hypertonia” if the infant had an increase in muscle tone or resistance to passive movement including dystonia not associated with or suspect for cerebral palsy.

Check “Both (hypotonia and hypertonia)” if the infant had a decrease and increase in muscle tone or resistance to passive movement including dystonia not associated with or suspect for cerebral palsy.

Check “Normal” if the infant did not have any abnormalities in muscle tone.

d. Section D: Gross Motor Milestones

ITEM 10: Sits independently

Indicate whether the infant can sit independently. Independent sitting is defined as sitting without holding on to anyone or anything, and does not require assistance to assume sitting. An infant can be considered to “sit independently” even if she/he has difficulty with balance when both hands are free.

Correlation to the Gross Motor Function Classification System (GMFCS) (1)

An infant who can sit independently would be graded on the GMFCS at Level 1 or 2. An infant who cannot sit independently would be graded on the GMFCS at Level 3 or above.

Check “Yes” if the infant can sit independently.

Check “No” if the infant cannot sit independently.

ITEM 10a: If No, sits with support

If the answer to Item #10 is “Yes”, do not answer Item #10a. If the answer to Item #10 is “No”, indicate whether the infant can sit with support in his/her current usual activity. An infant who can sit with support may sit in a “W” position (sitting between flexed and internally rotated hips and knees) and may need adult help to assume sitting. In general the infant’s lower back is supported when sitting; the infant may need to use his/her hands to maintain balance.

Correlation to the Gross Motor Function Classification System (GMFCS)

An infant who can sit with support would be graded on the GMFCS at Level 3 or 4. An infant who cannot sit with support is limited in antigravity control: such an infant would be graded on the GMFCS at level 5.

Check “Yes” if the infant can sit with support.

Check “No” if the infant cannot sit with support.

ITEM 11: Walks ten (10) steps independently

Indicate whether the infant can walk ten (10) steps independently. Independent walking is defined as walking without holding on to anyone or anything; there is no need for any assistive device. Gait can be symmetric or asymmetric when walking independently.

Correlation to the Gross Motor Function Classification System (GMFCS)

An infant who can walk ten (10) steps independently would be graded on the GMFCS at Level 1. An infant who cannot walk ten (10) steps independently would be graded on the GMFCS at Level 2 or above.

Check “Yes” if the infant can walk ten (10) steps independently.

Check “No” if the infant cannot walk ten (10) steps independently.

ITEM 11a: If No, walks ten (10) steps with support

If the answer to Item #11 is “Yes”, do not answer Item #11a. If the answer to Item #11 is “No”, indicate whether the infant can walk ten (10) steps with support in his/her current usual activity. An infant walking ten (10) steps with support may use furniture or an assistive mobility device and need adult assistance for steering and turning.

Correlation to the Gross Motor Function Classification System (GMFCS)

An infant who is able to walk ten (10) steps with support would be graded on the GMFCS at Level 2 or 3. An infant unable to walk ten (10) steps with support would be graded on the GMFCS at Level 4 or 5.

Check “Yes” if the infant can walk ten (10) steps with support.

Check “No” if the infant cannot walk ten (10) steps with support.

e. Section E: Developmental Testing

ITEM 12: Bayley Scales of Infant Development: Indicate whether the infant’s development was evaluated at the Developmental Follow-up visit using the Bayley Scales of Infant Development (BSID). Either the BSID-II (2nd Edition) or the BSID-III (3rd Edition) may have been used in the assessment.

Check “Completed” if the infant’s development was evaluated with the Mental Developmental Index (MDI) and Psychomotor Developmental Index (PDI) of the BSID-II or with the Cognitive Language and Motor subtests of the BSID-III. **If “Completed” is checked, items 12a and 12b must be answered.**

Check “Partially completed” if the infant’s development was evaluated with either the Mental Developmental Index (MDI) or Psychomotor Developmental Index (PDI) of the BSID-II or with any one or two of the Cognitive Language or Motor subtests of the BSID-III. **If “Partially completed” is checked, items 12a, 12b and 12c must be answered.**

Check “Not performed” if the infant’s development was not evaluated with any of the subtests of the BSID-II or BSID-III. **If “Not performed” is checked, item 12c must be answered.**

ITEM 12a: Age at assessment

If the answer to Item #12 is “Completed” or “Partially completed”, enter the age at assessment in months and days.

ITEM 12b: Results (Check all sections that apply)

If the answer to Item #12 is “Completed” or “Partially completed”, enter the results for the BSID test administered. For each subtest completed enter the corresponding score.

If the Bayley II was performed, one or both of the following two questions need to be answered.

1. BSID-II MDI

If the MDI subtest of the BSID II was completed, check the box. Enter the Raw Score and the Index Score.

2. BSID-II PDI

If the PDI subtest of the BSID II was completed, check the box. Enter the Raw Score and the Index Score.

If the Bayley III was performed, some or all of the following three questions need to be answered:

1. BSID-III Cognitive

If the Cognitive subtest of the BSID III was completed, check the box. Enter the Scaled Score and the Composite Score for the Cognitive Subtest.

2. BSID-III Language

If the Language subtest of the BSID III was completed, check the box. Enter the Sum Scaled Score and the Composite Score for the Language subtest. The Sum Scaled Score is the sum of the Receptive Communication (RC) and the Expressive Communication (EC) scaled scores.

3. BSID-III Motor

If the Motor subtest of the BSID III was completed, check the box. Enter the Sum Scaled Score and the Composite Score for the Motor subtest. The Sum Scaled Score is the sum of the Fine Motor (FM) and the Gross Motor (GM) scaled scores.

ITEM 12c: Check why

If the answer to Item #12 is “Partially completed” or “Not performed”, indicate the reason why.

Check “Neurosensory impairment (blind or deaf)” if the child had one or both of these impairments and could not complete the test.

Check “Too severely delayed” if the child was too severely delayed to administer testing. Do not check this reason if the BSID was not administered because the child had a neurosensory impairment (was blind or deaf).

Check “Uncooperative” if the child was unable to sufficiently cooperate for the exam to be performed.

Check “Other” if there was another reason the BSID was not administered.

ITEM 13: Other Developmental or Cognitive Test Performed

Indicate whether another developmental or cognitive test was performed (i.e. Peabody).

Check “Yes” if another developmental or cognitive test was performed.

Check “No” if another developmental or cognitive test was not performed.

ITEM 13a: If “Yes”, Abnormal results

If another developmental or cognitive test was performed, indicate the results of the test.

Check “Yes” if the infant was assessed as abnormal from the other developmental or cognitive test.

Check “No” if the infant was assessed as not abnormal from the other developmental or cognitive test.

f. Section F: Overall Clinical Appraisal

Item 14: Clinical Appraisal

Cognitive Function

Indicate the clinical appraisal of the infant’s cognitive functioning. Appraisal of the cognitive function should be **independent** of the infant’s language abilities. The clinical appraisal is a summary of the impressions of the health care team upon seeing the infant at the Developmental Follow-up visit. The clinical appraisal is based on observation and examination of the infant during the visit.

Check “Normal” if the infant’s cognitive functioning is appropriate for two years (24 months).

Check “Suspect” if it is unclear whether the infant’s cognitive functioning is delayed for two years (24 months).

Check “Impaired” if the infant’s cognitive functioning is abnormal for two years (24 months).

Language

Indicate the clinical appraisal of the infant’s language functioning. The clinical appraisal is a summary of the impressions of the health care team upon seeing the infant at the

Developmental Follow-up visit. The clinical appraisal is based on observation and examination of the infant during the visit.

Check “Normal” if the infant’s language functioning is appropriate for two years (24 months).

Check “Suspect” if it is unclear whether the infant’s language functioning is delayed for two years (24 months).

Check “Impaired” if the infant’s language functioning is abnormal for two years (24 months).

Motor Function

Indicate the clinical appraisal of the infant’s motor functioning. The clinical appraisal is a summary of the impressions of the health care team upon seeing the infant at the Developmental Follow-up visit. The clinical appraisal is based on observation and examination of the infant during the visit.

Check “Normal” if the infant’s motor functioning is appropriate for two years (24 months).

Check “Suspect” if it is unclear whether the infant’s motor functioning is delayed for two years (24 months).

Check “Impaired” if the infant’s motor functioning is abnormal for two years (24 months).

IV. HOW TO TRANSMIT DATA

Mail or Fax All Data to:

NER Infant Follow-up Project
Vermont Oxford Network
33 Kilburn St.
Burlington, VT 05401
Fax: 802-865-9613
Fax: 802-865-0359

1. Do not photocopy the infant's name or medical record number on the top of the *NER Infant Follow-up Project Data Forms*. This information should remain confidential.
2. Keep your original *NER Infant Follow-up Project Data Forms* on file. Send copies only.
3. Complete all data on the data forms. Confirm accuracy of all data before submission. Check that all forms have the correct Center number, VON ID number, and Infant Year of Birth. Do not submit incomplete forms.
4. Care should be taken anytime a form is changed or updated, since the most recent data received will be entered into the database without further verification. All changes/updates made on *NER Infant Follow-up Project Data Forms* previously submitted should be highlighted or noted as being "corrected" when the forms are mailed to VON.
5. Keep your *NER Infant Follow-up Project Report Log* secure. The *NER Infant Follow-up Project Report Log* is the only way to identify infants and to track their status in the follow-up project. You may need to use the logs to find specific charts for review. We recommend making copies of the *NER Infant Follow-up Project Report Log* as each page of the Log is completed in case the original is lost.
6. Keep your *NER Infant Follow-up Project Report Log* up to date. Enter data on the Log as data forms are submitted.

V. PUBLICATIONS

Vermont Oxford Network will author all publications, which are based on data collected at all centers during the conduct of NER and NER Follow-up. An appendix listing each participating center, up to two investigators from each of the centers, and the study coordinator from each center will be included. The centers will be listed in alphabetical order. The appendix will also list the members of NER Infant Follow-up Project Steering Committee and the NER Steering Committee and Staff. All investigators listed in the appendix will be considered co-authors of the manuscript and entitled to include the publication in their curricula vitae.

Publications based on follow-up data collected at individual centers or a subgroup of centers which address ancillary research questions may be authored by the individual investigators responsible, but will not be submitted for publication until after the primary follow-up manuscript has been submitted. All ancillary studies must have prior approval of the Registry Steering Committee to ensure that these studies will not interfere with the main study.

VI. REFERENCES

1. Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Child Neurol.* 1997, 39:214-223.

VII APPENDICES

Appendix A: Neonatal Encephalopathy Registry – Birth Year 2006 Center List

Cape Fear Valley Medical Center	Salem Hospital
Children’s Hospital Medical Center Akron	St. Luke’s Hospital
Children’s Hospital of Greenville	Thomas Jefferson University Hospital
DeVos Children’s/Spectrum Health	University of Michigan –Holden NICU
Kosair Children’s Hospital	University of Tennessee Medical Center at Knoxville
Legacy Emanuel Children’s Hospital	WakeMed Medical Center
Monroe Carell Jr. Children’s Hospital	Women’s Hospital of Greensboro
Poudre Valley Health System	Yale-New Haven Children’s Hospital
Providence St. Vincent Medical Center	
Sacred Heart Medical Center	

Appendix B: Surgical Procedure Codes (P-Codes)

<u>P-CODE</u>	<u>CATEGORY</u>
P-101	<u>Central Nervous System Surgery</u> Shunt or shunt revision for hydrocephalus
P-102	Other neurosurgical procedure
P-201	<u>Congenital Heart Defect Surgery</u> Cardiac surgery
P-301	<u>Gastrointestinal Surgery</u> Gastrostomy tube placement
P-302	Inguinal hernia repair
P-303	Other gastrointestinal surgical procedure
P-304	Fundoplication
P-401	<u>Genitourinary Surgery</u> Circumcision
P-402	Other genitourinary surgical procedure
P-501	<u>Otolaryngology Surgery</u> Tracheostomy
P-502	Tympanostomy tubes
P-503	Other ENT surgical procedure
P-603	<u>Ophthalmologic Surgery</u> Strabismus surgery
P-604	Other ophthalmologic surgical procedure
P-900	<u>Other Surgical Procedure</u>

Appendix C: Sample Data Forms

1. Sample: NER Follow-up Log

Neonatal Encephalopathy Registry Infant Follow-Up Project REPORT LOG								
CENTER: XXXX		CENTER NAME: Your Hospital Name				Birth Year: 2006		
Network ID Number	Date of Birth	Patient's Name	NE Registry	Hypothermic Therapy	24 Months Age Date	Health and Developmental Status Follow-up Date	Health and Developmental Status Follow-Up Report Mailed	
789			Y	Y				
791			Y	Y				
797			Y	Y				
801			Y	Y				
804			Y	Y				
808			Y	Y				
809			Y	Y				
810			Y	Y				
816			Y	Y				
819			Y	Y				
822			Y	Y				
825			Y	Y				
826			Y	Y				
827			Y	Y				
829			Y	Y				
830			Y	Y				
832			Y	Y				
833			Y	Y				

nerfup@vtoxford.org © Vermont Oxford Network, Inc.

3. Sample: Poverty Guidelines

Script for Question 8 (Health Status Report)

We would like to ask you a question about your household income in calendar year.

Your household income is the amount of money earned by adults living in your house.

After thinking about this for a minute, please take a look at the following table and tell us whether your household income in for the year 2006 was below the number listed in the table.

To use this table look at the column on the left and find the number of adults and children who lived in your home for part or all of 2006. Next look at the column on the right and answer “Yes” or “No” to the question “Was your household income for the year 2006 below the number in the column?”

Interviewer hands table to parent; parent answers question and returns table to interviewer.

HOUSEHOLD INCOME Tool

Persons in Household	Household Income in 2006
2	\$13,200
3	\$16,600
4	\$20,000
5	\$23,400
6	\$26,800
7	\$30,200
8	\$33,600
9	\$37,000
10	\$40,400
Each additional person	\$3,400

4. Sample: Developmental Status Report

Patient's Name: _____	Medical Record: _____
<i>(Please do not transmit information in this box.)</i>	

VERMONT OXFORD NETWORK
Neonatal Encephalopathy Registry Follow-Up
DEVELOPMENTAL STATUS REPORT

Center Number: _____	Center Name: _____
Network ID Number: _____	Year of Birth (YYYY): _____
SECTION A: GROWTH PARAMETERS	
1. Weight: _____ kg	2. Head Circumference: _____ cm
SECTION B: VISION & HEARING POST DISCHARGE	
3. Ophthalmologic Exam: <input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Blindness: <input type="checkbox"/> One eye <input type="checkbox"/> Both eyes <input type="checkbox"/> Not blind <input type="checkbox"/> Unsure	
5. Prescription Glasses: <input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Hearing Test: <input type="checkbox"/> Yes <input type="checkbox"/> No	
7. Hearing Impairment: <input type="checkbox"/> One ear <input type="checkbox"/> Both ears <input type="checkbox"/> Not impaired <input type="checkbox"/> Unsure	
8. Amplification: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Section C: Cerebral Palsy	
9. Cerebral Palsy: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>IF Yes, a. Impairment:</i> <input type="checkbox"/> Diplegia <input type="checkbox"/> Hemiplegia <input type="checkbox"/> Quadriplegia	
<i>IF No, b. Muscle tone:</i> <input type="checkbox"/> Hypotonia <input type="checkbox"/> Hypertonia <input type="checkbox"/> Both (hypo- & hypertonia) <input type="checkbox"/> Normal	
SECTION D: GROSS MOTOR MILESTONES	
10. Sits independently: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>IF No, a. Sits with support:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	
11. Walks ten (10) steps independently: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>IF No, a. Walks ten (10) steps with support:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	
SECTION E: DEVELOPMENTAL TESTING	
12. Bayley Scales of Infant Development: <input type="checkbox"/> Completed <input type="checkbox"/> Partly completed <input type="checkbox"/> Not performed	
<i>IF completed or partially completed,</i>	
a. Age at assessment: _____ months _____ days	
b. Results: Check (✓) all sections that apply.	
<input type="checkbox"/> BSID-II MDI: Raw Score: _____ Index Score: _____	
<input type="checkbox"/> BSID-II PDI: Raw Score: _____ Index Score: _____	
<input type="checkbox"/> BSID-III Cognitive: Scaled Score: _____ Composite Score: _____	
<input type="checkbox"/> BSID-III Language: Sum Scaled Score: _____ Composite Score: _____	
<input type="checkbox"/> BSID-III Motor: Sum Scaled Score: _____ Composite Score: _____	
<i>IF partially completed or not performed,</i>	
c. Check (✓) why: <input type="checkbox"/> Neurosensory impairment (blind or deaf) <input type="checkbox"/> Too severely delayed	
<input type="checkbox"/> Uncooperative <input type="checkbox"/> Other reason	
13. Other Developmental Test Performed: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>IF Yes, a. Abnormal results:</i> <input type="checkbox"/> Yes <input type="checkbox"/> No	
SECTION F: OVERALL CLINICAL APPRAISAL	
14. Clinical Appraisal: Cognitive Function: <input type="checkbox"/> Normal <input type="checkbox"/> Suspect <input type="checkbox"/> Impaired	
Language: <input type="checkbox"/> Normal <input type="checkbox"/> Suspect <input type="checkbox"/> Impaired	
Motor Function: <input type="checkbox"/> Normal <input type="checkbox"/> Suspect <input type="checkbox"/> Impaired	