THE INFANT FOLLOW-UP PROJECT

Extremely-Low-Birth-Weight Infant

Birth Year 2018 Cohort

For infants born between January 1, 2018 and December 31, 2018

MANUAL OF OPERATIONS

VERMONT OXFORD NETWORK

August 2019

Version 21

THE INFANT FOLLOW-UP PROJECT
ELBW Infant - Birth Year 2018 Cohort

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VERSION 21

INFANT ELIGIBILITY for the ELBW Infant Follow-up: Birth Year 2018 Cohort

Eligibility criteria for the ELBW Infant Follow-up Project include infants whose birth weights are between 401 and 1000 grams (inclusive) OR whose gestational ages are between 22 weeks, 0 days and 27 weeks, 6 days (inclusive).

Examples

Date of Birth	Birth Weight	Gestational Age (Weeks/Days)	Eligibility Year 2018 Cohort
December 30, 2017	500	25	No
January 5, 2018	400	21/6	No
January 5, 2018	400	22/0	Yes
January 5, 2018	401	22/0	Yes
January 5, 2018	380	22/0	Yes
January 5, 2018	1000	28/0	Yes
January 5, 2018	1001	28/0	No
January 5, 2018	1001	27/6	Yes
January 5, 2018	1100	27/6	Yes

I. INFANT FOLLOW-UP PROJECT OVERVIEW

A. Purpose

The purpose of the Infant Follow-up Project is to determine the health and neurodevelopmental outcomes of infants at 2 years of age. Follow-up for extremely low birth weight infants is inclusive of surviving infants with birth weights between 401 and 1000 grams (inclusive) OR with gestational ages between 22 weeks, 0 days and 27 weeks, 6 days (inclusive). Follow-up for these infants occurs at 18 months, 0 days - 24 months, 30 days corrected age. Follow-up for infants enrolled in Vermont Oxford Network clinical trials is specific to infants enrolled in that clinical trial.

B. Goals

- To link Neonatal Intensive Care Units and their Follow-up Clinics.
- To provide a method to evaluate the impact of perinatal events and neonatal interventions on short-term outcome status.
- To provide "gold standard" data collection sets for future testing of simplified follow-up tools.
- To describe, for extremely-low-birth-weight infants, the 2 year corrected age health and developmental status of surviving infants at participating Vermont Oxford Network Centers.
- To describe, for infants enrolled in a Vermont Oxford Network clinical trial, the 2 year health and developmental status of enrolled infants.

C. Center Eligibility

- The Center has contributed to the VON VLBW database from January 1, 2018.
- The Center is affiliated with a Follow-up Clinic which assesses all surviving ELBW infants cared for at the Center. Infant follow-up assessment should routinely use the Bayley Scales of Infant Development.
- The Center designates one specific Project Coordinator to manage data submission.
- The Center discusses the need for Institutional Review Board review and patient consent with its local Institutional Review Board (IRB).

D. Extremely-Low-Birth-Weight Infant Eligibility

- The infant was born between January 1, 2018 and December 31, 2018;
- The infant had a birth weight of between 401 to 1000 grams (inclusive); OR
- The infant had a gestational age of between 22 weeks, 0 days and 27 weeks, 6 days (inclusive);
- The infant survived until ultimate hospital discharge; and
- The infant completes a follow-up visit between 18 months, 0 days - 24 months, 30 days corrected age.

E. Outcome Measures

- Health Status: survival status, support after discharge, medical re-hospitalizations, and surgical procedures for the infant.
- Developmental Status: growth parameters, visual and auditory impairments, the presence of cerebral palsy, achievement of gross motor milestones, and results of the Bayley Scales of Infant Development -4 for the infant.

F. Version 21 updates: Health Status Report

The Health Status Report is designed to facilitate data submission using REDCap.
Question 6, income levels are amended in accordance with the 2018 Health and Human Services (HHS) Poverty Guidelines (35). The remaining data items are unchanged.

G. Version 21 updates: Developmental Status Report

The Developmental Status Report is designed to facilitate data submission using REDCap. The data items are unchanged.

II. STUDY ADMINISTRATION

A. Overview

The ELBW Infant Birth Year 2018 Cohort follow-up is a project conducted by Vermont Oxford Network (VON), Division of Clinical Trials & Follow-up. The VON Clinical Trials & Follow-up Data Coordinating Center will administer data collection, data management, and data analysis. Each participating Network Center will designate a Center Principal Investigator, who will be the contact person at that institution, and a Center Study Coordinator, who will coordinate data collection at the local Center. VON does not require Institutional Review Board approval or patient consent from each hospital. Instead, each participating Network Center determines with its local Institutional Review Board whether the local Institutional Review Board needs to review the project, and whether patient consent for data submission needs to be obtained.

B. VON Clinical Trials & Follow–up Data Coordinating Center

The VON Clinical Trials & Follow-up Data Coordinating Center will be responsible for all aspects of biostatistical design, data analysis, and data management for the study. The VON Clinical Trials & Follow-up Data Coordinating Center will submit periodic progress reports to the ELBW Infant Follow-up Project Steering Committee. The staff at the VON Clinical Trials & Follow-up Data Coordinating Center can be reached between 9:00 am - 5:00 pm, Eastern Standard Time. You may contact Sharla Crowley at the Clinical Trials & Follow-up Data Coordinating Center by email scrowley@vtoxford.org), telephone (802) 865-4814 ext. 232, or fax (802) 865-9613.

III. CENTER PARTICIPATION

A. Center Responsibilities

The Center's Principal Investigator is responsible for reviewing the need for IRB approval and patient consent with their local Institutional Review Board (IRB). The Center Investigator oversees accurate data collection and assures any training that may be necessary.
The Center's Project Coordinator is responsible for managing data submission. The Project Coordinator maintains logs to identify infants eligible for follow up, ensures completeness and accuracy of data collection and submission in REDCap and works with VON to reconcile any data errors or omissions or both.

B. Center Project Materials.

The VON Clinical Trials & Follow-up Data Coordinating Center will send the Center's Principal Investigator and Project Coordinator directions for accessing the ELBW Infant Follow-up Project Report Log for all Center-eligible infants from your Center, as well as access information to REDCap, a browser based electronic data entry tool for submitting study data.

C. Center Project Timeline

Data is to be collected during the time of the infant's follow-up visit between 18 months, 0 days - 24 months, 30 days corrected age. Although exact dates of follow-up visits will depend on the infants' gestational ages and dates of birth, the visits are expected to occur between October 2019 and April 2021.

IV. DATA COLLECTION & SUBMISSION

A. Data Collection

Data may be collected using paper-based Birth Year 2018 Cohort Infant Follow-up Data Forms or electronically using REDCap data instruments.

B. Data Submission

For Birth Year Cohort 2018 **all study data is submitted using REDCap data instruments**. Centers may choose to use available paper-based forms for initial data collection, but these forms will no longer be accepted for data submission. If paper forms are used for data collection, data must be transcribed to the corresponding REDCap data instrument for submission.
Please ensure that the correct VON ID number is used when collecting and submitting data. It is the responsibility of the individual center to verify the accuracy of the patient information submitted.

C. Which Infants Need Data Submitted for ELBW Infant Follow-up Project

Infants eligible for the ELBW Infant Follow-up Project include all infants with birth weight between 401 and 1000 grams (inclusive) **OR** gestational age between 22 weeks, 0 days and 27 weeks, 6 days (inclusive) who are

- born at your Center, and survive until ultimate hospital disposition;
- born at another hospital, transferred to your Center on or before day 28, and survive until ultimate hospital disposition;
- born at your Center, transferred on or before day 28 from your center, readmitted to your center after transfer, and survive until ultimate hospital disposition.

Ultimate hospital discharge is the infant's final discharge from the hospital to home or chronic care facility. The ultimate hospital discharge may or may not be from your Center. Do not complete logs or collect data for infants who were **never** admitted to your Center, but who are patients in your Follow-up Clinic.

D. HIPAA Compliance

In accordance with the Federal Health Insurance Portability and Accountability Act (HIPAA), all data collected for the ELBW Infant Follow-up Project is de-identified data.

V. ELBW INFANT FOLLOW-UP PROJECT REPORT LOG

A. Introduction

The *ELBW Infant Follow-up Report Log* identifies infants from your Center who qualify for the ELBW Infant Follow-up Project. The VON Clinical Trials & Follow-up Data Coordinating Center will send you instructions for accessing the *ELBW Infant Follow-up Report Log* for your Center. To complete this Log, you will need your Vermont Oxford Network Database Patient Log and your 28-Day Forms.

1. Establish an Infant's Eligible Follow-up Dates

Dates for follow-up are between the 18 months, 0 days - 24 months, 30 days corrected age date for each infant. You will use the infant's date of birth and gestational age in weeks and days to determine the 18 months corrected age date and the 24 months corrected age date. An on-line corrected age calculator supported by the NICHD Neonatal Research Network can be found at: https://neonatal.rti.org/index.cfm?fuseaction=AdjustedAgeCalculator.main.

2. Track the Progress of the Infant's Follow-up

Enter the date of the infant's scheduled health follow-up visit and the developmental follow-up visit in the appropriate columns in the *ELBW Infant Follow-up Project Report Log*. When the *Health Status Report* and the *Developmental Status Report* have been completed, enter the date on which the data were submitted using REDCap. Some infants from your Center may not have data from a *Health Status Report* or a *Developmental Status Report* completed.

Keep your *ELBW Infant Follow-up Report Log*. This Log is the only way to identify infants in the ELBW Infant Follow-up Project. You may need to use this Log to find specific charts for review. You may wish to make copies of this Log in case the originals are lost. Keep your log in a safe and secure place.

VI. INFANT FOLLOW-UP PROJECT DATA

The purpose of the *Infant Follow-up Project Data Forms* is to provide a tool to document the health and developmental status of the infant from the time of ultimate hospital discharge to the follow-up visit. Paper-based *Infant Follow-up Project Data Forms* include the *Health Status Report* and the *Developmental Status Report*. **Please be sure to use version 21 of these forms for when collecting data for the Birth Year 2018 Cohort Follow-up.** The electronic-based REDCap *Infant Follow-up Project Data Forms* (referred to as Data Collection Instruments) include the *ELBW Header*, the *Health Status Report* and the *Developmental Status Report.*

A. ELBW HEADER

The *ELBW Header* data collection instrument documents the patient, center and study identification. Open the ELBW Header data instrument, complete the data items and either save and exit the form or save and go to the next form.

Record ID

The Record ID is the first pre-populated field on the *ELBW Header* data collection instrument and corresponds to the infant VON ID and the center number – for example 999-1234.

Center Number

The Center Number is the second pre-populated field on the *ELBW Header* data collection instrument. It is the number that identifies your center.

VON Network ID Number

The VON Network ID Number is the third pre-populated field on the *ELBW Header* data collection instrument. It is the number assigned to the infant for the VON Database according to the VON Database Manual of Operations. In REDCap, the infant VON Network ID number should **exactly** match the Record ID.

Year of Birth

The Year of Birth is the fourth pre-populated field on the *ELBW Header* data collection instrument. It identifies the Infant Year of Birth.

Follow-up Category

Indicate the infant follow-up category.

Check "ELBW 2018" for follow-up related to the Birth Year Cohort 2018.

Check "Clinical Study" for follow-up related to a VON Clinical trial.

Status at 18-24 Months' Corrected Age

Indicate the infant's status at the time of the follow-up visit between the 18 - 24 months corrected age dates.

Check "Alive" if the infant is known to be alive at the 18 - 24 months corrected age health follow-up visit date.

Check "Expired" if the infant died between the ultimate hospital discharge date and the 18 - 24 months corrected age health follow-up visit date.

Check "Unknown" if the status of the infant is unknown at the 18 - 24 months corrected age health follow-up visit date, because the infant was lost to follow-up.

IF "Expired" or "Unknown" is checked, you may stop here: the record is complete.

Did the infant complete a follow-up visit between 18- and 24-months corrected age?

The target follow-up visit will occur between 18 and 24 months corrected age. For the 2018 birth year cohort, data will not be accepted for follow-up at less than 18 months corrected age or more than 24 months correct age. If two follow-up visits occur between 18 and 24 months corrected age, only submit date from the most recent visit. For example, if a visit occurs at 18 months and 23 months corrected age, only submit data from the 23 months corrected age visit.

Check "Yes" if a follow-up visit occurred between 18 and 24 months corrected age.

Check "No" if a follow-up visit did not occur between 18 and 24 months corrected age.

IF "No" is checked, you may stop here: the record is complete.

Form Status Complete?

Upon completion of the data entry, select the appropriate entry from the drop-down list. Choose "incomplete" if questions remain to be answered. Choose "unverified" if answers entered need verification. Choose "complete" if questions have been answered, and answers have been verified. Click "Save and Exit Form" or "Save and Go To Next Form".

B. HEALTH STATUS REPORT

The *Health Status Report* documents the health status of the infant at the 18 - 24 months corrected age health follow-up visit. The *Health Status Report* should be completed at a health follow-up visit between the 18 months corrected age date and the 24 months corrected age date. 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.

Header: Form Completed

Indicate when you completed this form.

Check "During Visit" if you completed this form during the infant's follow-up visit.

Check "From Chart" if you completed this form by chart review.

Check "Both" if you completed this form both during the infant's follow-up visit and by chart review.

Section A: Health Status

ITEM 1: Corrected Age at the Follow-up Visit (months/days)

Enter the months and days of the corrected age at the follow-up visit. You will use the infant's date of birth and gestational age in weeks and days and the follow-up visit date to determine the infant's corrected age. An on-line corrected age calculator supported by the NICHD Neonatal Research Network can be found at:
https://neonatal.rti.org/index.cfm?fuseaction=AdjustedAgeCalculator.main.

Section B: Living Situation

ITEM 2: Maternal Age at Infant Birth (years)

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

Enter "unknown", if the maternal age at the infant's birth is unknown.

ITEM 3: Home Child Resides

Indicate the infant's home living situation between the ultimate hospital discharge and the 18 - 24 months corrected age 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 "Institutional " if the infant lives and is cared for in an institution or chronic care facility.
Check "Unknown" if the infant's home living situation is not known or is unclear.

ITEM 4: Caregivers

Indicate the type of social support in the infant's home living situation between the ultimate hospital discharge and the 18 - 24 months corrected age 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 with other related adults 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 with other related adults in the home.
Check "Institutional" if the infant lives in a chronic care facility or remains hospitalized.
Check "Unknown" if the infant's home caregiver is not known or is unclear.

ITEM 5: Primary Caregiver Education

Indicate the highest level of education of the primary care giver in the home between the ultimate hospital discharge and the 18 - 24 months corrected age 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 degree" if the primary caregiver has graduated from a college or university.
Check "Not applicable" only if the infant lives in a chronic care facility or institution.
Check "Unknown" if the highest level of education is unknown or is unclear.

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ITEM 6: Income Below 2018 HHS Poverty Guideline

Indicate whether the household income for 2018 was below the 2018 HHS Poverty Guideline (35) 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 B). 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 2018. 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 2018 below the number in the column?"

Check "Yes" if the 2018 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 2018 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 2018 household income.

ITEM 7: Caregiver(s) Primary Language

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

Section C: Support After Discharge

ITEM 8: Any Outpatient Support After Discharge

Indicate whether the infant had any of the listed supports or interventions at any time between the ultimate birth hospital discharge and the 18 - 24 months corrected age health follow-up visit. The support or intervention may have been initiated prior to ultimate birth hospital discharge (and continued after discharge) or may have been initiated between the ultimate birth hospital discharge and the follow-up visit. The support may have been discontinued before the follow-up visit, or be in place at the time of the follow-up visit. These supports or interventions are specific to the outpatient setting. Do not check a support or intervention that was started AND stopped during a medical or surgical readmission. However, if a support was started during a readmission and continued upon discharge from the readmission, then the support qualifies as applied.

Check "Yes" if the infant received any of the listed supports or interventions after the ultimate birth hospital discharge.

Check "No" if the infant did not receive any of the listed supports or interventions after the ultimate birth hospital discharge.

Check "Unsure" if you are not sure if the infant received any of the listed supports or interventions listed after the ultimate birth hospital discharge.

If Yes, complete the following

If "Yes" is checked, assess each category of support. For support at any time after discharge, answer "Yes,", "No", or "Unsure"; for support at present clinic visit, answer "Yes" or "No". Be sure to answer both ("Any time after discharge" and "At present clinic visit") for each category of support.

Tracheostomy: Indicate whether the infant had a functional tracheostomy.

Ventilator: Indicate whether the infant received ventilator support. Ventilator support includes intermittent mandatory ventilation or continuous positive airway pressure.

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.

Gastrostomy: Indicate whether the infant had a functional gastrostomy.

Nasogastric or Post-pyloric Feeds: Indicate whether the infant received nasogastric or post-pyloric (e.g. naso-duodenal or naso- jejunal) feeds.

Apnea or CP monitor: Indicate whether the infant was on an apnea monitor or a cardiopulmonary

(CP) monitor.

Pulse Oximetry: Indicate whether the infant was on a Pulse Oximeter Monitor.

Respiratory Medication: Indicate whether the infant was receiving a respiratory medication(s). Respiratory medications may include diuretic therapy, inhaled or nebulized bronchodilators or steroid medications. Medications may be given on any interval (e.g. daily) or used PRN. For the purpose of this category of support, Palivizumab (Synagis®) or other antiviral prophylactic agents are **not** considered respiratory medications.

Oral Feeding Support: Indicate whether the infant is receiving any support to promote, establish or maintain oral feeding.

Speech Support: Indicate whether the infant is receiving any support to promote or establish speech.

Motor Support: Indicate whether the infant is receiving any support to promote, establish or maintain gross or fine motor activities.

Section D: Medical Re-Hospitalizations

ITEM 9: Medical Readmissions (after ultimate discharge)

Indicate whether the infant was re-hospitalized at any time between the ultimate birth hospital discharge and the 18 - 24 months corrected age 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.

If "Yes" is checked, indicate whether the infant was hospitalized for each of the specific medical re-hospitalization categories listed. A hospital admission should be assigned to only one re-hospitalization category. Check "Yes", "No", or "Unsure" for each of the re-hospitalization categories. Enter the "Number of Admissions" as the number of medical re-hospitalizations for each category marked "Yes".

Respiratory Illness: This category 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 re- hospitalizations as related to pulmonary infections (e.g. "RSV- bronchiolitis"), "Acute Life Threatening Event", or "Near SIDS".

Nutrition/Failure to Thrive: This category includes medical re-hospitalizations for nutritional issues or failure to gain weight. This category excludes medical re-hospitalizations related to gastrointestinal infections.

Seizure Disorder: This category includes medical re-hospitalizations for partial, generalized or unclassified seizures and convulsive disorders which may or may not have EEG correlates. Non epileptic paroxysmal physiologic events which mimic seizures (e.g. migraines) or pseudo-seizures should be included in this category. This category excludes medical re-hospitalizations as related to CNS infections: if the seizure is sequelae of a specific acute infection of the cerebrum or meninges, the re-hospitalization should be coded under the appropriate category of "Infection".

Shunt Complication: This category includes medical re-hospitalizations for complications related to or associated with cerebrospinal fluid shunts and re-hospitalizations as related to shunt infections. Fever, irritability, vomiting, and abdominal symptoms typically indicate shunt infection. The diagnosis of a shunt infection does not require blood or CSF culture to be positive. Shunt malfunction may occur.

Infections (not respiratory or shunt infections)

Meningitis: This category includes medical re-hospitalizations for bacterial or aseptic meningitis. The diagnosis of meningitis requires a single CSF culture to be positive. Infections related to or associated with cerebrospinal fluid shunts are excluded from this category.

Urinary Tract Infection: This category 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.

Gastrointestinal Infection: This category includes medical re-hospitalizations for infectious diarrhea illnesses such as endemic diarrhea, food-borne or water borne diarrhea, 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.

Other Infection (specify): This category includes medical re-hospitalizations for infections not meeting the inclusion requirements of one of the above categories. Enter a specific infection.

Other Medical Readmission (specify): This category includes medical re-hospitalizations that do not meet the inclusion requirements of one of the above categories. This category excludes re-hospitalizations for surgeries, or for monitoring after a surgery.

Section E: Surgeries

ITEM 10: Surgical Procedures (after ultimate discharge)

Indicate whether the infant had a surgical procedure performed after ultimate birth hospital discharge. This would include one or more surgical procedures performed at any time between the ultimate birth hospital discharge date and the 18 - 24 months corrected age health follow-up visit. Surgical procedures may occur as outpatient or day surgeries, or may require re-hospitalization.

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.

Please note that the surgical procedure codes for the ELBW Infant Follow-up Project are NOT the same as codes used to record surgeries in the VON VLBW Database. ELBW Infant Follow -up Procedure codes (P-codes) can be found on the reverse side of the Health Status Report Form or in Appendix C.

Enter the three digit "P- Code" from the list of surgical procedures on the back of the Health Status Report; or refer to Appendix C: 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 the Health Status Report or in Appendix C, 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 marked "Yes".

Form Status Complete?

Upon completion of the data entry, select the appropriate entry from the drop down list. Choose "incomplete" if questions remain to be answered. Choose "unverified" if answers entered need verification. Choose "complete" if questions have been answered, and answers have been verified. Click "Save and Exit Form" or "Save and Go To Next Form".

C. DEVELOPMENTAL STATUS REPORT

The *Developmental Status Report* documents the neurodevelopmental status of the infant at the 18 - 24 months' corrected age developmental follow-up visit. The *Developmental Status Report* should be completed at a developmental follow-up visit between the 18 months' corrected age date and the 24 months corrected age date. 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.

Header: Form Completed

Indicate when you completed this form.

Check "During Visit" if you completed this form during the infant's follow-up visit.

Check "From Chart" if you completed this form by chart review.

Check "Both" if you completed this form both during the infant's follow-up visit and by chart review.

Section A: Growth Parameters

ITEM 1: Corrected Age Growth Parameters Were Obtained (months/days)

Enter the months and days of the corrected age at the follow-up visit. You will use the infant's date of birth and gestational age in weeks and days and the follow-up visit date at which the growth parameters were obtained to determine the infant's corrected age. An on-line corrected age calculator supported by the NICHD Neonatal Research Network can be found at: https://neonatal.rti.org/index.cfm?fuseaction=AdjustedAgeCalculator.main.

ITEM 2: Weight (kg)

Enter the weight recorded at the developmental follow-up visit. Enter the weight in kilograms (kg), to the tenths place. If the weight is unknown because it was not measured at the developmental follow-up visit, enter "99.9". Do not enter a weight measured at another visit.

ITEM 3: Head Circumference (cm)

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 is unknown because it was not measured at the developmental follow-up visit, enter "99.9". Do not enter a head circumference measured at another visit.

Section B: Vision & Hearing

ITEM 4: Post Discharge Eye Treatment

Indicate whether the infant received post discharge eye treatment at any time from the ultimate hospital discharge to the 18-24 months corrected age follow-up visit. Check only one.

Check "Laser Therapy" if the infant received laser therapy for ROP in one or both eyes.

Check "Anti-VEGF Drug" if the infant received bevacozumab (Avastin®) or other anti-vascular endothelial growth factor (Anti-VEGF) drug in one or both eyes for the treatment of ROP.

Check "Both" if the infant received both laser therapy and an Anti-VEGF drug for the treatment of ROP.

Check "Neither" if the infant did not receive either laser therapy or an Anti-VEGF drug.

Check "Unsure" if you are unsure whether the infant received either laser therapy or and anti-VEGF drug.

ITEM 5: 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 "Neither" 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 6: 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.

Check "Unsure" if you are unsure if the infant currently uses prescription glasses.

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 "Neither" 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.

Check "Unsure" if you are unsure if the infant currently uses corrective hearing aids.

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.

Check "Unsure" if you are unsure if the infant has cerebral palsy.

If Yes, impairment

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.

Check "Unsure" if you are unsure how the infant is affected.

If No, muscle tone

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.
Check "Unsure" if you are unsure of the infant's muscle tone.

Section D: Gross Motor Milestones

ITEM 10: Sits independently

Indicate whether the infant can sit independently. Independently is defined as sitting without holding on to anyone or anything.
Check "Yes" if the infant can sit independently.
Check "No" if the infant cannot sit independently.
Check "Unsure" if you are unsure whether the infant can sit independently.

If No, sits with support

Check "Yes" if the infant can sit with support.
Check "No" if the infant cannot sit with support.
Check "Unsure" if you are unsure whether the infant can sit without support.

ITEM 11: Walks ten (10) steps independently

Indicate whether the infant can walk ten (10) steps independently. Independently is defined as walking without holding on to anyone or anything. Gait can be symmetric or asymmetric when walking independently.
Check "Yes" if the infant can walk ten (10) steps independently.
Check "No" if the infant cannot walk ten (10) steps independently.
Check "Unsure" if you are unsure whether the infant can walk ten (10) steps independently.

If No, walks ten (10) steps with support

Check "Yes" if the infant can walk ten (10) steps with support.
Check "No" if the infant cannot walk ten (10) steps with support.
Check "Unsure" if you are unsure whether the infant can walk ten (10) steps with support.

Section E: Developmental Testing

ITEM 12: Developmental Evaluation

Indicate whether the infant's development was evaluated at the 18 - 24 months corrected age developmental follow-up visit using either the Bayley Scales of Infant Development 4th edition (BSID-4) or another developmental assessment tool.

Check "Completed" if the infant's development was evaluated using any developmental assessment tool.

Check "Partially completed" if the infant's development was partially evaluated with any one or more of the subtests of the BSID-4 or any part of another developmental assessment tool.

Check "Not done" if the infant's development was not evaluated with any of the subtests of the BSID-4 or with any other developmental assessment tool.

- If "Partially completed" or "not done" is checked, then the reason why **must** be answered.
- If "Completed" or "Partially completed" is checked, the test used **must** be answered.

ITEM 12a: If partially completed or not done, check (√) why

Check "Neurosensory impairment" if the child was blind or deaf or both 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 test 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 test to be performed.

Check "Other" if there was another reason the test was not administered.

ITEM 12b: IF completed or partially completed, check (√) which test

Check "the Bayley Scales of Infant Development-4" if the BSID-4 was used in the developmental evaluation.

Check "Other" if another assessment tool was used in the developmental evaluation.

ITEM 13: Corrected Age Used In Scoring (months/days)

If the answer to Item #13 is "Completed" or "Partially completed", enter the corrected age used in scoring the BSID-4 as the age in months and days. You will use the infant's date of birth and

gestational age in weeks and days and the follow-up visit date at which the developmental assessment was administered to determine the infant's corrected age. An on-line corrected age calculator supported by the NICHD Neonatal Research Network can be found at: https://neonatal.rti.org/index.cfm?fuseaction=AdjustedAgeCalculator.main.

ITEM 14: Results (BSID-4)

Enter the results for the BSID-4. There are three scales: the cognitive scale, the language scale and the motor scale. For each of these, check "Yes" if the scale was performed; check "No" if the scale was not performed. If the scale was performed enter the corresponding composite score.

Both the Language and Motor scale have two subtests: for the Language scale, expressive and receptive communication; for the Motor scale, gross and fine motor. For each, check "Yes" if the subtest was performed; check "No" if the subtest was not performed. If the subtest was performed enter the corresponding scaled score.

Section F: Overall Clinical Appraisal

Item 16: Clinical Appraisal: Cognitive Function

Indicate the clinical appraisal of the infant's cognitive functioning. The clinical appraisal is a summary of the impressions of the health care team upon seeing the infant at the 18 - 24 months corrected age 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 18-24 months age.

Check "Suspect" if it is unclear whether the infant's cognitive functioning is delayed for 18-24 months age.

Check "Impaired" if the infant's cognitive functioning is abnormal for 18-24 months age.

Check "Unsure" if you are unsure of the infant's cognitive functioning at 18-24 months.

Item 16: Clinical Appraisal: Language

Indicate the clinical appraisal of the infant's language. The clinical appraisal is a summary of the impressions of the health care team upon seeing and listening to the infant at the 18 - 24 months corrected age 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 is appropriate for 18-24 months age.

Check "Suspect" if it is unclear whether the infant's language is delayed for 18-24 months age.

Check "Impaired" if the infant's language is abnormal for 18-24 months age.
Check "Unsure" if you are unsure of the infant's language at 18-24 months.

Item 16: Clinical Appraisal: 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 18 - 24 months corrected age 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 18-24 months age.
Check "Suspect" if it is unclear whether the infant's motor functioning is delayed for 18-24 months' age.
Check "Impaired" if the infant's motor functioning is abnormal for 18-24 months age.
Check "Unsure" if you are unsure of the infant's motor functioning at 18-24 months.

Form Status Complete?

Upon completion of the data entry, select the appropriate entry from the drop down list. Choose "incomplete" if questions remain to be answered. Choose "unverified" if answers entered need verification. Choose "complete" if questions have been answered, and answers have been verified. Click "Save and Exit Form" or "Save and Stay".

VII. HOW TO TRANSMIT DATA

All study data is submitted using REDCap data instruments. Centers may choose to use available paper- based forms for initial data collection, but these forms will not be accepted for data submission. If paper forms are used for data collection, data is transcribed to the corresponding REDCap data instrument for submission.

Keep your ELBW Infant Follow-up Project Report Log secure. The ELBW 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 ELBW Infant Follow-up Project Report Log as each page of the Log is completed in case the original is lost.

Keep your ELBW Infant Follow-up Project Report Log up to date. Enter data on the Log as data forms are submitted.

VIII. PUBLICATIONS

Vermont Oxford Network will author all publications, which are based on data collected at all centers during the conduct of this follow-up project. 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 Infant Follow-up Project Steering Committee and the VON Clinical Trials & Follow-up Data Coordinating Center. The appendix will list Charles E. Mercier, MD (Principal Investigator); Roger F. Soll, MD (co-Principal Investigator, Vermont Oxford Network Trials & Follow-up Director); Erika Edwards (Data Science); Kate Morrow (Study Statistician); and Sharla Crowley, Study Coordinator. 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 Steering Committee to ensure that these studies will not interfere with the main study.

IX. REFERENCES

1. The Vermont-Oxford Trials Network: very low birth weight outcomes for 1990. Investigators of the Vermont-Oxford Trials Network Database Project. *Pediatrics*. 1993;91:540-5.

2. Horbar, JD, Carpenter JH, Badger GJ, Kenny MJ, Soll RF, Morrow KA, Buzas JS. Mortality and neonatal morbidity among infants 501 to 1500 grams from 2000 to 2009. *Pediatrics.* 2012;129(6): 1019-1026.

3. Mercier CE, Dunn, MS, Ferrelli KR, Howard DB, Soll RF, and the Vermont Oxford Network ELBW Follow-up Study Group. Neurodevelopmental Outcome of Extremely Low Birth Weight Infants from the Vermont Oxford Network: 1998-2003. Neonatology. 2010;97:329-338.

4. Department of Health and Human Services. Annual update of the HHS Poverty Guidelines. *Federal Register*. 2017 Jan 31; 82(19):8831-8832.

Appendix A: ELBW Infant Follow-up Project – 2017 Cohort Center List

Akron Children's Hospital / OH

Baystate Medical Center / MA

Cape Fear Valley Medical Center / NC

Children's Hospital of Wisconsin / WI

Children's Hospitals and Clinics / MN

CHOI at OSF St. Francis Medical Center / IL

Cone Health Women's Hospital / NC

CT Children's Medical Center / CT

Dartmouth Hitchcock Medical Center / NH

DeVos Children's/Spectrum Health / MI

Driscoll Children's Hospital / TX

Golisano Children's Hospital of SW FL / FL

Goryeb Children's Hospital / NJ

Henry Ford Hospital / MI

IRCCS Ospedale Maggiore di Milano / Italy

K.K. Women's & Children's Hospital / Singapore

Mass General Hospital for Children / MA

Mercy San Juan Medical Ctr /CA

NHRMC-Betty H. Cameron Women & Children's Hosp / NC

O.U. Health Sciences Center / OK

Providence Tarzana Medical Center / CA

Rainbow Babies & Children's Hospital / OH

Rocky Mountain Hospital for Children at P/SL / CO

St. Barnabas Medical Center / NJ

Sunnybrook Health Sciences Centre / Canada

Tufts Medical Center / MA

UCSF Benioff Children's Hosp / CA

UMass Memorial Health Care / MA

University Hospital San Antonio / TX

University of Iowa Children's Hospital / IA

University of Louisville / KY

University of Vermont Children's Hospital / VT

USA Children's and Women's Hospital / AL

Vidant Medical Center / NC

WakeMed Faculty Physicians / NC

Women & Infants Hospital / RI

Yale-New Haven Children's Hosp **Bridgeport** / CT

Yale-New Haven Children's Hosp / CT

Continued participation of centers in the Year 2017 Cohort is anticipated for the Year 2018 Cohort. New centers, having completed center eligibility requirements are welcome.

Appendix B: Script for Question 6 (Health Status Report)

We would like to ask you a question about your household income in the 2018 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 is for the year 2018 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 2018. Next look at the column on the right and answer "Yes" or "No" to the question "Was your household income for the year 2018 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 2018
2	$ 16,460
3	$ 20,780
4	$ 25,100
5	$ 29,420
6	$ 33,740
7	$ 38,060
8	$ 42,380
Each additional person	$ 4,320

Source: Federal Register Vol. 83, No.12, January 18, 2018. pp 2642-2643.

Appendix C: Surgical Procedure Codes (P-Codes)

P-CODE	CATEGORY
	Central Nervous System Surgery
P-101	Shunt or shunt revision for hydrocephalus
P-102	Other neurosurgical procedure
	Congenital Heart Defect Surgery
P-201	Cardiac surgery
	Gastrointestinal Surgery
P-301	Gastrostomy tube placement
P-302	Inguinal hernia repair
P-303	Other gastrointestinal surgical procedure
	Genitourinary Surgery
P-401	Circumcision
P-402	Other genitourinary surgical procedure
	Otolaryngology Surgery
P-501	Tracheostomy
P-502	Tympanostomy tubes
P-503	Other ENT surgical procedure
	Ophthalmologic Surgery
P-601	Retinal cryosurgery or laser surgery: single eye
P-602	Retinal cryosurgery or laser surgery: both eyes
P-603	Strabismus surgery
P-604	Other ophthalmologic surgical procedure
P-900	**Other Surgical Procedure**

Appendix D: Sample Report Log and Data Forms

1. Extremely Low Birth Weight Infant Follow-up Report Log

Center: **xxx**

Birth Year: 2018 ▾ (2018, 2017, 2016)
Download

ELBW Follow-up Project Report Log
Births During 2018, Center xxx

Risk Factors for Severe Disability:
CLD - Chronic Lung Disease
sIVH - Severe Intraventricular Hemorrhage
PVL - Periventricular Leukomalacia
sROP - Severe Retinopathy of Prematurity

Network ID	Date of Birth	Patient's Name	GA Weeks	GA Days	CLD	sIVH	PVL	sROP	18 Months Corrected Age Date	24 Months Corrected Age Date	Follow Up Visit Date	REDCap Completed Date
1788			26	1	Y	Y		Y				
1789			26	6	Y	Y	Y					
1803			28	6								
1807			27	6	Y							
1808			27	6								
1811			27	5								
1814			24	5	Y		Y					
1819			27	1	Y							
1821			25	4	Y							
1822			27	4								
1823			30	6								
1827			27	5								

VERMONT OXFORD NETWORK

THE EXTREMELY-LOW-BIRTH-WEIGHT INFANT FOLLOW-UP PROJECT: 2018 COHORT

MANUAL OF OPERATIONS Release 21

2. Sample: Health Status Report (Version 21)

Patient's Name: _____ Medical Record:_____

(Please do not transmit information in this box)

VERMONT OXFORD NETWORK - Infant Follow-Up - *HEALTH STATUS REPORT*

Center Number: _____ Center Name: _____

Network ID Number: _____ Year of Birth (YYYY): _____

Form Completed: ☐ During Visit ☐ From Chart ☐ Telemedicine

Status at 18 – 24 Months Corrected Age: ☐ Alive ☐ Expired ☐ Unknown

SECTION A: HEALTH STATUS

1. Corrected Age at the follow-up visit (months/days): ___ ___ months ___ ___ days

SECTION B: LIVING SITUATION

2. Maternal Age at Infant Birth: ___ ___years ☐ Unknown
3. Home Child Resides: ☐ Parent/Family member ☐ Foster care ☐ Institutional ☐ Unknown
4. Caregivers: ☐ Single parent ☐ Two parent ☐ Institutional ☐ Unknown
   Check (✓) only one ☐ Single parent extended family ☐ Two parent extended family
5. Primary Caregiver Education: ☐ Some High School or less ☐ Some college/university
   Check (✓) only one ☐ High School degree/GED ☐ College/university degree
   ☐ Not applicable ☐ Unknown

USA CENTERS ONLY

6. Income Below 2018 HHS Poverty Guideline: ☐ Yes ☐ No ☐ Unknown
7. Caregiver(s) Primary Language: ☐ English ☐ Spanish ☐ Other

Income 2018 HHS Poverty Guidelines (48 contiguous states and District of Columbia)			
Persons	Income	Persons	Income
2	$ 16,460	6	$ 33,740
3	$ 20,780	7	$ 38,060
4	$ 25,100	8	$ 42,380
5	$ 29,420	Additional	$ 4,320
***Source:* Federal Registrar Vol. 83, No.12, January 18, 2018, pp.2642-2643.**			

SECTION C: SUPPORT AFTER DISCHARGE

8. Any Outpatient Support: ☐ Yes ☐ No ☐ Unsure

***If yes,** complete the following*	Any time *after discharge*			At present *clinic visit*		
a. Tracheostomy:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
b. Ventilator:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
c. Oxygen:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
d. Gastrostomy:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
e. Nasogastric or Post-pyloric Feeds:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
f. Apnea or CP monitor:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
g. Pulse Oximetry:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
h. Respiratory Medications:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
i. Oral Feeding Support:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
j. Speech Support:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure
k. Motor Support:	☐ Yes	☐ No	☐ Unsure	☐ Yes	☐ No	☐ Unsure

SECTION D: MEDICAL RE-HOSPITALIZATIONS AFTER DISCHARGE

9.	Any Medical Readmissions (after ultimate discharge):		☐ Yes	☐ No	☐ Unsure
	If yes, *complete the following*				# Admissions
a.	Respiratory Illness:	☐ Yes	☐ No	☐ Unsure	____ ____
b.	Nutrition/ Failure to Thrive:	☐ Yes	☐ No	☐ Unsure	____ ____
c.	Seizure Disorder:	☐ Yes	☐ No	☐ Unsure	____ ____
d.	Shunt Complication:	☐ Yes	☐ No	☐ Unsure	____ ____
e.	*Infections (not respiratory or shunt infections)*				
	i. Meningitis:	☐ Yes	☐ No	☐ Unsure	____ ____
	ii. Urinary Tract Infection:	☐ Yes	☐ No	☐ Unsure	____ ____
	iii. Gastrointestinal Infection:	☐ Yes	☐ No	☐ Unsure	____ ____
	iv. Other infection:	☐ Yes	☐ No	☐ Unsure	
	If yes, specify: _____				____ ____
f.	Other Medical Readmissions:	☐ Yes	☐ No	☐ Unsure	
	If yes, specify: _____				____ ____

SECTION E: SURGERIES

10.	Surgical procedures (after ultimate discharge):	☐ Yes	☐ No	☐ Unsure
	If Yes, *put all that apply*		# Procedures	
a.	*(P-Code)* _____		____ ____	
b.	*(P-Code)* _____		____ ____	
c.	*(P-Code)* _____		____ ____	
d.	*(P-Code)* _____		____ ____	
e.	*(P-Code)* _____		____ ____	

SURGICAL PROCEDURE CODES (P-CODES)

P-Code	Procedure	P-Code	Procedure
	Central Nervous System Surgery		Otolaryngology Surgery
P-101	Shunt or shunt revision for hydrocephalus	P-501	Tracheostomy
P-102	Other neurosurgical procedure	P-502	Tympanostomy tubes
	Congenital Heart Defect Surgery	P-503	Other ENT surgical procedure
P-201	Cardiac surgery		Ophthalmologic Surgery
	Gastrointestinal Surgery	P-601	Retinal cryosurgery or laser surgery: single eye
P-301	Gastrostomy tube placement	P-602	Retinal cryosurgery or laser surgery: both eyes
P-302	Inguinal hernia repair	P-603	Strabismus surgery
P-303	Other gastrointestinal surgical procedure	P-604	Other ophthalmologic surgical procedure
	Genitourinary Surgery		
P-401	Circumcision	P-900	Other Surgical Procedure
P-402	Other genitourinary surgical procedure		

3. Sample: Developmental Status Report (Version 21)

Patient's Name: _____ Medical Record:_____

(Please do not transmit information in this box)

VERMONT OXFORD NETWORK - Infant Follow-up - *DEVELOPMENTAL STATUS REPORT*

Center Number: _____ Center Name: _____

Network ID Number: _____ Year of Birth (YYYY): _____

Follow-up Category: ☐ ELBW Birth Year 2018 ☐ Clinical trial (*specify*): _____

Form Completed: ☐ During Visit ☐ From Chart ☐ Telemedicine

SECTION A: GROWTH PARAMETERS

1.Corrected Age Growth Parameters Were Obtained (months/days): _____months _____days

2. Weight: ___ ___.___ ___ kg

3.Head Circumference: ___ ___.___ cm

SECTION B: VISION & HEARING

3.	Post Discharge Eye Treatment:	☐ Laser	☐ Anti-VEGF	☐ Both	☐ Neither	☐ Unsure
4.	Blindness:	☐ One eye	☐ Both eyes	☐ Neither	☐ Unsure	
5.	Prescription Glasses:	☐ Yes	☐ No	☐ Unsure		
6.	Hearing Impairment:	☐ One ear	☐ Both ears	☐ Neither	☐ Unsure	
7.	Amplification:	☐ Yes	☐ No	☐ Unsure		

SECTION C: CEREBRAL PALSY

8.	Cerebral Palsy:	☐ Yes	☐ No	☐ Unsure		
	If Yes, impairment:	☐ Diplegia	☐ Hemiplegia	☐ Quadriplegia	☐ Unsure	
	If No, muscle tone:	☐ Hypotonia	☐ Hypertonia	☐ Both	☐ Normal	☐ Unsure

SECTION D: GROSS MOTOR MILESTONES

9.	Sits independently:	☐ Yes	☐ No	☐ Unsure
	If No, sits with support:	☐ Yes	☐ No	☐ Unsure
10.	Walks ten (10) steps independently:	☐ Yes	☐ No	☐ Unsure
	If No, walks ten (10) steps with support:	☐ Yes	☐ No	☐ Unsure

SECTION E: DEVELOPMENTAL TESTING

11. Developmental Evaluation: ☐ Completed ☐ Partially completed ☐ Not done

a. If partially completed or not done, check (✓) why:

☐ Neurosensory impairment ☐ Too Severely Delayed ☐ Uncooperative ☐ Done via Telemedicine ☐ Other

b. If completed or partially completed, check (✓) which test:

☐ Bayley Scales – 3rd Edition ☐ Bayley Scales – 4th Edition ☐ Other test

12. Corrected Age Used In Scoring (months/days): _____months _____days

13. Results (BSID 3rd or 4th Edition):

			Scaled Score	Composite Score
☐Cognitive:	☐ Not Done	☐ Done	___ ___	___ ___
☐Language:	☐ Not Done	☐ Done	(Sum) ___ ___	___ ___
Expressive Communication:			___ ___	Not applicable
Receptive Communication:			___ ___	Not applicable
☐Motor:	☐ Not Done	☐ Done	(Sum) ___ ___	___ ___
Gross Motor:			___ ___	Not applicable
Fine Motor:			___ ___	Not applicable

SECTION F: OVERALL CLINICAL APPRAISAL

15. Clinical Appraisal:	Cognitive function:	☐ Normal	☐ Suspect	☐ Impaired	☐ Unsure
	Language:	☐ Normal	☐ Suspect	☐ Impaired	☐ Unsure
	Motor function:	☐ Normal	☐ Suspect	☐ Impaired	☐ Unsure

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