THE INFANT FOLLOW-UP PROJECT

Extremely-Low-Birth-Weight Infant
Birth Year 2016 Cohort
For infants born between January 1, 2016 and December 31, 2016

MANUAL OF OPERATIONS

THE VERMONT OXFORD NETWORK

September 2017

Version 19.1

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THE INFANT FOLLOW-UP PROJECT
ELBW Infant - Birth Year 2016 Cohort

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VERSION 19.1

INFANT ELIGIBILITY for the ELBW Infant Follow-Up: Birth Year 2016 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

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Birth Weight</th>
<th>Gestational Age (Weeks/ Days)</th>
<th>Eligibility Year 2016 Cohort</th>
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<tr>
<td>December 30, 2015</td>
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<td>No</td>
</tr>
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</tr>
<tr>
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<td>Yes</td>
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<td>January 5, 2016</td>
<td>401</td>
<td>22/0</td>
<td>Yes</td>
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<tr>
<td>January 5, 2016</td>
<td>380</td>
<td>22/0</td>
<td>Yes</td>
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<td>January 5, 2016</td>
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<tr>
<td>January 5, 2016</td>
<td>1100</td>
<td>27/6</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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 - 24 months’ 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, 2016.
- 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 3rd edition (BSID-III): participating centers outside North America may use the Griffiths Mental Development Scales Revised 0 - 2 Years (GMDS).
- The Center designates one specific Project Coordinator to manage data submission.
- The Center obtains local Institutional Review Board (IRB) approval for the project.

D. Extremely-Low-Birth-Weight Infant Eligibility

- The infant was born between January 1, 2016 and December 31, 2016;
- 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

• Parental consent for participation, as determined by local IRB approval, is obtained.

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 3rd Edition (BSID-III) or the Griffiths Mental Development Scales Revised 0-2 Years (GMDS) for the infant.

F. **Version 19.1 updates: Health Status Report**

The overall format of the Health Status Report has been changed to facilitate study data submission using REDCap. This has resulted in a re-numbering of data variable items.

There are two modifications to data variables in Version 19.1. First, in Section C: Support After Discharge, if Question 8 (Any Outpatient Support) is answered “Yes”, all categories of outpatient support should be answered as “Yes”, “No” or “Unsure” for support “any time after discharge” and as “Yes” or “No” for support “at present clinic visit”. For the support category specific to nasogastric feeds, the definition has been expanded to include all post-pyloric feeds (i.e. naso-duodenal or naso-jejunal). The remaining data items are unchanged: for question 6, income levels are amended in accordance with the 2016 Health and Human Services (HHS) Poverty Guidelines (35).

G. **Version 19.1 updates: Developmental Status Report**

The overall format of the Developmental Status Report has been changed to facilitate study data submission using REDCap.

There is one modification to data variables in Version 19.1. In Section B: Vision and Hearing Question 5 (Post Discharge Eye Treatment) now allows for checking either laser therapy for ROP treatment, Anti-VEGF for ROP treatment or both. Options for “Neither” (“None”) and “Unsure” remain unchanged for this variable.

There are two changes to the data variables collected. First, in Section B: Vision & Hearing, Question 4 (Post Discharge Eye Exam) and Question 7 (Post Discharge Hearing Test) have been
dropped. Second, in Section E: Developmental Testing Question 14 Results (BSID III), scaled scores for Receptive Communication, Expressive Communication, Gross Motor and Fine Motor function have been added. It is still expected that North American centers will continue to use the BSID-III as an assessment tool, while centers outside North America will likely use the GMDS.

Table 1. Changes to the Data Forms in Version 19.1

<table>
<thead>
<tr>
<th>Health Status Report: Question modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section C: Support After Discharge</td>
</tr>
<tr>
<td>Question 8: Any Outpatient Support: If yes, complete the following</td>
</tr>
<tr>
<td>Answer all categories of outpatient support at any time after discharge as “Yes”, “No”, or “Unsure”.</td>
</tr>
<tr>
<td>Answer all categories of outpatient support at the present clinic visit as “Yes”, or “No”.</td>
</tr>
<tr>
<td>Item e: Nasogastric or Post-pyloric Feeds</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Developmental Status Report: Question modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section B: Vision &amp; Hearing</td>
</tr>
<tr>
<td>Question 5: Post Discharge Eye Treatment</td>
</tr>
<tr>
<td>Answer choices: Laser, Anti-VEGF, Both, Neither, Unsure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Developmental Status Report: Questions dropped</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section B: Vision &amp; Hearing</td>
</tr>
<tr>
<td>Question 4: Post Discharge Eye Exam</td>
</tr>
<tr>
<td>Question 7: Post Discharge Hearing test</td>
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</table>

<table>
<thead>
<tr>
<th>Developmental Status Report: Questions added</th>
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</thead>
<tbody>
<tr>
<td>Section E: Developmental Testing</td>
</tr>
<tr>
<td>Question 14. Results (BSID III)</td>
</tr>
<tr>
<td>Receptive Communication Scaled Score</td>
</tr>
<tr>
<td>Expressive Communication Scaled Score</td>
</tr>
<tr>
<td>Gross Motor Scaled Score</td>
</tr>
<tr>
<td>Fine Motor Scaled Score</td>
</tr>
</tbody>
</table>

H. Parental Interview and Reporting Questionnaire

The Parental Interview and Reporting Questionnaire (PIRQ) is no longer being collected or reported at the time of the 18 - 24 months’ corrected age follow-up visit.

II. STUDY ADMINISTRATION

A. Overview

The ELBW Infant Birth Year 2016 Cohort follow-up is a project conducted by the Vermont Oxford Network (VON), Division of Clinical Trials & Follow-Up. The VON Clinical Trials & Follow-Up Data
The 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. Each participating Network Center will obtain approval for the study from their Institutional Review Board and submit a copy of the approval to the VON Clinical Trials & Follow-Up Data Coordinating Center.

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 - 17:00 pm, Eastern Standard Time. You may contact Karla Ferrelli at the Clinical Trials & Follow-Up Data Coordinating Center by email karla@vtoxford.org, telephone (802) 865-4814 ext. 212, or fax (802) 865-9613 or (802) 865-0359 with any questions.

III. CENTER PARTICIPATION

A. Center Responsibilities

The Center’s Principle Investigator is responsible for obtaining local Institutional Review Board (IRB) approval for the project. If required, the Center Investigator completes periodic IRB reviews, and submits necessary amendments or renewals or both. The Center Investigator is also responsible for sending a copy of current IRB approval to the VON Clinical Trials & Follow-Up Data Coordinating Center. Finally, 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, submits data forms to VON, and works with VON to reconcile any data errors or omissions or both. The Project Coordinator may also assist in obtaining IRB approval for project participation.

B. Center Project Materials

Upon receiving a copy of the Network Center’s Institutional Review Board (IRB) approval, the VON Clinical Trials & Follow-Up Data Coordinating Center will send the Center’s Principal Investigator a set of *The ELBW Infant Follow-Up Project 2016* data collection log, paper forms
and access information to REDCap, a browser based electronic data entry tool for submitting study data. All participating Centers must obtain IRB approval at their respective center before initiating data collection. Documentation of IRB approval must be received by the VON Clinical Trials & Follow-Up Data Coordinating Center before data will be accepted.

C. Center Project Timeline

Data is to be collected during the time of the infant's follow-up visit between 18 and 24 months’ 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 2017 and April 2019.

IV. DATA COLLECTION & SUBMISSION

A. Data Collection

Data may be collected using paper-based Birth Year 2016 Cohort Infant Follow-Up Data Forms or electronically using REDCap data instruments.

B. Data Submission

For Birth Year Cohort 2016 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 is 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, admitted to your NICU, 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, admitted to your NICU, transferred on or before day 28 from your center and survive until ultimate hospital disposition. To be eligible for follow-up at your center the infant must be re-admitted to your center after transfer.
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 the ELBW Infant Follow-Up Report Log for your Center. To complete this Log, you will need your Vermont Oxford Network Database Patient Log, your 28-Day Forms, and the corrected age calculator (refer to Appendix B, Instructions for Using the Corrected Age Calculator).

B. Using the ELBW Infant Follow-Up Project Report Log

The ELBW Infant Follow-Up Project Report Log is a tool for establishing eligible follow-up dates, noting the follow-up report progress of infants from your Center who are eligible for the ELBW Infant Follow-Up Project, and coordinating follow-up visits for infants from your Center who are eligible to participate in the Project but who may not receive their 18 to 24 Months’ Corrected Age Follow-Up Visit at your follow-up clinic. The Clinical Trials & Follow-Up Data Coordinating Center will send you the ELBW Infant Follow-Up Project Report Log for all eligible infants from your Center.

1. Establishing an Infant’s Eligible Follow-Up Dates

Dates for follow-up are between the 18 months’ corrected age date and the 24 months’ corrected age date for each infant. You will determine the 18 months’ corrected age date and the 24 months corrected age date using the corrected age calculator and correcting for the number of weeks the infant was premature (Refer to Appendix B, Instructions for Using the Corrected Age Calculator). The VON Clinical Trials & Follow-Up Data Coordinating Center will send you a list of the gestational ages for each eligible infant. You may enter the infant’s date of
birth and the infant’s gestational age in weeks and days into the corrected age calculator to
determine the 18 months’ corrected age date and the 24 months’ corrected age date.

2. Tracking 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 (Refer to
Sections VIII: Health Status Report, and IX: Developmental Status Report), enter the date on
which the data were submitted using REDCap reports were mailed or faxed to the Clinical Trials
& Follow-Up Data Coordinating Center in the appropriate columns. Some infants from your
Center may not have data from a Health Status Report or a Developmental Status Report
completed (Refer to Section VIII: A: Infant Status at the 18 to 24 Months’ Corrected Age Visit).
Remember, data should be submitted within one month of the 24 months’ corrected age date
listed on the ELBW Infant Follow-Up Project Report Log (Refer to Section X: How To Transmit
Data).

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. The paper-based Infant Follow-Up Project Data Forms include the Health Status
Report and the Developmental Status Report. Please be sure to use version 19.1 of these
forms for when collecting data for the Birth Year 2016 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.

RecordID
The RecordID is the first pre-populated field on the *ELBW Header* data collection instrument and corresponds to the infant VON ID.

**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 and is assigned to your center for the VON Nightingale database.

**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 RecordID.

**Year of Birth**

The Year of Birth is entered using four digits. For example, an infant born in 2016 will have the Infant Year of Birth entered as “2016”.

**Follow-up Category**

Indicate the infant follow-up category.

Check “ELBW 2016” for follow-up related to the Birth Year Cohort 2016.

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 and mark the record as complete.**
Consent Obtained

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 18 - 24 months’ corrected age health follow-up visit.

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

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

**IF “No” is checked, you may stop here and mark the record as 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.

**Section A: Health Status**

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

You can determine the infant’s corrected age in months and days using the corrected age calculator (refer to Appendix B, Instructions for Using the Corrected Age Calculator). To use the calculator, enter the infant’s date of birth, gestational age at birth in weeks and days, and the date of the follow-up visit. The corrected age calculator will display the infant’s corrected age on the date of the health follow-up visit. Enter the months and days of the corrected age at the follow-up visit.

**Section B: Living Situation**

**ITEM 2: Maternal Age at Infant Birth (years)**

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

Enter “999”, 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.

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.

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 of the primary caregiver is not known or is unclear.

USA CENTERS ONLY

ITEM 6: Income Below 2016 HHS Poverty Guideline

Indicate whether the household income for 2016 was below the 2016 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 C). 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 2016. 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 2016 below the number in the column?”

Check “Yes” if the 2016 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 2016 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 2016 household income.

ITEM 7: 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.

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.
ITEM 8a Tracheostomy

Indicate whether the infant had a functional tracheostomy at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8b Ventilator

Indicate whether the infant received ventilator support at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both. Ventilator support includes intermittent mandatory ventilation or continuous positive airway pressure.

ITEM 8c Oxygen

Indicate whether the infant received supplemental oxygen at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both. Supplemental oxygen includes oxygen given with a ventilator, as well as free flow oxygen through a nasal cannula or hood.

ITEM 8d Gastrostomy

Indicate whether the infant had a functional gastrostomy at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8e Nasogastric or Post-pyloric Feeds

Indicate whether the infant received nasogastric or post-pyloric (e.g. naso-duodenal or naso-jejunal) feeds at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8f Apnea or CP monitor

Indicate whether the infant was on an apnea monitor or a cardiopulmonary (CP) monitor at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8g Pulse Oximetry

Indicate whether the infant was on a Pulse Oximeter Monitor at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8h Respiratory Medication

Indicate whether the infant was receiving a respiratory medication(s) at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both. 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.

ITEM 8i Oral Feeding Support
Indicate whether the infant receiving any support to promote, establish or maintain oral feeding at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8j Speech Support
Indicate whether the infant receiving any support to promote or establish speech at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

ITEM 8k Motor Support
Indicate whether the infant receiving any support to promote, establish or maintain gross or fine motor activities at any time after the ultimate hospital discharge, or at the follow-up clinic visit, or both.

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.

ITEM 9a: 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”.

ITEM 9b: 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.

ITEM 9c: 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”.

ITEM 9d: 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.

ITEM 9e: Infections (not respiratory or shunt infections)

ITEM 9ei: 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.

ITEM 9eii: 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.
ITEM 9eiii: 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.

ITEM 9eiv: 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.

ITEM 9f: 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 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.

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.

Section A: Growth Parameters

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

You can determine the infant’s corrected age in months and days using the corrected age calculator (refer to Appendix B, Instructions for Using the Corrected Age Calculator). Enter the infant’s date of birth, the gestational age at birth in weeks and days, and the date when growth parameters were obtained. The corrected age calculator will display the infant’s corrected age on the date of the developmental follow-up visit when the growth parameters were obtained. Enter the months and days of the corrected age at the follow-up visit.

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 developmental 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 an 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.

**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.

**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.

*If yes to cerebral palsy, cerebral palsy 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.

*If no to cerebral palsy, 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.

**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.

*If no, sits with support*

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. 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.

*If no to walks 10 steps independently, 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.
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 3rd edition (BSID-III), or the Griffiths Mental Development Scales Revised 0-2 Years (GMDS), 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-III, any one or more of the subtests of the GMDS, 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-III, or of the GMDS, 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-III” if the BSID-III was used in the developmental evaluation.

Check “Griffiths Mental Development Scales” if the GMDS 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-III or GMDS as the age in months and days. You can determine the infant’s corrected age in months and days using the corrected age calculator (refer to Appendix B, Instructions for Using the Corrected Age Calculator). To use this calculator, enter the infant’s date of birth, gestational age at birth in weeks and days, and the date on which developmental testing was performed. The corrected age calculator will display the infant’s corrected age on the date of the developmental testing. Enter the months and days of the corrected age used in scoring the BSID-III or GMDS.

**ITEM 14: Results BSID**

Enter the results for the BSID-III. For each subtest completed, check whether the subtest was performed. Check “Yes” if the subtest was performed; check “No” if the subtest was not performed. If the subtest was performed enter the corresponding scaled and composite scores.

For the Cognitive subtest, enter the Scaled Score and the Composite Score. For the Language, and Motor subtests, enter the Sum Scaled Score and the Composite Score. The Language Sum Scaled Score is the sum of the Expressive Communication (EC) and the Receptive Communication (RC) scaled scores; the Motor Sum Scaled Score is the sum of the Gross Motor (GM) and the Fine Motor (FM) scaled scores.

**ITEM 15: Results (GMDS)**

Enter the results for the GMDS. For each subtest completed check whether the subtest was performed. Check “Yes” if the subtest was performed; check “No” if the subtest was not performed. If the subtest was performed enter the corresponding uncorrected and corrected 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 corrected for prematurity.

Check “Suspect” if it is unclear whether the infant’s cognitive functioning is delayed for 18-24 months’ age corrected for prematurity.

Check “Impaired” if the infant’s cognitive functioning is abnormal for 18-24 months’ age corrected for prematurity.

**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 corrected for prematurity.

Check “Suspect” if it is unclear whether the infant’s language is delayed for 18-24 months’ age corrected for prematurity.

Check “Impaired” if the infant’s language is abnormal for 18-24 months’ age corrected for prematurity.

**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 corrected for prematurity.

Check “Suspect” if it is unclear whether the infant’s motor functioning is delayed for 18-24 months’ age corrected for prematurity.

Check “Impaired” if the infant’s motor functioning is abnormal for 18-24 months’ age corrected for prematurity.

**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

For Birth Year Cohort 2016 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 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); Michael Dunn, MD, FRCPC (Senior Study Consultant) and Karla Ferrelli, 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


## APPENDICES

### Appendix A: ELBW Infant Follow-Up Project - 2016 Cohort Center List

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>State/Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akron Children’s Hospital / OH</td>
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</tr>
<tr>
<td>Aurora Baycare Medical Center/ WI</td>
<td>WI</td>
</tr>
<tr>
<td>Cape Fear Valley Medical Center/ NC</td>
<td>NC</td>
</tr>
<tr>
<td>Children’s Hospital of Wisconsin/ WI</td>
<td>WI</td>
</tr>
<tr>
<td>Children's Hospitals and Clinics/ MN</td>
<td>MN</td>
</tr>
<tr>
<td>Children's of Orange County/ CA</td>
<td>CA</td>
</tr>
<tr>
<td>CHOI at OSF St. Francis Medical Center/ IL</td>
<td>IL</td>
</tr>
<tr>
<td>Cone Health Women’s Hospital/ NC</td>
<td>NC</td>
</tr>
<tr>
<td>DeVos Children's/Spectrum Health/ MI</td>
<td>MI</td>
</tr>
<tr>
<td>Driscoll Children’s Hospital / TX</td>
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<tr>
<td>Golisano Children’s Hosp of SW FL/ FL</td>
<td>FL</td>
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<tr>
<td>Goryeb Children’s Hospital / NJ</td>
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<tr>
<td>Henry Ford Hospital/ MI</td>
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<tr>
<td>IRCCS Ospedale Maggiore di Milano / Italy</td>
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</tr>
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</tr>
<tr>
<td>Mercy San Juan Medical Center/ CA</td>
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<td>NHRMC-Betty H. Cameron Women’s &amp; Clinics/ NC</td>
<td>NC</td>
</tr>
<tr>
<td>O.U. Health Sciences Center/ OK</td>
<td>OK</td>
</tr>
<tr>
<td>Providence Tarzana Regional Medical/ CA</td>
<td>CA</td>
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</table>

Rainbow Babies & Children’s Hospital/OH
Randall Children’s Hospital at Legacy Emanuel / OR
Rocky Mountain Hospital for Children at P/SL / CO
St. Barnabas Medical Center/NJ
St. John Hospital & Medical Center/ MI
Sunnybrook Health Science Centre/ Canada
UCSF Benoît Children’s Hospital / CA
UMass Memorial Health Care/ MA
USA Children’s and Women’s Hospital/ AL
University Hospital San Antonio/ TX
University of Illinois at Chicago/ IL
University of Iowa Children’s Hospital/ IA
University of Louisville Hospital / 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’s Hospital / IN

Continued participation of centers in the Year 2015 Cohort is anticipated for the Year 2016 Cohort. New centers, having completed center eligibility requirements are welcome.
Appendix B: Instructions for Using the Corrected Age Calculator

The Corrected Age calculator is intended to easily and accurately provide you with the infant’s corrected gestational age at the time of the follow-up visit, as well as the 18-24 month corrected age test date range. The calculator is available on the Vermont Oxford Network website (www.vtoxford.org) under “Membership/Member Tools”.

To calculate the infant’s corrected gestational age:

- Click on the tab labeled “Corrected Age” at the top of the calculator on the screen.
- Enter the infant’s date of birth. Confirm with your records that this is the correct date of birth.
- Enter the developmental test date. Confirm that this is the correct developmental test date.
- Enter the infant’s gestational age in weeks. Confirm that this is the correct age in weeks.
- Enter the infant’s gestational age in days. Confirm that this is the correct age in days.
- Hit the “Calculate” tab at the bottom of the calculator. The infant’s corrected gestational age will appear in the box labeled “Corrected Age”. This is the corrected age that you will use on the Health and Developmental Status Reports. Do not round these numbers.

To calculate the follow-up test date range for the infant:

- Click on the tab labeled “Test Date Range” at the top of the calculator on the screen.
- Enter the infant’s date of birth. Confirm that the date of birth is correct.
- Enter the infant’s gestational age in weeks. Confirm that this is the correct age in weeks.
- Enter the infant’s gestational age in days. Confirm that this is the correct age in days.
- Hit the “Calculate” tab at the bottom of the calculator. The test date range will appear in the boxes labeled “18 Month Corrected Age Date” and “24 Month Corrected Age Date”.

Helpful hint: In order to accurately calculate the infant’s corrected gestational age and the follow-up test date range, you must use the gestational age in weeks and days listed on the infant’s VON 28 Day form. (If you do not have direct access to these forms, please contact your center’s VON data...
In calculating the Corrected Age:

The corrected age of the child is calculated based upon the Bayley Scales of Infant Development formula.

1. Calculate the child’s chronological age by subtracting the date of birth from the date of testing. As per the BSID, all months are assumed to have 30 days.

2. Compute the months and days the child was premature by subtracting the number of days gestational age from the number of days in a 40-week gestation. Divide the number of days premature by 30 to get the months, and its remainder is the number of days.

3. Subtract the time the child was premature from the chronological age to compute the corrected age in months and days.

Example: An infant born on 1/1/2003 with a gestational age of 26 weeks and 2 days and tested on 11/15/2004 will have an corrected age of 19 months and 8 days.

1. | Year | Month | Day |
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>2004</td>
<td>11</td>
<td>15</td>
</tr>
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<td>2003</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>14</td>
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</tbody>
</table>

2. \((40 \times 7) - ((26 \times 7) + 2) = 96\)

3. \(96 \div 30 = 3\) months with remainder of 6 days

4. | Year | Month | Day |
<table>
<thead>
<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td></td>
</tr>
<tr>
<td>1</td>
<td>7</td>
<td>8</td>
</tr>
</tbody>
</table>

5. Convert the 1 year to 12 months. \(12 + 7 = 19\) months
1. Corrected Age = 19 months 8 days
Appendix C: Script for Question 6 (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 2016 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 2016. Next look at the column on the right and answer “Yes” or “No” to the question “Was your household income for the year 2016 below the number in the column?”

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

HOUSEHOLD INCOME Tool

<table>
<thead>
<tr>
<th>Persons in Household</th>
<th>Household Income in 2016</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>$ 16,020</td>
</tr>
<tr>
<td>3</td>
<td>$ 20,160</td>
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<td>$ 40,890</td>
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<td>Each additional person</td>
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## Appendix D: Surgical Procedure Codes (P-Codes)

<table>
<thead>
<tr>
<th>P-CODE</th>
<th>CATEGORY</th>
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<tbody>
<tr>
<td>P-101</td>
<td><strong>Central Nervous System Surgery</strong></td>
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<td>Shunt or shunt revision for hydrocephalus</td>
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<td>Other neurosurgical procedure</td>
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<td>Cardiac surgery</td>
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<td><strong>Gastrointestinal Surgery</strong></td>
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<td>Gastrostomy tube placement</td>
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<td>P-501</td>
<td><strong>Otolaryngology Surgery</strong></td>
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<td>Tracheostomy</td>
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<td>Tympanostomy tubes</td>
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<td>Other ENT surgical procedure</td>
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<td>Retinal cryosurgery or laser surgery: single eye</td>
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<td>Retinal cryosurgery or laser surgery: both eyes</td>
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<td><strong>Other Surgical Procedure</strong></td>
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Appendix E: Sample Report Log and Data Forms

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

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<th>Patient's Name</th>
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<th>GA Days</th>
<th>18 Months Adjusted Age Date</th>
<th>24 Months Adjusted Age Date</th>
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</table>
2. Sample: Health Status Report (Version 19.1)

<table>
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<th>Patient's Name: __________________</th>
<th>Medical Record: __________________</th>
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</table>

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

Center Number: __________________ | Center Name: __________________ |

Network ID Number: _____________ | Year of Birth (YYYY): __________ |

Follow-up Category: □ ELBW 2016 □ Clinical study (specify): __________________ |

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

Consent Obtained: [ ] Yes [ ] No

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

4. Caregivers: [ ] Single parent [ ] Two parent [ ] Institutional [ ] Two parent extended family

5. Primary Caregiver Education: [ ] Some High School or less [ ] Some college/university [ ] College/university degree [ ] Not applicable [ ] Unknown

[ ] Single parent extended family

[ ] Two parent extended family

[ ] Single parent

USA CENTERS ONLY

5. Income Below 2016 HHS Poverty Guideline: [ ] Yes [ ] No [ ] Unknown

7. Caregiver(s) Primary Language: [ ] English [ ] Spanish [ ] Other

<table>
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<tr>
<th>Persons</th>
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<tbody>
<tr>
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<tr>
<td>3</td>
<td>$20,160</td>
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</tbody>
</table>

5 additional $4,160

Source: Federal Registrar Vol. 81, No.15, January 25, 2016, pp.4036-4037

SECTION C: SUPPORT AFTER DISCHARGE

8. Any Outpatient Support: [ ] Yes [ ] No [ ] Unsure

If yes, complete the following

a. Tracheostomy: [ ] Yes [ ] No [ ] Unsure

b. Ventilator: [ ] Yes [ ] No [ ] Unsure

c. Oxygen: [ ] Yes [ ] No [ ] Unsure

d. Gastrostomy: [ ] Yes [ ] No [ ] Unsure

e. Nasogastric or Post-pyloric Feeds: [ ] Yes [ ] No [ ] Unsure

f. Apnea or CPAP monitor: [ ] Yes [ ] No [ ] Unsure

g. Pulse Oximetry: [ ] Yes [ ] No [ ] Unsure

h. Respiratory Medications: [ ] Yes [ ] No [ ] Unsure

i. Oral Feeding Support: [ ] Yes [ ] No [ ] Unsure

j. Speech Support: [ ] Yes [ ] No [ ] Unsure

k. Motor Support: [ ] Yes [ ] No [ ] Unsure

At present clinic visit: [ ] Yes [ ] No

Complete form on reverse side
SECTION D: MEDICAL RE-HOSPITALIZATIONS AFTER DISCHARGE

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

SECTION E: SURGERIES

10. Surgical procedures (after ultimate discharge):  
    □ Yes  □ No  □ Unsere  # Procedures
    If Yes, put all that apply: ______________________
    a. (P-Code) ______________________
    b. (P-Code) ______________________
    c. (P-Code) ______________________
    d. (P-Code) ______________________
    e. (P-Code) ______________________

SURGICAL PROCEDURE CODES (P-CODES)

<table>
<thead>
<tr>
<th>P-Code</th>
<th>Procedure</th>
<th>P-Code</th>
<th>Procedure</th>
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</thead>
<tbody>
<tr>
<td>P-101</td>
<td>Shunt or shunt revision for hydrocephalus</td>
<td>P-501</td>
<td>Otolaryngology Surgery</td>
</tr>
<tr>
<td>P-102</td>
<td>Other neurosurgical procedure</td>
<td>P-502</td>
<td>Tracheostomy</td>
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<td>P-201</td>
<td>Congenital Heart Defect Surgery</td>
<td>P-503</td>
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<td>P-401</td>
<td>Circumcision</td>
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</tr>
<tr>
<td>P-402</td>
<td>Other genitourinary surgical procedure</td>
<td>P-900</td>
<td>Other Surgical Procedure</td>
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</tbody>
</table>

VERMONT OXFORD NETWORK
THE EXTREMELY-LOW-BIRTH-WEIGHT INFANT FOLLOW-UP PROJECT: 2016 COHORT
MANUAL OF OPERATIONS
Release 19.1

© 2017 Vermont Oxford Network, Inc.
### 3. Sample: Developmental Status Report (Version 19.1)

<table>
<thead>
<tr>
<th>Patient's Name</th>
<th>Medical Record</th>
<th>(Please do not transmit information in this box)</th>
</tr>
</thead>
</table>

**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 2016  □ Clinical trial (specify): ____________________________

#### 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

4. Post Discharge Eye Treatment: □ Laser  □ Anti-VEGF  □ Both  □ Neither  □ Unsure

5. Blindness: □ One eye  □ Both eyes  □ Neither  □ Unsure

6. Prescription Glasses: □ Yes  □ No

7. Hearing Impairment: □ One ear  □ Both ears  □ Neither  □ Unsure

8. Amplification: □ Yes  □ No

#### SECTION C: CEREBRAL PALSY

9. Cerebral Palsy: □ Yes  □ No

  - If yes, impairment: □ Diplegia  □ Hemiplegia  □ Quadriplegia

  - If no, muscle tone: □ Hypotonia  □ Hypertonia  □ Both  □ Normal

#### SECTION D: GROSS MOTOR MILESTONES

10. Sits independently: □ Yes  □ No

  - If no, sits with support: □ Yes  □ No

11. Walks ten (10) steps independently: □ Yes  □ No

  - If no, walks ten (10) steps with support: □ Yes  □ No

#### SECTION F: DEVELOPMENTAL TESTING

12. Developmental Evaluation: □ Completed  □ Partially completed  □ Not done

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

     □ Neurosensory impairment  □ Too severely delayed  □ Uncooperative  □ Other

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

     □ Bayley Scales of Infant Development-III  □ Griffiths Mental Development Scales  □ Other

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

14. Results (BSID-III):

   - Scaled Score

   - Composite Score

   - BSID-III Cognitive: (Sum) __________

   - BSID-III Language: (Sum) __________

   - Expressive Communication: __________

   - Receptive Communication: __________ Not applicable

   - BSID-III Motor: (Sum) __________

   - Gross Motor: __________ Not applicable

   - Fine Motor: __________ Not applicable

15. Results (GVDS):

   - Uncorrected Score

   - Corrected Score

   - Total Scale (GQ): __________

   - Locomotor: __________

   - Personal-Social: __________

   - Hearing and Speech: __________

   - Hand and Eye Coordination: __________

   - Performance Tests: __________

#### SECTION F: OVERALL CLINICAL APPRAISAL

16. Clinical Appraisal:

   - Cognitive function: □ Normal  □ Suspect  □ Impaired

   - Language: □ Normal  □ Suspect  □ Impaired

   - Motor function: □ Normal  □ Suspect  □ Impaired