

# **NEW ENGLAND FOLLOW-UP NETWORK**

## **ELBW INFANT EARLY FOLLOW-UP PROJECT at 3 to 6 MONTHS' CORRECTED AGE**

### **Birth Year 2024 Cohort**

For infants born between January 1, 2024 and December 31, 2024

## **MANUAL OF OPERATIONS**

**September 2024**

Version 2

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## INFANT ELIGIBILITY for ELBW Infant Follow-up at 3 to 6 Months

Eligibility criteria for ELBW Infant Follow-up at 3 to 6 months' corrected age include infants whose birth weights are  $\leq$  1000 grams (inclusive) OR whose gestational ages are  $\leq$  27 weeks, 6 days (inclusive).

### Examples

<b>Date of Birth</b>	<b>Birth</b>	<b>Gestational Age (Weeks/Days)</b>	<b>Eligibility Year 2024 Cohort</b>
December 30, 2023	500	25	No
January 5, 2024	400	21/6	Yes
January 5, 2024	400	22/0	Yes
January 5, 2024	401	22/0	Yes
January 5, 2024	380	22/0	Yes
January 5, 2024	1000	28/0	Yes
January 5, 2024	1001	28/0	No
January 5, 2024	1001	27/6	Yes
January 5, 2024	1100	27/6	Yes

## **I. INFANT FOLLOW-UP PROJECT OVERVIEW**

### **A. Purpose**

The mission of the New England Follow-Up Network (NEFUN) is to be a network of interdisciplinary health care communities in partnership with families dedicated to improving care and well-being for all infants and children following Neonatal Intensive Care in New England. The purpose of the NEFUN Early Follow-up Project is to determine the health and early neurodevelopmental status of infants at 3 to 6 months' corrected age. Follow-up for extremely low birth weight infants includes surviving infants with birth weights  $\leq 1000$  grams OR gestational ages  $\leq 27$  weeks, 6 days. Follow-up for these infants should be targeted for **3 months, 0 days - 6 months, 30 days corrected age**.

### **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 early outcome status.
- To describe, for extremely-low-birth-weight infants, the health and developmental status of surviving infants at 3 to 6 months' corrected age.

### **C. Center Eligibility**

- The Center is a member of Vermont Oxford Network and has contributed to the VON VLBW database from January 1, 2024.
- The Center is affiliated with a Follow-up Clinic that 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 is a member of the New England Follow-up Network (NEFUN).
- 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's date of birth was between January 1, 2024 and December 31, 2024;
- The infant's birth weight was  $\leq 1000$  grams OR the infant's gestational age was  $\leq 27$  weeks, 6 days; and
- The infant survived until ultimate hospital discharge; and
- The infant completed a follow-up visit from 3 months, 0 days to 6 months, 30 days corrected age.

### **E. Outcome Measures**

- Growth: weight, head circumference and length at a specified corrected age.
- Early Developmental Status: Vision (ROP) and hearing status, developmental screening by caregiver, clinical appraisal, and active services supporting development.
- Health Related Social Needs screening.

## **II. STUDY ADMINISTRATION**

### **A. Overview**

The NEFUN Early Follow-up Project is a project conducted by Vermont Oxford Network (VON). VON administers data collection, data management, and data analysis. Each participating center will designate a Center Follow-up Database Contact and a Center Follow-up Data Coordinator to coordinate data collection at the local Center. VON **does not** require Institutional Review Board approval or patient consent from each hospital. Instead, each participating 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. Getting Help**

The ELBW database coordinators are available to assist participating centers with data submission. The coordinators will answer any questions you may have about collecting, recording, or submitting data, as well as questions you may have about the data definitions in this manual. You may contact the ELBW administrators by email ([elbwfup@vtoxford.org](mailto:elbwfup@vtoxford.org)) or telephone (802) 865-4814 between the hours of 9:00am – 5:00pm Eastern Time.

## **III. CENTER PARTICIPATION**

### **A. Center Responsibilities**

The Center's Follow-up Database Contact (Data User) is responsible for reviewing the need for IRB approval and patient consent. The Center Follow-up Data User oversees accurate data collection and assures any training that may be necessary. The Center's Follow-up Data User is responsible for managing data submission. The ELBW Follow-up Data User utilizes logs to identify infants eligible for follow up, ensures completeness and accuracy of data collection and submission in the VON data entry tool, and works with VON to reconcile any data errors or omissions.

### **B. Center Project Materials**

VON will grant the Center's ELBW Data User access to the ELBW Follow-Up section of the Member Portal to access the Infant Follow-up Database Report Log for all eligible infants, error reporting, the data entry tool, and annual reports.

## **IV. DATA COLLECTION & SUBMISSION**

### **A. Data Collection**

Data may be collected using paper-based Birth Year 2024 Cohort Infant Follow-up Data Forms and then typed into the data entry tool or entered directly into the data entry tool. 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 information submitted.

## **B. 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 weights  $\leq$  1000 grams (inclusive) **OR** gestational age  $\leq$  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.

## **C. 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 Early Infant Follow-up Report Log identifies infants from your Center who qualify for the ELBW Early Infant Follow-up Project. VON will send you instructions for online access to the ELBW Early 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 3 months, 0 days to 6 months, 30 days corrected age. You will use the infant's date of birth and gestational age in weeks and days to determine the 3 months corrected age date and the 6 months corrected age date. An online 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 Early Infant Follow-up Project Report Log. When the forms are complete, enter the date on which the data were submitted using the data entry tool. Some infants from your Center may not have data.

Keep your Infant Follow-up Report Log. This log is the only way to identify infants in the ELBW Early Infant Follow-up Database. 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. EARLY INFANT FOLLOW-UP PROJECT DATA**

### Status at 3-6 months' corrected age

Indicate the infant's status at the time of the 3-to-6-month follow-up visit.

Check "Alive" if the infant is known to be alive at the 3-to-6-month follow-up visit.

Check "Expired" if the infant died between the ultimate hospital discharge date and the 3-to-6-month follow-up visit.

Check "Unknown" if the status of the infant is unknown at the 3-to-6-month follow-up visit because the infant was lost to follow-up.

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

### Do you have any data to provide between 3 to 6 months' corrected age?

The target follow-up visit will occur between 3 to 6 months' corrected age. If two follow-up visits occur between 3 to 6 months' corrected age, **only submit data from the most recent visit.** For example, if a visit occurs at 3 months' corrected age and 6 months' corrected age, only submit data from the visit at 6 months' corrected age.

Check "Yes" if a follow-up visit occurred between 3 to 6 months' corrected age.

Check "No" if a follow-up visit did not occur between 3 to 6 months' corrected age.

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

## **Health Status Report**

### Form completed

Indicate how this form was completed. It may be completed from more than one source.

*Check "Yes" or "No" for each source of information.*

In person visit

Virtual/video visit

Health record

## **Section A: Growth**

### ITEM 1: Weight (kg)

Enter the weight recorded at the 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 "999.9". Do not enter a weight measured at another visit.

### ITEM 2: Head circumference (cm)

Enter the head circumference recorded at the 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 "999.9". Do not enter a head circumference measured at another visit.

### ITEM 3: Length (cm)

Enter the length recorded at the follow-up visit. Enter the length in centimeters (cm), to the tenths place. If the length is unknown because it was not measured at the developmental follow-up visit, enter "999.9". Do not enter a length measured at another visit.

### ITEM 4: Corrected age growth measurements 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>.

## Section B: Early Neurodevelopmental Status

### ITEM 5: ROP at Discharge

Indicate the infant's ROP status at ultimate hospital discharge. *Check only one.*

Check "Mature" if the infant had mature retina (no active ROP) in **both** eyes at discharge.

Check "Active" if the infant had immature retina or any stage of ROP in either or both eyes at discharge.

*If "Active",* indicate the **worst** stage documented in the eye with the most advanced stage.

Stage 0: No evidence of ROP

Stage 1: Presence of demarcation line (+/- abnormal vascularization)

Stage 2: Presence of intraretinal ridge

Stage 3: Presence of a ridge with extraretinal fibrovascular proliferation

Stage 4: Partial retinal detachment

Stage 5: Total retinal detachment

### ITEM 6: ROP at 3-6 Months

Indicate the infant's ROP status at the 3-to-6-month follow-up visit. *Check only one.*

Check "Mature" if the infant had mature retina (no active ROP) in **both** eyes at the follow-up visit.

Check "Active" if the infant had immature retina or any stage of ROP in either or both eyes at the follow-up visit.

*If "Active",* indicate the **worst** stage documented in the eye with the most advanced stage.

Stage 0: No evidence of ROP

Stage 1: Presence of demarcation line (+/- abnormal vascularization)

Stage 2: Presence of intraretinal ridge

Stage 3: Presence of a ridge with extraretinal fibrovascular proliferation

Stage 4: Partial retinal detachment

Stage 5: Total retinal detachment

Check "Resolved ROP" if the infant had active ROP in either eye at the time of discharge but the ROP had subsequently resolved in **both** eyes at the 3-to-6-month follow-up visit.

#### ITEM 7: Post-discharge ROP treatment

Indicate whether the infant received post discharge eye treatment at any time from the ultimate hospital discharge to the 3-to-6-month follow-up visit. *Check only one.*

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

Check "Anti-VEGF Drug" if the infant received bevacizumab (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 "None" 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 8: Hearing screen at discharge

Indicate the results of the hearing screen at ultimate hospital discharge. *Check only one.*

Check "Pass" if the infant passed the hearing screen for **both** ears at ultimate hospital discharge.

Check "Referral for diagnostic evaluation" if the infant required referral for diagnostic evaluation for **one or both** ears as a result of the hearing screen at ultimate hospital discharge.

*If "Referral for diagnostic evaluation", ITEM 9: Diagnostic evaluation:*

If the infant required referral for diagnostic evaluation due to the hearing screen at ultimate hospital discharge, indicate the results of the diagnostic evaluation. *Check only one.*

Check "To be scheduled" if the diagnostic evaluation had not yet taken place.

Check "Pass" if the diagnostic evaluation indicated "pass" for the ear evaluated.

Check "Hearing loss" if the diagnostic evaluation detected hearing loss in one or both ears.

*If "Hearing Loss", Which were assessed:*

Check "Yes" or "No" for each assessment (unilateral, bilateral, ENT referral, hearing aid, cochlear implant). *More than one may have been assessed.*

#### ITEM 10: Developmental screen completed by caregiver:

Indicate whether the infant's caregiver completed a developmental screening questionnaire for the 3-to-6-month follow-up visit. *Check only one.*

Check "Yes" if a developmental screening questionnaire was completed.

Check "No" if a developmental screening questionnaire was not completed.

Check "Unsure" if you are unsure if a developmental screening questionnaire was completed.

*If "Yes", check only one.*

Check "Ages and Stages Questionnaire" if this was the questionnaire was completed by the caregiver.

Check "Other" if a developmental questionnaire other than the Ages and Stages Questionnaire was completed by the caregiver.

Check "Unsure" if you know that the caregiver completed a questionnaire but you are unsure of which one.

*If "Ages and Stages Questionnaire", check only one.*

Check "4-month form" if the Ages and Stages 4-month form was completed by the caregiver.

Check "6-month form" if the Ages and Stages 6-month form was completed by the caregiver.

*If "Ages and Stages Questionnaire", check only one result for each of the five domains (Communication, Gross motor, Fine motor, Problem solving, and Personal-Social).*

Check "Concern" if there was a concern indicated by the results of the developmental questionnaire for the specific domain.

Check "Possible concern" if there was a possible concern indicated by the results of the developmental questionnaire for the specific domain.

Check "No concern" if there was not a concern indicated by the results of the developmental questionnaire for the specific domain.

Check "Unsure" if you are unsure if there was a concern or possible concern indicated by the results of the developmental questionnaire for the specific domain.

#### ITEM 11. Clinical appraisal

The clinical appraisal is a summary of the impressions of the health care team upon seeing the infant at the 3-to-6-month follow-up visit. The clinical appraisal is based on observation and examination of the infant during a face to face or virtual visit or both. The clinical appraisal may be informed by results of a development screen completed by a caregiver or a developmental assessment performed by an experienced clinician or both.

Indicate the clinical appraisal of the infant's communication and motor function. *Check only one for each domain.*

Check "Impaired" if the infant's functioning is abnormal for 3 to 6 months' corrected age.

Check "Suspect" if it is unclear whether the infant's functioning is normal or delayed for 3 to 6 months' corrected age.

Check "Normal" if the infant's functioning is appropriate for 3 to 6 months' corrected age.

Check "Unsure" if you are unsure of the infant's functioning at 3 to 6 months' corrected age.

Indicate the sources assessment used to inform the clinical appraisal. *Check all that apply.*

Check "Clinical Assessment" if an evaluation by a clinician was used to inform the clinical appraisal.

Check "Caregiver questionnaire" if a caregiver-completed questionnaire was used to inform the clinical appraisal.

Check "Both" if both methods were used to inform the clinical appraisal.

Check "Neither" if neither method was used to inform the clinical appraisal.

#### ITEM 12. Services active

Indicate whether the infant is receiving care from a developmental specialist, an occupational therapist or a physical therapist for movement, or a speech/language pathologist or an occupational therapist for feeding at 3 to 6 months' corrected age. Services may be provided by Early Intervention (EI), Home Health (HH), or other clinic or agency. Services planned as a result of an assessment during the 3-to-6-month follow-up visit are **not** considered to be in place at the time of the follow-up visit. *Check one for each service.*

Check "Yes" if the infant is receiving the service at 3 to 6 months' corrected age.

Check "No" if the infant is not receiving the service at 3 to 6 months' corrected age.

Check "Unsure" if you are unsure if the infant is receiving the service.

#### ITEM 13. Health Related Social Needs Screen

Indicate whether one or more of the infant's caregivers was screened for social needs at the infant's 3 to 6 months' corrected age follow-up visit. *Check only one.*

Check "Completed" if one or more of the infant's caregivers was screened.

Check "Not completed" if one or more of the infant's caregivers was not screened.

Check "Unsure" if you are unsure if one or more of the infant's caregivers was screened.

*If "Completed", check all of the social needs that were assessed (food insecurity, financial strain, housing instability, interpersonal safety, transportation needs, employment/underemployment, utility needs, other). Check one for each assessment.*

Check "Yes" if an assessment was completed at the 3-to-6-month follow-up visit.

Check "No" if an assessment was not completed at the 3-to-6-month follow-up visit.

Upon completion of the data entry, click "Save" to save your changes. You may click "Exit" to leave the form without saving any changes.

## **VII. PUBLICATIONS**

The data collected as part of this effort may be used to publish original research. Proposals to use the data for research can be made by NEFUN centers or by Vermont Oxford Network staff. All studies must have prior approval of the NEFUN Early Infant Follow-up Project Committee (see page 13). Members of the Vermont Oxford Network staff will be co-authors of all publications, which are based on data collected at all centers during the conduct of this 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 the NEFUN Early Infant Follow-up Project Committee and VON staff. 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 a primary follow-up manuscript has been submitted.

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