

FOLLOW-UP STUDY

22-26 Month Follow-up Visit of High-Risk Infants

Manual of Operations

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development
(NICHD) Neonatal Research Network**

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TABLE OF CONTENTS

TABLE OF CONTENTS	ii
Chapter 1. OBJECTIVES AND STUDY DESIGN	1-1
1.1 Introduction	1-1
1.2 Generic Data Base Follow-up Study - Objectives	1-1
1.2.1 Generic Data Base Follow-up - Study Design	1-1
1.2.1.1 Generic Data Base Follow-up Study - Assessment Battery	1-2
1.2.1.2 Follow-up Study - Summary	1-2
1.2.1.3 Definition of NDI.....	1-2
1.3 Informed Consent.....	1-4
1.4 Children Who Move Away	1-4
1.4.1 Extensive Travel Mechanism.....	1-4
1.5 Scheduling Another Visit	1-5
1.6 Performing the Follow-up Visit at Child's Home	1-5
1.7 Follow-up Compliance.....	1-6
Chapter 2. ADMINISTRATION	2-1
2.1 Organizational Structure	2-1
2.1.1 Participating Centers	2-1
2.1.1.1 Clinical Centers.....	2-1
2.1.1.2 Data Coordinating Center	2-1
2.1.2 NICHD	2-1
2.2 Committees	2-1
2.2.1 Steering Committee.....	2-1
2.2.2 Members of the Follow-up Study.....	2-1
Chapter 3. FOLLOW-UP FORMS.....	3-1
3.1 Data Forms	3-1
3.1.1 Generic Data Base Follow-up.....	3-1
3.2 Reports Available Through the web-based electronic data capture system (EDC)	3-1
3.3 Data Management.....	3-2
3.3.1 Administration and Coordination of Forms	3-2
3.3.2 Form Completion and Missing Values.....	3-2
3.3.3 Creation and Handling of Edits.....	3-2
3.3.4 Discontinued Forms	3-3
Chapter 4. INTERVIEWING TECHNIQUES.....	4-1
4.1 Principles and Concepts of Interviewing	4-1
4.2 Types of Interviews	4-1
4.3 Interviews at the Follow-up Visit.....	4-1
4.4 Set - up of the Interview	4-1
4.5 Scripts	4-2
4.5.1 Opening Script.....	4-2
4.5.2 Introduction to the Interview Session.....	4-2
4.6 Tips on Interviewing	4-3
4.6.1 Giving Positive Reinforcement	4-3
4.6.2 Probing Rules.....	4-4
4.6.3 "I Don't Know" Responses.....	4-4
4.6.4 Do's and Don'ts of Probing	4-4
4.7 Interviewer Training.....	4-5
Chapter 5. ENROLLMENT INTO THE STUDY.....	5-1
5.1 Assignment of Follow - up Number by Computer	5-1
5.2 Identification Information (NF00) (rev 4/20/2022).....	5-1

5.3	Form Completion If the Follow-up Visit Takes Place at Another Network Center	5-2
Chapter 6.	DISCHARGE INFORMATION.....	6-1
6.1	SES at Discharge (NF01)(v11/5/2012)	6-1
6.1.1	Heading	6-1
6.1.2	Section A. Demographic Data	6-2
6.1.3	Section B. Household Composition	6-3
6.1.4	Section C. Education and Occupation.....	6-4
6.1.5	Section D. Form Completion	6-5
Chapter 7.	TRACKING	7-1
7.1	Incentive for Recruitment, Follow-up, and Tracking	7-1
7.2	Other Ideas for Tracking	7-2
Chapter 8.	FOLLOW-UP VISIT OVERVIEW	8-1
8.1	Order of Administration	8-1
Chapter 9.	VISIT LOG AND SOCIO-ECONOMIC STATUS AT FOLLOW-UP	9-1
9.1	Visit Log (NF02) (rev 4/1/2011).....	9-1
9.2	SES at Follow-up (NF03) (rev 11/5/2012).....	9-1
9.2.1	Heading	9-1
9.2.2	Section A. Demographic Data	9-2
9.2.3	Section B. Household Composition	9-4
9.2.4	Section C. Education and Occupation.....	9-4
9.2.5	Section D. Household Information.....	9-6
9.2.6	Section E. Special Child Services	9-7
9.2.7	Section F. Day Care/Child Care in the past month.....	9-8
9.2.8	Section G. Form Completion	9-9
Chapter 10.	MEDICAL HISTORY AND EXAMINATION	10-1
10.1	Medical History Form (NF04) (rev 11/5/2012).....	10-1
10.1.1	Heading.....	10-1
10.1.2	Section A. Medical History	10-2
10.1.3	Section B. Form Completion	10-6
10.2	Readmission Form (NF04A) (rev 4/1/2011)	10-6
10.2.1	Heading.....	10-6
10.2.2	Section A. Hospitalizations.....	10-7
10.2.3	Section B. Form Completion	10-9
10.3	Examination Form (NF05) (rev 2022/12/14)	10-9
10.3.1	Heading.....	10-9
10.3.2	Section A - PHYSICAL EXAMINATION	10-10
10.3.3	Section B - NEUROLOGIC EXAMINATION.....	10-10
10.3.4	Section C. REFLEXES / MOTOR SKILLS / DIAGNOSES	10-19
10.3.5	Section D - FORM COMPLETION	10-28
10.3.6	Certification for the Neurological Exam.....	10-28
Chapter 11.	CHILD BEHAVIOR CHECKLIST (CBCL).....	11-1
11.1	Child Behavior Checklist	11-1
11.1.1	Procedural Guidelines.....	11-1
11.1.2	Completing the CBCL Summary Scores Form (NF16) (7/12/2019).....	11-2
11.1.2.1	Section A. IDENTIFICATION	11-2
11.1.2.2	Section B. SYNDROME SCALE SCORES.....	11-2
11.1.2.3	Section C. INTERNALIZING, EXTERNALIZING, AND TOTAL PROBLEMS	11-3
11.1.2.4	Section D. DSM-ORIENTED SCALES	11-3
Chapter 12.	BAYLEY SCALES OF INFANT DEVELOPMENT.....	12-1
12.1	Bayley 4	12-1

12.1.1	Reliability and Certification	12-1
12.1.2	User Qualifications	12-2
12.1.3	Procedural Guidelines	12-3
12.1.4	Administration	12-5
12.1.4.1	Home Visits	12-7
12.1.5	Scripts	12-7
12.1.6	Heading	12-8
12.1.7	Section A. Bayley Information	12-8
12.1.8	Section B. Form Completion	12-12
Chapter 13.	STATUS OF CHILD	13-1
13.1	Status Form (NF10) (rev 1/18/2017)	13-1
13.1.1	Heading	13-1
13.1.2	Section A. Status Information	13-2
13.1.3	Section B. Form Completion	13-3
13.2	Status Form (NF10A) (rev 4/1/2011)	13-4
Chapter 14.	SUMMARY OF FOLLOW-UP VISIT	14-1
14.1	Summary of Follow-up Visit (NF11) (rev 7/26/21)	14-1
14.1.1	Heading	14-1
14.1.2	Section A. Identification Information	14-1
14.1.3	Section B. Assessment Information	14-1
14.1.4	Section C. Form Completion	14-2
Chapter 15.	LOST TO FOLLOW-UP	15-1
15.1	Lost to Follow-up Questionnaire (NF12) (7/26/2021)	15-1
15.1.1	Heading	15-2
15.1.2	Lost to Follow-up Indicator	15-2
15.1.3	Section A. Source of Information and Vital Status	15-2
15.1.4	Section B. Caretaker Questionnaire	15-4
15.1.5	Section C. Chart Review Information or Report from Physician	15-7
15.1.6	Section D. NDI Assessment	15-10
15.2	Ages and Stages (ASQ-3) Summary	15-12
15.2.1	Introduction	15-12
15.2.2	When to obtain the ASQ-3	15-12
15.2.3	Questionnaire selection and administration	15-13
15.2.3.1	Selection of appropriate ASQ-3 age interval questionnaire:	15-13
15.2.3.2	Administration	15-13
15.2.3.3	Scoring	15-15
15.2.4	Completing the Ages and Stages (ASQ-3) Summary Scores Form (NF19) (v2/14/222)	15-16
APPENDIX A.	APPROPRIATE RESPONDENT TO INTERVIEWS / QUESTIONNAIRES	1
APPENDIX B.	RELATIONSHIP CODES	1
APPENDIX C.	LIVING ARRANGEMENT CODES	1
APPENDIX D.	BIRTH DEFECT CODES	1
APPENDIX E.	DATA FORMS	1
REFERENCES	1

Chapter 1. OBJECTIVES AND STUDY DESIGN

1.1 Introduction

The Follow-up Study examines at 22-26 months corrected age infants that meet the following criteria:

- A subset of Generic Data Base (GDB) infants less than or equal to 26 completed weeks gestational age (GA) (up to and including 26 6/7 weeks), and
- Infants enrolled in a randomized trial or approved observational study with 22-26-month follow-up as a predefined primary or secondary outcome.

This manual is meant to serve as a reference guide for study staff, including investigators, coordinators, technicians, and data managers. The study objectives and design are summarized below for infants in the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Neonatal Research Network (NRN) Generic Data Base Study who are eligible for the Follow-up Study.

1.2 Generic Data Base Follow-up Study - Objectives

The study objectives for the follow-up program are the following:

- To track and successfully follow at 22-26 months of age more than 80% of babies who are eligible for the Follow-up Study.
- To characterize development of the study population by standardized methods in the areas of: motor skills, cognitive skills, language and behavior.
- To determine the 22-26-month (corrected age) mortality and the prevalence of specific medical morbidities.
- To characterize growth outcome and its relationship to neurodevelopmental outcome in this population at 22-26 months corrected age.
- To identify the socioeconomic status of the families in this population and its relationship to developmental outcome.
- To assess the utilization of special support services and early intervention programs by this population.

1.2.1 Generic Data Base Follow-up - Study Design

This study is a long-term follow-up program for all GDB infants [less than or equal to 26 completed weeks GA (up to and including 26 6/7 weeks) admitted to the NICU of participating centers. Infants enrolled in a randomized trial or approved observational study with 22-26-month follow-up as a predefined primary or secondary outcome will also be followed up at 22-26 months. An assessment, which includes all aspects of growth and development, will be undertaken for all infants at 22-26 months corrected age based on **best OB estimate**. (If the gestational age by best OB estimate is missing, the gestational age by Ballard should be used). Outborn infants will be excluded from the Follow-up Study after January 1, 2008, unless enrolled in a randomized trial or approved observational study with 22-26-month follow-up as a predefined primary or secondary outcome.

1.2.1.1 Generic Data Base Follow-up Study - Assessment Battery

The assessment battery at 22-26 months corrected age includes the following:

- Demographic and medical history
- Physical/neurological examination
- Neurodevelopmental and behavioral assessment using the Bayley Scales of Infant Development 4
- Behavior assessment using the Child Behavior Checklist [CBCL (ages 1.5-5 yrs.)].

1.2.1.2 Follow-up Study - Summary

Infants less than or equal to 26 completed weeks GA (up to and including 26 6/7 weeks) who are admitted to the NICU of participating centers will be identified. Infants enrolled in a randomized trial or approved observational study with 22-26-month follow-up as a predefined primary or secondary outcome will also be identified. Infants who are born or who are hospitalized at the start of the study or after will have a Discharge SES Data Form (NF01) completed at the time of their discharge. Tracking information will be collected to enable study staff to keep in contact with the family until the time of the follow-up visit. Each center will implement procedures to track and keep in contact with the family over the next two years.

Study staff will schedule the follow-up visit. When the mother and child come to the visit, the Follow-up Visit Log (NF02) will be completed. The Follow-up Visit Log is not sent to the Data Coordinating Center (DCC) but rather used at the centers as an internal management tool. At the follow-up visit, the Bayley 4 Examination will be completed, and the summary scores copied to the Bayley Summary Sheet (NF09B4). The physical and neurological exam will be performed and the Infant Examination Form (NF05) will be completed. The questionnaires that will be administered are the following:

- SES at Follow-up (NF03)
- Medical History Form (NF04)
- Hospital Readmission Form (NF04A) (if applicable)
- Child Behavior Checklist (CBCL)

A Status Form (NF10) will be completed for all children who are discharged alive. It will be completed at the time of the follow-up visit for all children who are discharged alive and attend the visit. The form will be completed for children who are lost to follow-up or who have died when that information becomes available. At the latest, the Status Form will be completed at the end of the 22-26-month window. For all children who come to the 22-26-month visit, the Summary of Follow-up Visit Form (NF11) should be completed. For any children lost-to-follow-up, the NF12 should be completed.

Tracking information will be updated at the 22-26-month follow-up visit for future visits.

1.2.1.3 Definition of NDI

As of March 2023, we assume the cut points for Bayley III and Bayley 4 are comparable. Therefore, we will leave the current NDI definitions with Bayley III reference in the 22-26 Month

Follow Up Manual of Procedures, with the understanding this may be amended at a later time upon the collection of additional data.

The following definition of NDI was voted on by the Follow-up PIs and agreed upon by the Steering Committee during the July 20, 2018 meeting. It is acknowledged and understood that there are no perfect “definitions”, and that “NDI” should not be considered the outcome of choice for all analyses or trials. But as the Follow-up and Steering Committees have discussed at length, it is important to clarify some basic definitions.

1) “Binary” definition of moderate-severe NDI: Bayley III Cognitive < 85, Bayley III Motor <85, GMFCS 2 or greater, or bilateral “blind” despite corrective lenses (NF05 B.1.e = 4 OR 5 in both eyes) or bilateral no functional hearing with or without amplification.

2) Severity levels:

Domain	“Normal, at risk or mild”	Moderate NDI	Severe/Profound NDI*
Bayley III Cognitive	>=85	70-84	<70 / <=54
Bayley III Motor	>=85	70-84	<70 / <=46
GMFCS	Level “0” or I	Level II or III	Level IV or V
Vision	†	†	Bilateral “legally blind” NF05 B.1.e = 4 <u>OR</u> 5 in both eyes
Hearing	†	†	Bilateral hearing impaired +/- amplification

† Given lack of granularity of vision and hearing data, “levels” of vision and hearing are not assigned to these categories.

* As relevant, consider reporting severe NDI as a secondary outcome

3) The current and past NICHD NRN approach of using GMFCS levels for NDI definition, regardless of whether CP is diagnosed, was supported.

4) For analyses including ND outcome data spanning Bayley II and III eras, which include Bayley III data with and without Motor scores: to promote consistency of definition across the timespan, removing PDI/Motor scores from the definition of “binary” moderate-severe NDI was supported as follows (*note*: this was the approach used for Younge N, et al. NEJM 2017).

- Any of:
 - Bayley II MDI cut point is <70; Bayley III Cognitive cut point <85;
 - GMFCS 2 or greater
 - Bilateral “blind” despite corrective or bilateral hearing impaired with no functional hearing +/- amplification (as above previously noted)

5) It is recommended that verbiage be included in Methods sections of NRN publications using ND data spanning Bayley II and III eras 1) clearly describing definition used, 2) noting Bayley II/III issues in general (citing appropriate references), 3) indicating Bayley Motor was not collected in NRN for a period as appropriate, and 4) noting that prevalence of moderate-severe NDI may be affected due to the approach to combine data over time. Furthermore, the limitations and challenges of “NDI” definitions and its utilization as an outcome in general should be acknowledged.

1.3 Informed Consent

Each center will submit and follow local Institutional Review Board guidelines. The Network will not object to individual centers obtaining dispensation from signed consent.

Check with the local Institutional Review Board guidelines on procedures for informing the caretaker that information pertaining to child abuse or neglect will be reported to the proper authorities.

Check with the local Institutional Review Board guidelines on procedures for informing the caretaker that a summary report of the medical exam and Bayley scores will be sent to the child's primary physician.

1.4 Children Who Move Away

If a child moves away from the network center and moves close to another network center, that child can be examined at the second network center at the follow-up visit. If a child moves away and is not close to any Network center, then that child is considered lost to follow-up.

1.4.1 Extensive Travel Mechanism

As per Technical Memo 43, the NRN Steering Committee approved on March 7, 2018 additional funding (up to \$800) for extensive travel for **TRIAL** infants only for the 22-26 month follow-up visit:

The extensive travel mechanism addresses the need for NRN teams (including psychologists, neurologic examiners, coordinators) to travel from their clinics to conduct home visits for families that have moved far away (>200 miles), or for families that have moved far away to travel to the clinic for the study visit as further detailed below.

The extensive travel mechanism will allow Centers to receive **up to \$800** additional funds per study visit for TRIAL infants only to cover pre-approved travel expenses (airline/train tickets, hotel, rental car, mileage reimbursement, etc.) for:

- 1) clinic staff to travel to conduct home visits for study patients that have moved far away (i.e., >200 miles), or
- 2) families that have moved far away (i.e., >200 miles) to travel to the clinic for the school age visit.

Pre-authorization decisions will be made on a case-by-case basis, with no guaranteed approval.

Only **prospective** requests (visits to be conducted) will be considered.

Process for Submitting Requests for the Extensive Travel Mechanism

Centers will submit details for pre-authorization using the Extensive Travel Request Form (NF17) in the web-based electronic data capture (EDC) system. The RTI Follow-up Coordinator, Jamie Newman (newman@rti.org), and other members of the Data Coordinating Center (DCC)

at RTI will receive an email from the EDC notifying them when an Extensive Travel Request Form (NF17) has been submitted. This will prompt the DCC to request a review by the Extensive Travel Request Committee, which will include Dr. Rosemary Higgins (higginsr@mail.nih.gov), Dr. Susan Hintz (srhintz@stanford.edu), Dr. Abhik Das (adas@rti.org), and/or their designees. Information that the requesting Center will need to submit (prior to the visit) using the Extensive Travel Request Form (NF17) includes: trial(s) in which the infant was enrolled, staff members traveling (Neuro examiner, coordinator, Bayley III examiner), estimated date for scheduling the visit, details on travel including whether airline/train tickets will be purchased, estimated distance from clinic, whether hotel is required for overnight stay, whether mileage reimbursement is needed, per diem for meals, and whether research team will travel to the family or whether the family will travel to the clinic.

The requesting Center will receive notification of the committee's decision by email. If the committee approves the use of the extensive travel mechanism, the Center will receive the additional travel funds (up to \$800) after the visit has been conducted and the Extensive Travel Request Form (NF17) and Status Form (NF10) have been keyed as follows:

- Extensive Travel Request Form (NF17) Question B.2. Amount approved by the committee
- Status Form (NF10) Question A.2.c. If final status is 1 (Child seen, visit complete) or 6 (Child seen, visit incomplete)

The up to \$800 in capitation for the activation of the extensive travel provision will appear as a separate line item on your Center's monthly capitation statement. RTI will not request that the Center submit travel receipts or ticket stubs. However, Centers may need to keep travel receipts on file for their own recordkeeping purposes.

Please submit any questions to the NRN Follow-up Study Coordinators, Dr. Jamie Newman (newman@rti.org) and Lindsay Parlberg (lparlberg@rti.org).

1.5 Scheduling Another Visit

It is important to attempt to perform the complete assessment at the first visit. If it is not possible to complete the assessment at that visit, additional visits may be scheduled but must be completed before 26 months corrected age + 2 weeks. If the caretaker does not come to the first visit, it is preferable to obtain the questionnaire information from her in person. If this is not possible, then the questionnaire information may be obtained by telephone.

1.6 Performing the Follow-up Visit at Child's Home

Always refer to local IRB requirements before performing follow up visits at another location than the center clinic.

Performance of the protocol assessments at the study patient's home or elsewhere is acceptable, as there is a longstanding precedent in other developmental follow-up studies to do so.

An overview of the Follow-up Study Procedures is given in Figure 1, page 1-6.

1.7 Follow-up Compliance

The following elements must be completed for center's Official Follow-Up Rate

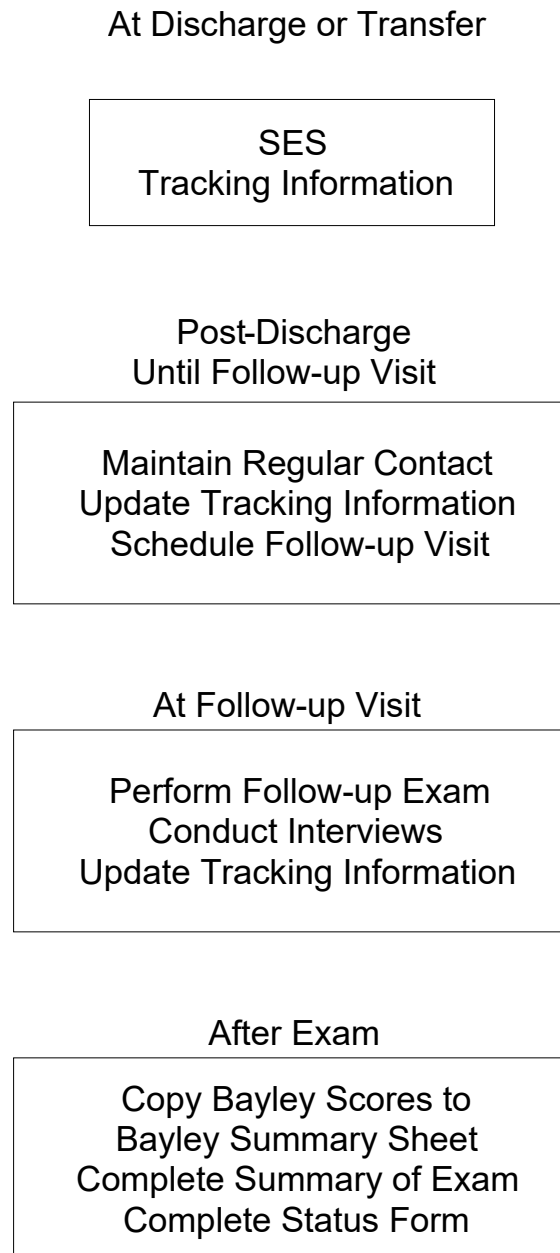
- Child seen
- Anthropometrics completed
- Questionnaires completed
- Bayley4 Summary Score (NF09B4 Form - successfully completed Cognitive and Language or coded as 4 if unsuccessfully completed)
- The Neurologic exam (NF05)
- Palisano (NF05 question B6 Gross Motor Function Level)
- If not possible, to obtain a complete Follow Up visit, the following is requested for a Partial Follow-Up visit:
 - The Bayley and Palisano OR
 - A Neurologic exam and Palisano
 - Complete the NF10A and submit to RTI
- **NF05**
 - Current Gross Motor Function
 - Weight
 - Recumbent Length
 - Vision
 - Strabismus Right/Left
 - Nystagmus Right/Left
 - Roving Eye Right/Left
 - Tracks Right/Left
 - Vision Right/Left
 - Hearing Impaired
 - Swallowing
 - Abnormal Movements at Rest
 - Motor Skill
 - Head
 - Trunk
 - Lower Limb Right/Left
 - Upper Limb Right/Left
 - Hand Function Right/Left
 - Normal Neurologic/Motor
 - Does Child Have Cerebral Palsy?
 - Congenital/Acquired Abnormalities
- **NF09B4 (Bayley 4)**
 - Successfully Tested for Cognitive?
 - Reason No Success Cognitive Tested (coded 4)
 - Successfully Tested for Expressive or Receptive Language?

- Reason No Success for either Expressive or Receptive Language Tested (coded 4)
- Successfully Tested for Fine or Gross Motor? (coded 4 or 5)
- Reason No Success for either Fine or Gross Motor (coded 4 or 5)

Discussion of the NF10A form

The NF10A should be completed for a visit where the child was seen but the visit was not completed. In other words, for each visit with an NF10 Final Status code of 6 “child seen, but incomplete visit” an accompanying NF10A should be keyed. This is for administrative purposes only to determine compensation for the incomplete visit. Upon completing the form, it must be keyed into the web-based electronic data capture (EDC) system and transmitted to RTI.

Figure 1: An Overview of the Follow-up Study Procedures



Chapter 2. ADMINISTRATION

2.1 Organizational Structure

The NICHD Neonatal Research Network coordinates the follow-up of infants enrolled in the Generic Database Study (GDB) or other NRN studies. The Network is funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) under cooperative agreements with institutions, comprising Clinical Centers and a Data Coordinating Center (DCC). The Steering Committee for the Network consists of the Principal Investigator from each Clinical Center, the Data Coordinating Center, and the NICHD project officer. The Steering Committee Chairman, who is not participating as a principal investigator from any of the clinical sites, is appointed by the NICHD.

2.1.1 Participating Centers

2.1.1.1 Clinical Centers

The Principal Investigators representing the Clinical Centers participating in the cooperative agreement these clinics have agreed to abide by the study protocol and, in addition, to have comparable staff, facilities, and equipment.

2.1.1.2 Data Coordinating Center

The Data Coordinating Center (DCC) is responsible for all aspects of statistical design and analysis as well as data management of the study. In concert with the Steering Committee, the DCC is responsible for protocol, manual and forms development and testing. The DCC, in collaboration with the subcommittee, conducts all statistical analyses and collaborates with the other Steering Committee members in the preparation of reports based on the study results. The Principal Investigator of the DCC reports to the Steering Committee.

2.1.2 NICHD

In addition to its role as funding agency, the NICHD participates in the activities of the cooperative agreement by being represented on the Steering Committee. NICHD staff participates in the development of protocols and in assisting the Steering Committee in the conduct of the studies conducted by the Network.

2.2 Committees

2.2.1 Steering Committee

The Steering Committee Chairman participates in the planning of Network activities and chairs all Steering Committee meetings. In cases of a tie vote, the Chairman casts the tie-breaking vote. The chairman also participates as a member of the Advisory Committee.

2.2.2 Members of the Follow-up Study

The Steering Committee's Follow-up Subcommittee, developed the framework for the Follow-up Study. Each center must have a designated Follow-up Study Principal Investigator and a

Follow-up Coordinator. The Follow-up Study PI and Network PI may be the same individual and the Network Coordinator and Follow-Up Coordinator may be the same individual. The subcommittee also decided to designate one Follow-up PI to be the chair for the study, which includes managing and coordinating the Follow-up Study, in collaboration with the DCC PI, NICHD Program Official, the Steering Committee and other Follow-up Study PIs.

The members of the Follow-up Study thus include:

- Follow-up Study PI from each participating institution;
- PI from each participating institution;
- Follow-up Study Coordinator from each participating institution;
- Follow-up Study chair

The Network Follow-up Study Subcommittee is responsible for designing and monitoring the conduct of the Follow-Up study. This subcommittee reports the progress of the study to the Steering Committee.

Chapter 3. FOLLOW-UP FORMS

3.1 Data Forms

3.1.1 Generic Data Base Follow-up

Infants eligible for the 22-26 month Follow-up Exam include:

- Generic Data Base infants less than or equal to 26 completed weeks gestational age (GA) (up to and including 26 6/7 weeks), and
- Infants enrolled in a randomized trial or approved observational study with 22-26-month follow-up as a predefined primary or secondary outcome.

A full follow-up assessment will be done and the following forms will be completed:

- SES at Follow-up (NF03)
- Medical History (NF04)
- Readmission Form (if readmitted after initial discharge) (NF04A)
- Infant Examination Form (NF05)
- Bayley 4 Summary Scores Forms (NF09B4)
- Child Behavior Checklist (CBCL) Summary Score Sheet (NF16)
- Status Form (NF10)
- Summary of Follow-up Visit (NF11)

3.2 Reports Available Through the web-based electronic data capture system (EDC)

Methods to enter the data from the data collection forms are discussed in detail in the *NRN Web-based EDC User's Manual*. In addition, four computerized reports are available within the Follow-up data entry system to help Follow-up Coordinators track and enter data. One of these reports is specific to Follow-up, the rest are available for the other protocols as well. The reports can be accessed by selecting 'Reports' in the navigation bar at the top of the EDC system and then selecting 'Study Report' from the dropdown menu. Then, find the Follow-up Protocol and each report will be listed on the right side of the screen under the 'Actions' column.

The Follow-up-specific report is the Pending Follow-up Windows Report. This report uses the information found in the GDB database to create a list of open windows for infants eligible for follow-up (infants that died or have already completed the follow-up are excluded). The cases listed in the report can be further limited by subsetting by the follow-up window start date.

The Adjusted Age Calculator tool is closely related to the Follow-up Study though it is available in the data entry software for all the protocols as well. This tool is used to calculate the adjusted age in weeks and months for the corresponding questions on the NF01 and NF03 forms. The inputs to the report are the Date of Birth (DOB), gestational age at birth, and an optional reference date. By specifying the interview date in the reference date field, the report will give the adjusted age in weeks and months for that date. The report also lists other dates such as

the 21st day of life, the 36-week gestational age date, and the start and stop of the 22-26 month follow-up window. The Adjusted Age Calculator is available by selecting the 'Tools' dropdown menu at the top of the NRN EDC.

There are three additional reports that are standard to all data entry programs (which includes Follow-up). These are used to list all forms that have been entered by infant, and to list the forms, by infant that are entered but not yet marked complete (see the *NRN Web-based EDC User's Manual* for a description of how a form is marked complete). These three reports are: Validation Issues, Temporary Values, and Form Statuses.

3.3 Data Management

3.3.1 Administration and Coordination of Forms

- The NRN Web-based electronic data capture (EDC) system. The Manual is located on the NRN Private website (neonatal.rti.org) here:
[Network Operations > Data Management System -> NRN Web-based EDC NRN Web-based EDC user's manual](#)
- It may be useful to make a folder for each eligible infant that contains the forms which will be completed for that infant, as the forms will vary.

3.3.2 Form Completion and Missing Values

Below are summarized the missing data symbols used for the NICU Network Studies.


Missing Data Codes

Each data field allows for missing codes if the question is required but can't be answered. The dropdown boxes to the right of each question allow for these codes. Shown below: are the allowable codes. Selecting one of these will allow the user to complete the form without error.

- Temporarily Missing (TM) —Select this if the value is unavailable but expected at a later date. A list of these values can be found in the Reports section.
- Permanently Missing (PM) —Select this if there is no way to get the value later.

3.3.3 Creation and Handling of Edits

- The new and updated data are run through a series of editing programs nightly. The edits check for possible data entry errors, logical errors and inconsistencies between values.
- The following types of edits will be produced:
 - Basic checks will be performed during data entry. These checks include ranges and missing values. For example, if a value is out of a given range the system will produce a query, prompting the data entry person for either a correction or an explanation.
 - Dictionary Edits - these edits are similar to the checks that are used during data entry (range checks and missing values). If a value is out of range at the time of data entry

- the data entry person will be prompted for a correction or an explanation. If a correction is not made during data entry an edit will be generated at the DCC.
- Single Form Edits - these edits check for logical inconsistencies within a form. For example, if there is no “Other Caretaker” identified in question A.6 however, in question C.2.c, “Other Caretakers highest grade completed” is “6 = college degree”, the data entry person will be prompted to correct the inconsistency (NF01). This edit is also performed again during nightly runs.
 - Inter Form Edits - these edits check for logical inconsistencies between forms. For example, if the date of birth is different on two separate forms the web-based electronic data capture (EDC) system will notify the data entry person of the inconsistency.
 - Inter Study Edits - these are edits that check for logical inconsistencies between studies. For example, if the date of birth is different on the Follow up forms and on the Generic forms, the EDC will notify the data entry person of the inconsistency.
- Certain edits can be verified by clicking the  icon located at the end of the query and then entering a valid reason. Not all types of edit failures can be defeated in this manner; usually only consistency and range checks.
 - What to do with the edits:
It is not necessary for Follow-up staff to return anything to the DCC regarding the edits; all actions are performed in the EDC system. As the edits for each case are resolved by correcting values or determining that the values are really correct (e.g., range edit failure); the Follow-up staff should access the EDC system for the protocol in question, access the patient’s data with the appropriate ID number, and make the corrections and verifications as indicated.

Any edits that are not resolved/verified before the edits are generated again the following day and are available in the validations report in the EDC.

3.3.4 Discontinued Forms

The following is a list of discontinued Follow Up forms and the dates of active data collection for these items:

Form	Title of Form	Date of Collection
NF07	Family Resource Scale	(pre1998-April 12, 2005)
NF07S	Family Resource Scale (Spanish version)	(pre1998-April 12, 2005)
NF09B	Bayley Rating Scale	(October 22, 2002 - April 25, 2005)
NF09M	Mental Scale MDI	(October 22, 2002 - April 25, 2005)
NF09P	Motor Scale PDI	(October 22, 2002 - April 25, 2005)
NF09	Bayley II Scales Summary Score Sheet	(pre1998-summer 2007)
NF09A	Bayley III Scales Summary Score Sheet	(summer 2007- 2022)
NF13	Brief Infant-Toddler Social Emotional Assessment (BITSEA)	August 2002 - August 2014

Chapter 4. INTERVIEWING TECHNIQUES

4.1 Principles and Concepts of Interviewing

The following list gives some principles and concepts to keep in mind in conducting a good interview. They are:

- The interviewer should display a clear and defined purpose.
- The subject should feel that their information is valuable.
- The interviewer has the responsibility for directing the interview - to keep it moving, to make it productive
- The interviewer sets the tone, the climate, and the attitude in which the interview is conducted.
- Questions should be asked clearly and comfortably. It is the interviewer's responsibility to make the subject feel that this is an appropriate and easily understood question.
- Confidentiality must be respected and addressed.
- Mutual trust, respect, and acceptance are at the very heart of a successful interview. (To show respect and trust, one must be respected and trusted.)

4.2 Types of Interviews

The interviews that will be used in the follow-up visit include Structured and Semi-structured Interviews.

Structured Interviews

The format of this interview is to read *word for word* the questions covered on the questionnaires. If necessary, a definition for a specific word can be obtained in the operation's manual or the dictionary.

Semi-Structured Interviews

This interview requires as much structure as possible but allows for minimal probing or 'bending' of the word for word format. The items should be administered in the order given on the form.

4.3 Interviews at the Follow-up Visit

- SES - Multi-sources, interview parts are semi-structured
- Medical History - Multi-sources, interview parts are semi-structured
- Readmission Form - Multi-sources, interview parts are semi-structured
- Child Behavior Checklist (CBCL) - Structured

4.4 Set - up of the Interview

The interviews should be conducted in a private room with the door closed. The interviews are confidential. Try to avoid extraneous noise and interruptions. If a desk is present in the room,

the chairs should be placed in a manner that minimizes the desk as a barrier to communication but does not allow the mother/caretaker to view the questionnaire.

If the child is present while the mother is being interviewed and starts to be disruptive, step back from the interview, wait until things have settled down, and then refocus her on the interview.

4.5 Scripts

The following give suggested scripts for the introduction to the visit and to the interview session. The interviewer can give this introduction in his/her own words but he/she should make sure the following five topics are covered:

1. Redundancy

Let the interviewee know that certain questions may have been asked before but the interviewer may have to ask similar questions again.

2. Confidentiality

Let the interviewee know that identifying information will not be disclosed or published. Consult the local IRB on how to discuss reporting of child neglect or abuse.

3. Referrals

Let the interviewee know that if she or the child needs any help or services that the staff can help make the necessary referrals.

4. Questions

Let the interviewee know that if she has any questions, she should feel free to ask them.

5. Content

Give the interviewee an idea of what the interviews are about.

4.5.1 Opening Script

Script:

"First, we want you to know how much we appreciate your coming here for the visit. Today, we will be examining your child for his/her growth and development. We will spend some time asking you questions about your child's medical history since he/she was first discharged from the hospital, and how your child eats, sleeps, and behaves. We will also ask some questions about your household and lifestyle since having this child.

Someone will give you a full explanation of each of the parts of the visit as we get to them. If you have any questions about any of the things we are doing, please let us know. Do you have any questions at this time?"

4.5.2 Introduction to the Interview Session

Script:

"During these interviews, I am going to ask you questions on several different topics. I will be asking many questions and in some cases, it will seem that I should already know the answer

from how you have responded to similar questions. For every mother that I interview I must ask all of the questions in the same order and each item as it is written.

I want to remind you that the session is strictly confidential, and any information that you give me will only be used for the purposes of this study. Your answers will only be seen by the select staff of the study, and only those staff who help in finding services or referrals for you will know the information you state. Your name or other identifying information will not be used in any material describing the results of the study."

Check the local Institutional Review Board guidelines on whether to discuss with the mother the need to report child abuse or neglect. If it is necessary, the following script can be added to the above script. *"The only exception to this confidentiality is if you provide information on child abuse or neglect."*

"At the end of the session we will spend some time discussing any referrals or help and services that you may wish to know about or that may be available to you.

Do you have any questions? Remember if you have any questions or do not understand what I am asking; please feel free to ask me during the interview. If there is a question that you do not wish to answer, please let me know."

4.6 Tips on Interviewing

Three key behaviors to guide respondents into comfortable conversational sharing of information are:

1. Listening
2. Reinforcing
3. Probing

4.6.1 Giving Positive Reinforcement

The following provides information for giving positive reinforcement:

- Keep it neutral
- Use standard phrases such as:
 - "uh-huh"
 - "OK"
 - "thanks"
 - "that's helpful"
 - "that's useful information"
 - "that kind of information is useful to the study"
 - "we appreciate getting your opinion on that"
 - "it's important to get that kind of information"
- Reward only good responses that are:
 - clear

- relevant
- complete
- Probe responses that do not meet these requirements to refocus and redirect the respondent's attention to the question. Your probe must not influence the content of the answer.

4.6.2 Probing Rules

When probing responses certain rules to follow are:

- Keep it neutral.
- Use standard probes such as:
 - "which would be closer?"
 - "could you be more specific?"
 - "so, would you say that is"
 - "could you say more about that?"
 - "are there any other reasons?"
 - "what else?"
- Use short expressions as prefaces to probes such as:
 - "yes, but"
 - "overall"
 - "but, generally speaking"
 - "but, in general"
 - "no one knows for sure"
 - "we're just interested in your opinion"

4.6.3 "I Don't Know" Responses

Reasons for "I don't know" responses include:

- Not understanding the question.
- Buying time to think of a response.
- Feeling uninformed or uncomfortable about the issue.
- Having no opinion or answer to the question.
- Use special probes for this response such as:
 - "your best estimate will be fine"
 - "take a moment to think about it"

4.6.4 Do's and Don'ts of Probing

- Do emphasize key words you think the respondent missed when repeating the question.
- Do read the question again more slowly if you think the respondent did not understand.
- Do repeat category choices that are not eliminated by respondent's answer if the response is not specific enough.

- Don't ask a respondent if she meant a particular thing.
- Don't assume what was meant.
- Don't ask did you mean "this or that" -- two alternate interpretations.
- Don't lead by summing up respondent's answer.

If the respondent can't or won't answer an item, then code as permanently missing '*'.

4.7 Interviewer Training

All interviewers must be trained before conducting the interview session by an experienced interviewer. Each center will have one designated staff person who receives initial training and then can train other staff personnel. To receive initial training, the staff person should do the following:

- Interview three caretakers.
- Note any definitions or word substitutions used or questions that were misunderstood or difficult for the caretaker to understand.
- Record the length of time for each questionnaire.

Chapter 5. ENROLLMENT INTO THE STUDY

5.1 Assignment of Follow - up Number by Computer

Follow-up numbers are generated at each site by computer. In order to obtain a Follow-up number, select the 'Auto Generate Follow Up ID' link next to question 1 'Follow up Number' on the Identification Information for use with Base Record 1.0 NF00 Form. This will automatically generate the follow up number for the particular child. This number is the child's unique identifying number and should be used for all subsequent forms in the Follow-up study.

For further reference, refer to the *NRN Web-based EDC User's Manual* for instructions on accessing and entering data into the Follow-up Data Base.

5.2 Identification Information (NF00) (rev 4/20/2022)

1. Follow-up number:

This number will be supplied by web-based electronic data capture (EDC) system once the auto-generate button is selected by the site. The rest of the subject identifying information should then be entered. These questions are described below. Record the number assigned by the EDC on the form.

2. Birth date:

The birth date of the child, recorded as mm/dd/yyyy.

4. Gestational age

Record in weeks, days. The value entered here should match what is recorded on the NG02 form question D6. If the values do not match, the Center will receive an edit.

Record the best estimate of gestational age using the following hierarchy (as is done for GDB form NG02 question D6):

- 1) Best OB estimate: Obstetrical measures based on last menstrual period, obstetrical parameters, and/or early prenatal ultrasound as recorded in the maternal chart.
- 2) Best Neonatologist estimate: Neonatologist's estimate based on physical criteria, neurologic examination, combined physical and gestational age exam (Ballard or Dubowitz). In instances when the gestational age in days is not recorded, enter '0' in the days field.

5. Birth Number:

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

65. Generic network number for the child

Record the Generic Network Number. If the child was not in the Generic Database, then leave blank and enter the appropriate Study specific ID.

7 Were generic forms completed at a different center?

Record YES if the patient was initially enrolled somewhere else and the GDB forms were completed at an NRN center different than the Follow-up NRN center. If a child moved and is being examined for Follow-up at another center, **both centers will fill out Form NF00**. The original center should answer this question NO. The center where the Follow-up exam is conducted should answer this question YES. Fill out Questions 6a – 6c, as appropriate.

a. If Yes, give previous center number:

Record the center number for the center where the Generic forms were completed using the following center codes.

- 03 = Case Western Reserve University
- 04 = University of Texas - Dallas
- 05 = Wayne State University
- 09 = Emory University
- 11 = University of Cincinnati
- 12 = Indiana University
- 14 = Brown University
- 15 = Stanford University
- 16 = University of Alabama
- 18 = University of Texas - Houston
- 19 = Duke University
- 22 = University of California at San Diego
- 25 = University of Utah
- 24 = University of Iowa
- 26 = University of New Mexico
- 27 = University of Pennsylvania/CHOP
- 28 = University of Rochester
- 29 = University of California-Los Angeles
- 30 = Nationwide
- 31 = Children's Mercy

8. Patient Study IDs

Enter the appropriate study ID for the child for any of the studies listed.

9. Date Form Completed

Enter the date the form was completed (Month, Day, Year)

5.3 Form Completion If the Follow-up Visit Takes Place at Another Network Center

If the Follow-up visit is conducted at a network center other than the center where the child was enrolled in the Generic Study, an NF00 Form will be completed by **each center**. The original center where the child was enrolled in the Generic Study will fill out NF00, answer Question 6 as NO, and will answer question 6c. The second center will also fill out NF00, answer Question 6 as YES, and answer questions 6a and 6b. The child will be assigned two Follow-up Study

numbers, one corresponding to the original center and one corresponding to the second center. Both centers should complete the NF10 (Status Form). On the NF10, a code of '5' (Follow-up visit completed at another Network center) should ONLY be recorded by the originating (GDB) center. For example, if the visit was completed at the new (transfer) center, then the new (transfer) center should record '1' (Child seen, Follow-up visit completed).

Chapter 6. DISCHARGE INFORMATION

6.1 SES at Discharge (NF01)(v11/5/2012)

Information pertaining to the socioeconomic status of the family will be collected at the time of discharge to home or to a long-term care facility. This information will be obtained by interviewing the mother/primary caretaker or informed household member. The interview will be conducted by the study coordinator or research nurse. This information should be obtained in person. However, if the interview cannot be done in person at the time of baby's discharge then interview of the mother/primary caretaker by telephone is allowed to obtain this information.

For babies who are discharged before 120 days, SES information should be obtained as close to discharge as possible. However, a window of 4 weeks is allowable. If the information is obtained before four weeks of discharge, it should be checked and updated at the time of discharge.

For babies who are hospitalized at 120 days or at a chronic care facility, complete the SES at discharge at this time. **Information obtained prior to discharge for infants still in the hospital at 120 days should be checked and updated at the time of discharge.**

Complete the form considering the baby's planned living arrangements. This information should be checked and updated at the time of discharge.

6.1.1 Heading

Information for the heading should be obtained from the **Base Form (NF00)**. If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the Base Form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc based on the order they were born.

Mother's Initials

Record the first letter of the mother's first, middle and last names. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier. Found as item 1 on the NF00.

6.1.2 Section A. Demographic Data

1. Date of discharge:

Record the date of discharge from the hospital to home or to a chronic care facility. Do not count date of TRANSFER TO Level Two "Grow Units" or Step-up Units as the date of discharge but rather the final date of discharge to home or to a chronic care facility.

For patients still in the hospital at 120 days, enter the date that the child reaches 120 days (at which time the NF01 should be completed). **When the child is discharged, the date should be updated to reflect the discharge date.**

2. Date of birth:

To avoid the need for multiple entries of the same data, the Web-based EDC will insert the date of birth that was keyed in the NF00 form. EDC users should verify that the date of birth that was entered in the NF00 form matches the date of birth entered on the NG02. (Day begins at 00:00 and ends at 23:59). If the date of birth was not correctly entered on the NF00, users should return to the NF00 form and enter the correct date of birth.

3. Age

Note: The Follow-up adjusted age calculator (available by selecting the 'Tools' dropdown menu at the top of the NRN EDC) can be used to obtain the following ages.

a. Chronological age:

The Web-based EDC will calculate and insert the chronological age based upon the date of discharge and the date of birth that was keyed in the NF00 form. EDC users should verify that the calendar age at discharge in weeks since birth without adjustment has been correctly imputed by the EDC.

b. Corrected age:

The EDC will calculate and insert the corrected age based upon the date of discharge and gestational age that was keyed in the NF00 form. EDC users should verify that corrected age has been correctly imputed by the DMS as per the following:

PLEASE NOTE: Using this method to determine adjusted age will result in an estimated value. The EDC will calculate the patient's actual full-term date and then subtract that date from the discharge date to determine the patient's adjusted age at that time. It is possible that the EDC value may vary slightly from the value obtained via a manual calculation.

If the infant was ≥ 38 weeks gestational age at birth by the best OB estimate, then the adjusted age at discharge is the same as the chronological age.

If the infant was < 38 weeks gestational age at birth by the best OB estimate, then subtract the gestational age at birth from 40. This will be the number of weeks premature. Subtract the number of weeks premature from the chronological age at discharge to get the adjusted age.

For example, if the gestational age at birth was 36 and the chronological age at discharge was 7 weeks. The number of weeks premature would be $40 - 36 = 4$. The adjusted age at discharge would be $7 - 4 = 3$. Record 3 in the most right-hand column.

4. Will the child be under state supervision?

Record YES if the baby is a ward of the court, in temporary custody in the home of a relative or other person by a state agency or the court system, or mother and child are supervised by a state agency and the court system.

5. Primary caretaker (Parent/Legal Guardian, the person who is primarily responsible for the child):

The primary caretaker is the person (parent and/or legal guardian) who is primarily responsible for parenting the child. If the Parent/Legal Guardian resides in the same household as the child, the Parent/Legal Guardian is considered to be the primary caretaker. If the mother resides in the same household as the child, she is considered to be the primary caretaker. If each caretaker has exactly 50% custody, record as the primary caretaker, the person who comes in for the visit.

See "RELATIONSHIP CODES" on page B.1 of Appendix B for the appropriate code for the primary caretaker.

6. Other caretaker:

Other Caretaker is a person other than the primary caretaker, (if any) who is responsible, in addition to the primary caretaker, for parenting the child. This is any person, other than the primary caretaker, who is parenting and taking care of the child's needs. Financial contribution does not necessarily qualify a person to be designated as such. This may be the biological father, foster father, adoptive parent, boyfriend, grandparent, etc. If there is no other caretaker, leave blank on the data form.

See "RELATIONSHIP CODES" in Appendix B for the appropriate code for the other caretaker.

7. Primary Caretaker's marital status:

Choose the appropriate marital status code (1= Married, 2=Single, 3=Divorced, 4=Widowed). If "common law" and the mother considers herself married, use '1' married. If she is currently married but separated (including legal separations) use '1' married.

6.1.3 Section B. Household Composition

1. Baby's planned living arrangements:

See "LIVING ARRANGEMENT CODES" on page C.1 for the appropriate codes and decision rules to be followed when choosing the living arrangement code.

IF BABY'S PLANNED LIVING ARRANGEMENTS ARE CODES 16, 17, OR 18, SKIP TO C.4 OF THIS FORM.

2. Number of people living in baby's household:

Record the total number of people, both children and adults, including the baby who resides in the baby's household. Anyone who is expected to stay or has stayed two weeks and is

living in the household at the time of the interview is considered a member of the household. (Do not include family vacations.)

6.1.4 Section C. Education and Occupation

1. Apart from the Primary caretaker, do others contribute money to the child's household:

If an individual other than the primary caretaker contributes some money to the household, record YES ('Y'). If the respondent is uncertain or the answer is implausible, the interviewer should assist the respondent by asking if others pay some of the rent and utilities or buy some of the food. Contributors do not necessarily have to live in the baby's household. If there are no contributors other than the primary caretaker, record NO ('N').

2. Highest grade completed or attended

Record '1', '<7th grade', if less than 7th grade was attended.

Record '2', '7th to 9th grade', if completed through 7th, 8th or 9th grade.

Record '3', '10th to 12th grade', if completed through 10th, 11th or 12th grade and high school diploma not received.

Record '4', 'High School Degree', if a high school diploma or GED was received and one full year of college was not attended.

Record '5', 'Partial college', if at least one year of college was attended or an Associate's degree attained but a B.A. or B.S. was not received.

Record '6', 'College degree', if a B.S. or B.A. was received but no higher degrees were obtained.

Record '7', 'Graduate degree', for degrees higher than a college degree.

Record '8' if unknown.

a. Primary Caretaker:

Record this information if respondent is the primary caretaker or the respondent knows the primary caretaker's education. If the information is not known and cannot be obtained, then code '8' unknown.

b. Other Caretaker:

If another caretaker was recorded in question A.6, record their level of education. Record this information if the respondent is the other caretaker or the respondent knows the education of the other caretaker. If the information is not known and cannot be obtained, then code '8' unknown.

3. Currently Working

Record YES ('Y') for both part-time and full-time work. If the individual reports student status or welfare receipt the correct response is NO.

a. Primary Caretaker?

b. Other Caretaker?

If another caretaker was recorded in question A.6, record whether or not they are working

4. Baby's medical insurance:

Record the primary method of payment as indicated on the chart. (NOTE: If a study infant has both private and Medicaid, record '3' Both)

1 = Public Insurance

This may include Medicaid, Medicare.

2 = Private

Select this choice if the child is covered under a private insurance policy through employment or purchased, Preferred Provider, self-pay (able to pay out of pocket for medical care), non-Medicaid HMO and medical care provided by the armed forces.

3 = Both Public and Private

Select this choice if method of payment is a combination of Public and Private Insurance.

4 = Uninsured

Select this choice if there is no insurance and either the family not able to pay out of pocket for medical care or is on a sliding-scale payment plan to pay for medical care.

5 = Unknown

In some instances, the method of payment is not yet known, but this should not be the option of choice. The chart or the financial office at each site should have all financial information available on each patient.

6.1.5 Section D. Form Completion

1. Where was interview conducted:

Record '1' if the interview was conducted at the clinic, '2' if at the child's home, '3' if by telephone, '4' if in the hospital, or '9' if in another setting.

2. Date of SES interview:

Record the date of the SES at discharge interview.

3. Initials of person administering SES at Discharge:

Record the first, middle and last initials of the person administering the SES at Discharge.

Chapter 7. TRACKING

Tracking infants who are discharged up until the 22-26-month visit is a vital part of the Follow-up Study. Each center will implement procedures to identify and track all infants eligible for the Follow-up Study who are discharged alive from the NICU.

Before discharge, adequate information should be obtained from the mother or other caretaker so that in case the family moves other relatives or friends can be contacted to find out the new address. Contact should be made at least every two to three months. Methods used to contact families include:

- Phone calls and text messages if the caregiver has agreed to be contacted in this manner
- Certified letters
- Reminder postcards (don't rely only on this method)
- Email, if the caregiver has provided an email address and has agreed to be contacted in this manner
- Social media, if acceptable to the local IRB
- If the phone number and/or address are unavailable it may be possible to contact service providers to the family, such as, the pediatrician, or early intervention clinics. Other sources include hospital admissions and county agencies. It may also be necessary to send people out into the field to track down the family. The methods and the number of attempts made to contact each family should be documented.

7.1 Incentive for Recruitment, Follow-up, and Tracking

Factors influencing compliance are the following:

- The patients perceive that they get some value for themselves or for their infants. Items that are perceived or described as "value" can be:
 - Information, which is useful now or later.
 - Perception that the people running the study truly care for them as well as their infant.
 - They see value in the project as helping themselves or future patients (few patients see value in being altruistic).
 - Healthcare/developmental assessments for their infant.
- Removal of "barriers" is important in recruiting and maintaining patients in the study. Major barriers are:
 - Transportation -- this can be resolved by providing transportation, such as, taxi service like uber or lyft, and gas cards, if the distances are not too great, or reimbursement for transportation expenses. Transportation is the major issue for people living in the city who do not have private means to keep health appointments.
 - Childcare for siblings -- this can be resolved by providing childcare when patients come back for follow-up assessment. Need for childcare frequently arises while the infant is still in the NICU. Providing some childcare to supervise older siblings while

the mother is visiting removes a barrier and is often perceived as a value and as a sign of caring.

- Clinic Costs for Follow-up Visits—Follow-up expenses may be covered under the site NRN funds for clinic charged for the neurologic, behavioral and developmental testing.
- Incentives - Incentives should not be used to influence the voluntary nature of participating in the study. Incentives are sometimes similar to perceived values based on parent/infant needs, i.e. free health care, developmental toys, or gift cards. Incentives can be given at the time of the visit and the parents can be told at the time of the enrollment what the incentive will be. Incentives can also be used to keep track of patients who are seen infrequently as motivation to keep their addresses current with the study coordinator.

Some other ideas for incentives are:

- Annual birthday cards can be incentives or perceived as a sign of value or care.
- Developmental toys.
- Gift certificates or gift cards
- Money given at the end of the study.
- Perception of care and trust - This is more difficult to define, however, people who perceive that the Study Center cares for them and trust that the Study Center has more than only their scientific goals in mind are much more likely to continue in the study. Thus, it is important to establish a relationship with the parents while the baby is in the hospital and continue this relationship. Ongoing contact at specific intervals (approximately every 3 months), either by mail or by phone/text, will reinforce the concept of caring, while enabling the Study Center to track patients.

Prior to discharge, verification of addresses and phone numbers of the patients and other family members and neighbors needs to be done. It is important that patients be made aware that any information regarding address or phone number remain strictly confidential and will not be shared with anyone for use for any other purpose but making appointments for the babies' benefit.

The overall framework for success in recruitment as well as tracking and follow-up compliance is to use the time while the baby is in the nursery to establish a caring, trustful relationship with the family and then maintain this relationship with spaced (maximum 3 months) contacts with the family. Prior to discharge a number of contact sources have to be identified and verified. Study obligations should be explained prior to enrollment to eliminate as many noncompliance problems as possible and ensure that the parent understands and is willing to commit to the study.

Providing care for an infant and at the same time collecting research data is an extremely efficient way of maintaining patients in long-term follow-ups. However, if the patient utilizes a local clinic or Primary Medical Doctor (PMD), it is important to establish a good relationship with the primary care provider. Informing the primary care provider of the enrollment of the infant helps to maintain patients in a longitudinal study, thus, keeping primary care providers informed about any information collected on the patient, especially if the information can be useful for patient care (for example, Bayley scale or neurologic exam) will be very useful as a means of support for study visits.

7.2 Other Ideas for Tracking

If acceptable to the local IRB, other ideas for tracking include:

- Contacting mother's obstetrician, child's pediatrician or other physicians.
- Using the Social Security Numbers of mother and baby
- Using online search tools as acceptable and appropriate
- Contacting well established state medical registries.
- Contacting Early Interventionists.
- Obtaining additional cell and telephone numbers.
- Obtaining permission to text with mother and/or other care givers.
- Obtaining permission to “follow” on social media as acceptable and appropriate.

In 2022, the NRN Follow Up teams developed the **Strategies for Successful Neonatal Research Network (NRN) Follow Up** living document highlighting tips, tricks, and other methods for ensuring follow up. This document is available on the NRN private website here:

[Protocols](#) > [Active Protocols](#) > [Follow-up](#) > [Training](#) > [Strategies for Successful Neonatal Research Network \(NRN\) Follow Up](#)

Chapter 8. FOLLOW-UP VISIT OVERVIEW

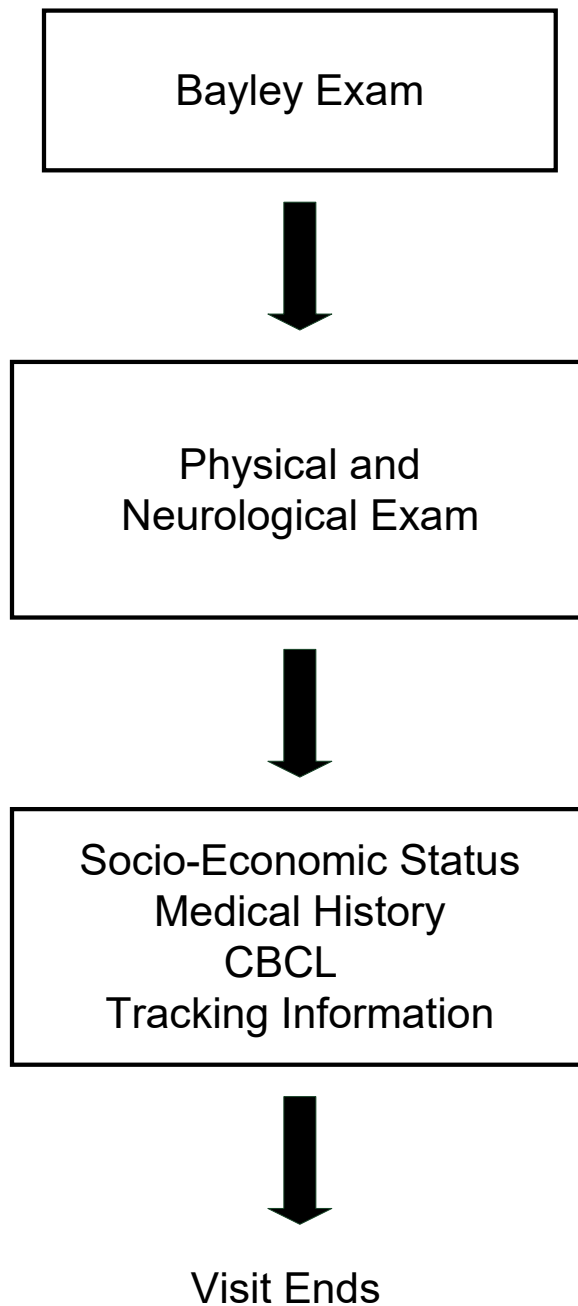
The Follow-up visit information should be obtained during the 22-26 month corrected age interval. Ideally, the examination should be scheduled as close to 24 months corrected age as possible. In the event it is difficult to schedule a visit at 24 months corrected age, the study protocol allows a TWO MONTH TIME INTERVAL PRECEEDING AND EXCEEDING 24 MONTHS CORRECTED AGE in which to schedule the visit. **Even where this protocol time interval is exceeded, follow-up sites are encouraged to schedule, and complete follow-up visits after the end of the follow-up window (i.e. up to 42 months corrected age).** *Remind caretaker that if child wears glasses, contact lenses, hearing aids and/or orthotics to make sure child wears them to the visit. This is important for the physical exam and the Bayley exam.*

8.1 Order of Administration

A suggested order of procedures is given in Figure 2 on page 8.2. Although the exact order of procedures at this visit cannot be predetermined as it depends on the appropriate state of the child, the Bayley Scales of Infant Development Fourth Edition (Bayley 4) should be administered early in the clinic visit before medical procedures or interviews, if possible. Best performance is compromised if the child is tired, hungry, or upset. The caretaker should be present for this exam.

Following the Bayley exam, the physical and neurological exam can be conducted. The caretaker may be present for the exam. If s/he is present for the exam, then the interviews can take place after the exam. The SES and Medical History should be conducted first, followed by the Child Behavior Checklist (CBCL).

Figure 2: Overview of Follow-up Visit



Chapter 9. VISIT LOG AND SOCIO-ECONOMIC STATUS AT FOLLOW-UP

9.1 Visit Log (NF02) (rev 4/1/2011)

The purpose of the Visit Log is to record all children who come in for their Follow-up visit. When a child comes in for his or her visit, record the child's first and last name, date of birth, date of visit, mother's initials (optional), birth number (only recorded in cases of multiple births), follow-up number and any comments that are relevant. Enter chronologically each child's information as he/she comes in for the visit. If the child comes in for two visits there should be a line for each visit on the Visit Log, each with a different date.

This form will not be entered into the Web-based EDC. It will be used in hard copy form by the centers as an internal management tool. Therefore, *it should be filled out as legibly and completely as possible*. The Visit Log should be comprehensive for the children who came in for a visit.

9.2 SES at Follow-up (NF03) (rev 11/5/2012)

Information pertaining to the socioeconomic status of the family will be collected at 22-26 months. This information will be obtained by interviewing the mother/caretaker or an informed household member. The interview will be conducted by the study coordinator or research nurse.

9.2.1 Heading

Information for the heading should be obtained from the **Base Form (NF00)**. If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the Base Form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the first letter of the mother's first, middle and last names. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

9.2.2 Section A. Demographic Data

1. Date of visit:

Record the date of visit as month, day, year.

2. Date of birth:

To avoid the need for multiple entries of the same data, the EDC will insert the date of birth that was keyed in the NF00 form. EDC users should verify that the date of birth that was entered in the NF00 form matches what was entered on the NG02. If the date of birth was not correctly entered on the NF00, users should return to the NF00 form and enter the correct date of birth.

3. Age: Note: The Follow-up adjusted age calculator (available anywhere in the Network software by pressing the F10 key) can be used to obtain the following ages.

a. Chronological age:

Chronological age refers to the age of the child in months since date of birth. The EDC will calculate and insert the chronological age based upon the date of the visit and the date of birth that was keyed in the NF00 form. EDC users should verify that chronological age has been correctly imputed by the EDC as per the following:

Record chronological age to the nearest month. If the child is examined within 16 days of the anniversary date, then record chronological age as 22 months. If the child is examined ≥ 16 days after this date, then record chronological age as 23 months. Use this method for each subsequent month of age.

The following table presents the age in months rounded to the closest month.

AGE	RANGE
22 months	22 months exactly to 22 months, 15 days
23 months	22 months, 16 days to 23 months, 15 days
24 months	23 months, 16 days to 24 months, 15 days
25 months	24 months, 16 days to 25 months, 15 days
26 months	25 months, 16 days to 26 months, 15 days
27 months	26 months, 16 days to 27 months, 15 days
28 months	27 months, 16 days to 28 months, 15 days
29 months	28 months, 16 days to 29 months, 15 days
30 months	29 months, 16 days to 30 months, 15 days
31 months	30 months, 16 days to 31 months, 15 days
32 months	31 months, 16 days to 32 months, 15 days
33 months	32 months, 16 days to 33 months, 15 days
34 months	33 months, 16 days to 34 months, 15 days

b. Corrected age:

The EDC will calculate and insert the corrected age based upon the date of the visit and gestational age that was keyed in the NF00 form. EDC users should verify that corrected age has been correctly imputed by the EDC as per the following:

Babies < 38 weeks GA at birth - From the report program which lists the eligible children, refer to the date that the child is 22 months corrected age. (This is obtained by counting a year and 10 months from the date the child was 40 weeks post-corrected age). Record corrected age to the nearest month. If the child is examined within 16 days of the anniversary date then record corrected age as 22 months. If the child is examined ≥ 16 days *after* this date then record corrected age as 23 months. Use this method of rounding for each subsequent month.

The following table presents the age in months rounded to the closest month.

AGE	RANGE
22 months	22 months exactly to 22 months, 15 days
23 months	22 months, 16 days to 23 months, 15 days
24 months	23 months, 16 days to 24 months, 15 days
25 months	24 months, 16 days to 25 months, 15 days
26 months	25 months, 16 days to 26 months, 15 days

Twenty-six months plus 15 days is the outside window for examining the child at the 22-26-month visit.

Babies ≥ 38 weeks GA at birth - Do not correct for prematurity. Use the birth date as the anniversary date.

4. Is the child under state supervision?

Record YES if the child is a ward of the court, in temporary custody in the home of a relative or other person by a state agency or through the court system, or mother and child are supervised by a state agency and the court system. Multiple sources may have to be checked to find out if the child is under state supervision.

5. Primary caretaker (Parent/Legal Guardian, the person who is primarily responsible for the child):

The primary caretaker is the person (parent and/or legal guardian) who is primarily responsible for parenting the child. If the Parent/Legal Guardian resides in the same household as the child, the Parent/Legal Guardian is considered to be the primary caretaker. If the mother resides in the same household as the child, she is considered to be the primary caretaker. If each caretaker has exactly 50% custody, record as the primary caretaker, the person who comes in for the visit.

See "RELATIONSHIP CODES" on page B.1 of Appendix B for the appropriate code for the primary caretaker.

6. Other caretaker:

Other Caretaker is a person other than the primary caretaker, (if any) who is responsible, in addition to the primary caretaker, for parenting the child. This is any person, other than the primary caretaker, who is parenting and taking care of the child's needs. Financial

contribution does not necessarily qualify a person to be designated as such. This may be the biological father, foster father, adoptive parent, boyfriend, grandparent, etc. If there is no other caretaker, leave blank on the data form.

See "RELATIONSHIP CODES" in Appendix B for the appropriate code for the other caretaker.

7. Primary Caretaker's marital status:

Choose the appropriate marital status code. (1= Married, 2=Single, 3=Divorced, 4=Widowed). If "common law" and the mother considers herself married, use '1' married. If she is currently married but separated (including legal separations) use '1' married.

9.2.3 Section B. Household Composition

1. Child's current living arrangements:

See "LIVING ARRANGEMENT CODES" on page C.1 of Appendix C for the appropriate codes and decision rules to be followed when choosing the living arrangement code. If the child is still hospitalized or in a chronic care facility, record 16 for "chronic care facility" and 19 for "Hospital", for the child's living arrangement.

In cases where the infant is never discharged from the hospital (i.e., goes directly from NICU to PICU), NF03 Living arrangement (question B1) should be coded as 19 Hospital as listed in App C. Key NF03 question F1 (Does the child reside in a chronic care facility) as Yes to skip the day care questions.

IF CHILD'S CURRENT LIVING ARRANGEMENTS ARE CODES 16, 17, 18, OR 19 SKIP TO C.4 (child's medical insurance).

2. Number of people living in child's household:

Record the total number of people, children and adults, including the child, who reside in the child's household. Anyone who is expected to stay or has stayed two weeks and is living in the household at the time of the interview is considered a member of the household. (Do not include family vacations.)

9.2.4 Section C. Education and Occupation

1. Apart from the Primary caretaker, do others contribute money to the child's household:

If an individual other than the primary caretaker contributes some money to the household, record YES ('Y'). If the respondent is uncertain or the answer is implausible, the interviewer should assist the respondent by asking if others pay some of the rent and utilities or buys some of the food. If there are no contributors other than the caretaker, record NO ('N').

2. Highest grade completed or attended

Record '1', '<7th grade', if less than 7th grade was attended.

Record '2', '7th to 9th grade', if completed through 7th, 8th or 9th grade.

Record '3', '10th to 12th grade', if completed through 10th, 11th or 12th grade and high school diploma not received.

Record '4', 'High School Diploma', if a high school diploma or GED was received and one full year of college was not attended.

Record '5', 'Partial college', if at least one year of college was attended or an Associate's degree attained but a B.A. or B.S. was not received.

Record '6', 'College degree', if a B.S. or B.A. was received but no higher degrees were obtained.

Record '7', 'Graduate degree', for degrees higher than a college degree.

Record '8' if unknown.

a. Primary Caretaker:

Record this information if respondent is the primary caretaker or the respondent knows the primary caretakers education. If the information is not known and cannot be obtained, then code '8' unknown.

b. Other Caretaker:

If another caretaker was recorded in question A.6, record their level of education. Record this information if the respondent is the other caretaker or the respondent knows the education of the other caretaker. If the information is not known and cannot be obtained, then code '8' unknown.

3. Currently working

Record YES ('Y') for both part-time and full-time work. If the individual reports student status or welfare receipt the correct response is NO.

a. Primary Caretaker?

b. Other Caretaker?

If another caretaker was recorded in question A.6, record whether or not they are working

4. Child's medical insurance:

Record the primary method of payment from best available information from all sources (e.g. medical chart, maternal interview). (NOTE: If a study infant has both private and Medicaid insurance, record '3' Both.

1 = Public Insurance

This may include Medicaid, Medicare.

2 = Private

Select this choice if the child is covered under a private insurance policy through employment or purchased, Preferred Provider, self-pay (able to pay out of pocket for medical care), non-Medicaid HMO and medical care provided by the armed forces.

3 = Both Public and Private

Select this choice if method of payment is a combination of Public and Private Insurance.

4 = Uninsured

Select this choice if there is no insurance and either the family not able to pay out of pocket for medical care or is on a sliding-scale payment plan to pay for medical care.

5 = Unknown

In some instances, the method of payment is not yet known, but this should not be the option of choice. The chart or the financial office at each site should have all financial information available on each patient.

9.2.5 Section D. Household Information

1. Primary language spoken to the child over the last year:

Record '1' if English was the primary language spoken to the child.

Record '2' if Spanish was the primary language spoken to the child. Spanish refers to any Hispanic language.

Record '3' if another language was the primary language spoken to the child.

If the primary language of the caretaker is different from the primary language used by other household members, refer to the primary language of the caretaker.

a. If Other, specify:

2. Was a second language spoken to the child over the last year?

Record YES ('Y') if caretaker or another household member speaks a second language to the child. Brief visits to a relative who speaks a second language to the child does not count.

b. If YES, secondary language:

Record '1' if English was the secondary language spoken to the child.

Record '2' if Spanish was the secondary language spoken to the child.

Record '3' if another language was the secondary language spoken to the child.

i. If Other, specify:

3. Number of places the child has lived since discharge:

This is defined as places of residence or address of the child. Record '1' if the child has not moved since initial hospital discharge with the mother. If the child has resided at the address greater than two weeks, it is considered a change of address. Do not include family vacations as a change of address.

9.2.6 Section E. Special Child Services

1. Is the child receiving or has (s)he received any of the following services:

For each of the following record '1' No if the child has not received the service, '2' if the child received the service but it was discontinued, '3' if the child is currently receiving the service, or '4' if the service was recommended by a medical professional but the child is not receiving the service. Record '1', '2', '3', or '4' in the column to the right.

a. Visiting nurse

Record whether or not the child receives or has been recommended by a medical professional to receive a visiting nurse, a nurse who visits the home to administer care for less than 3 hours.

b. Home nurse

Record whether or not the child receives or has been recommended by a medical professional to receive a home nurse, who stays for a shift of at least 4 hours to provide skilled nursing services.

c. OT/PT

Record whether or not the child receives or has been recommended by a medical professional to receive services from an Occupational Therapist or Physical Therapist. OT is as an Occupational Therapist who works on the child's ability to hear, use his or her hands, or play appropriately for age. PT is a Physical Therapist who works on child's ability to use their muscles, particularly for whole body movement.

d. Speech therapy

Record whether or not the child receives or has been recommended by a medical professional to receive speech therapy. Speech therapy is defined as one who works on the child's ability to understand or use language or other communication methods.

e. Early intervention program (infant stimulation)

Record whether or not the child receives or has been recommended by a medical professional to receive an early intervention program. This is defined as a program to teach the child developmentally appropriate skills, in the home, or in the center, alone or with other children (e.g. programs to help child with coordination with walking).

f. Social worker for the child

Record whether or not the child receives or has been recommended by a medical professional to receive a social worker from any agency or program. Do not record any social services assessment that is done to determine and assess the need for social services.

g. Specialty medical/surgical clinic visit

Record whether or not the child receives or has been recommended by a medical professional to receive services from a specialty medical/surgical clinic. A specialty medical clinic visit is a specialty other than pediatrics or family practice that provides more than primary care (e.g. Audiologist, Podiatrist, Cardiologist, Neurologist).

Please indicate whether or not the child receives or has been recommended by a medical professional to receive the following special services. Record '1', '2', '3', or '4' in the column to the right.

1. Pulmonary
2. Ophthalmologic
3. Gastrointestinal
4. Audiologic
5. Neurologic
6. ENT
7. Cardiology
8. Urology
9. Neurosurgery
10. General surgery
11. Other
- 11a. Other specify.

h. Neurodevelopmental/Behavioral clinical visits

Record whether or not the child has received or has been recommended by a medical professional to receive a neurodevelopmental/behavioral clinical visit, prior to this study visit. This refers to special tests to identify the child's abilities as compared to other children (e.g. walking, talking, or feeding themselves). Record '1', '2', '3', or '4' in the column to the right.

i. NICU Follow Up Clinic

Record whether or not the child was seen or has been recommended by a medical professional to be seen in a special NICU Follow-Up clinic for premature, low birth weight infants, whether it was a neurodevelopmental clinic, comprehensive health and development clinic, clinic for chronic conditions or other follow-up visit for premature infants. Record '1', '2', '3', or '4' in the column to the right.

2. Does the child have a regular doctor or clinic where the child is taken for routine healthcare?

Record YES 'Y' if the child sees a regular doctor or clinic, else record NO 'N'.

9.2.7 Section F. Day Care/Child Care in the past month

Record YES ('Y') or NO ('N') for all that apply.

1. Does this child reside in a chronic care facility?

Record YES ('Y') if the child resides in a chronic care facility, else record NO ('N').

IF YES, skip to section G, if NO continue to question 2.

2. Is your child taken care of by someone other than the primary caregiver?

If YES, answer all that apply

- a. **Traditional center-based day/child care**
 - i. **If YES, record the average hours per week.**
- b. **Medical (specialized) care by medical professionals (i.e. private duty nurses, respiratory therapists, etc.)**

Medical care includes Gastrostomy care, continuous feeds, ventilators, etc.

 - i. **If YES, record the average hours per week.**
 - ii. **If YES, record where (whether full time or part time)**
 - Record '1' if in primary caregivers home
 - Record '2' if in a relative's home
 - Record '3' if home is Other
 - Record '4' if in Facility
- c. **Traditional Home-based day/child care**
 - i. **If YES, record the average hours per week.**
 - ii. **If YES, whose home**
 - Record '1' if in primary caregiver's home
 - Record '2' if in a relative's home
 - Record '3' if home is Other
- d. **Babysitter/Au Pair**
 - i. **If YES, record the average hours per week.**
 - ii. **If YES, what is their relation to the child**
 - Record '1' if relative
 - Record '2' if non-relative

9.2.8 Section G. Form Completion

1. Primary Responder

Use codes in Appendix B to record the primary responder for this interview.

2. Where was interview conducted:

Record '1' if interview was conducted at the clinic, '2' if at the child's home, '3' if by telephone, '4' in a hospital or chronic care facility, or '9' if another setting.

3. Date of SES interview:

Record the date of the SES at Follow-up interview

4. Initials of person administering the SES at Follow-up:

Record the initials of the person administering the SES at Follow-up. Record the first, middle, and last initial.

Chapter 10. MEDICAL HISTORY AND EXAMINATION

10.1 Medical History Form (NF04) (rev 11/5/2012)

This form should be completed by the follow-up nurse, practitioner or designee using the best available information. If the medical chart is available, this information should be used along with history reported from the caretaker.

The interview with the primary caretaker or secondary caretaker familiar with the medical history should be conducted in person if possible. If this is not possible, a telephone interview may be conducted.

The Generic Data Base Study (GDB) includes information from date of admission to initial transfer > 7 days/discharge. The 22-26 month follow-up should include all illnesses, procedures, surgeries and follow-up needs following the **initial** transfer/discharge. There have been some questions about the use of the term "at-home" as some children have not been discharged out of the hospital or remain in chronic care facilities. When answering questions on the NF04 and NF04A consider the time period after initial transfer/discharge from the NICU.

10.1.1 Heading

Information for the heading should be obtained from the **Base Form (NF00)**. If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the Base Form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

10.1.2 Section A. Medical History

This form should be completed for all children examined at the Follow-up visit.

In rare cases where the infant is never discharged from the hospital (i.e., goes from NICU to PICU or other chronic inpatient unit), the NF04 Medical History form questions phrased “since discharge” should be thought of as “since one year”, which would have been the last GDB form was completed (NG05-Late Clinical Outcomes Form).

1. Has the child been re-hospitalized since discharge to home or to a chronic care facility?

Record YES if the child had **at least one overnight stay** in a hospital since initial discharge to home or to a chronic care facility.

IF YES, COMPLETE FORM NF04A

If YES,

a. How many times has the child been rehospitalized?

Count the number of times the child was re-hospitalized.

2. Has the child taken any of the following medications repeatedly in the last 3 months?

Record YES ('Y') if the child has repeatedly taken any of the medications listed in a-e below; else record NO ('N').

If YES, has the child taken:

For a - e below use the following codes to answer each of the following: 1=NO, 2= Yes, but stopped, 3=Yes, still using.

- a. Anti-reflux medications?** For example, PPIs (i.e., Prevacid, Prilosec), H2 inhibitors (i.e., Zantac), Prokinetics (i.e., Reglan). Record '1', '2', or '3' in the column to the right.
- b. Asthma/BPD medications?** For example, inhaled medications such as albuterol, or steroids, proventil, etc. Record '1', '2', or '3' in the column to the right.
- c. Anticonvulsants/Seizure medications?** For example, phenobarbital, dilantin, tegretol, etc. Record '1', '2', or '3' in the column to the right.
- d. Thyroid medications?** For example, synthroid, etc. Record '1', '2', or '3' in the column to the right.
- e. Muscle relaxants and/or antispasticity medications?** For example, baclofen, etc. Record '1', '2', or '3' in the column to the right.

3. Has the child had one or more seizures since discharge?

Record YES ('Y') or NO ('N').

4. Has the child been diagnosed with (or suspected to have) Autism Spectrum Disorders? Record YES ('Y') or NO ('N').

5. Is the child currently using any of the following?

- a. **Apnea monitor?** Record YES ('Y') or NO ('N').
- b. **Oxygen?** Record YES ('Y') or NO ('N').
- c. **Ventilator/CPAP?** Record YES ('Y') or NO ('N').
- d. **Gastrostomy tube and/or tube feeding?** Record YES ('Y') or NO ('N').
- e. **Tracheostomy?** Record YES ('Y') or NO ('N').
- f. **Pulse Oximeter?** Record YES ('Y') or NO ('N').

6. Oral Motor Skills (*choose one*)

Record '1', '2', '3', or '4' in the column to the right according to the following:

- 1= Independently feeds self most foods/liquids by mouth
- 2=Dependent oral feeding: all p.o., but requires more than occasional assistance
- 3=Limited oral feeding (requires some food via alternate route; specify below)
- 4=No oral feeding

If '3' or '4' is indicated for question 6 (Oral Motor Skills) answer YES 'Y' or NO 'N' to 6a and 6b.

6a. Tube (NG/ND, G-tube/button, other enteral): Record YES ('Y') or NO ('N').

6b. TPN: Record YES ('Y') or NO ('N').

7. Feeding behaviors/behavioral difficulties (answer YES 'Y' or NO 'N' to 7a-c)

- a. **Resists/refuses some/all food by mouth (due to oral aversion):** Record YES ('Y') or NO ('N').
- b. **Difficulty with swallowing food (at mouth or throat level due to dysphagia):**
Record YES ('Y') or NO ('N').
- c. **Documented aspiration (food down windpipe):** Record YES ('Y') or NO ('N').

8. High calorie supplements: Record YES ('Y') or NO ('N').

9. Oral diet texture: When asking this question series, prompt the caregiver to think of the child's general diet and what the child is able to tolerate. Answer YES 'Y' or NO 'N' to 9a-d. More than one 'Y' may be applicable.

a. Thin liquids: Record YES ('Y') or NO ('N'). For example, juice, water, milk, and formula.

b. Thickened liquids for dysphagia: Record YES ('Y') or NO ('N'). For example, this includes liquids that are thickened with cereal, xanthan gum, or modified corn starch (i.e., Simply Thick or Thick It). The intent of the 'Thickened liquids' question is for swallowing difficulties. It is intended to capture infants whose feeds are being thickened due to concerns of dysphagia but not gastroesophageal reflux disease (GERD). If a child has foods thickened for reflux, then this question should be coded NO

c. Soft solids (baby food, pureed food): Record YES ('Y') or NO ('N'). This question is intended to capture children who still require pureed texture of feedings rather than table foods.

d. Table food (requiring chewing): Record YES ('Y') or NO ('N').

For children with NO restrictions on the food they eat (i.e., those that tolerate any texture or liquid), code as follows:

- a. **Thin liquids – NO**, given they are not limited to just thin liquids
- b. **Thickened liquids for dysphagia – NO**, given they don't have to thicken liquids as an accommodation
- c. **Soft solids – NO**, given they don't need to have foods softened as an accommodation.
- d. **Table food - YES**

10. Does your child use any of the following equipment or has any been ordered?

Record YES if the child has any of the following equipment. This includes equipment that has been ordered for child but has not yet been received or equipment that has been received but not yet used. The purpose of the question is to get at the degree of dysfunction.

a. Adapted stroller/wheelchair?

b. Braces/orthotics?

This includes braces, splints, or other orthotics (e.g. AFOs, or ankle foot orthotics).

c. Walker?

Record YES ('Y') for a walker that has been prescribed for physical therapy and orthopedic prescriptions (not meant to be the "walker" people buy in the store).

- d. **Stander?**
- e. **Corner chairs or tumbler form?**

11. Has the child had any operations since discharge to home or chronic care facility?

Record YES ('Y') or record NO ('N'). Exclude circumcisions.

If YES, has the child had:

For a - m below answer YES ('Y') or NO ('N') to each of the following.

- a. **Tympanostomy (PE or ear) tubes placed?**
- b. **Tracheostomy (placed or removed)?**
Record YES for placement or removal.
- c. **Eye surgery?**
 - c1. **If YES, indicate reason for eye surgery?**
Record '1' if strabismus (extropia, exophoria, esotropia, esophoria)
Record '2' if cataract
Record '3' if Retinopathy of Prematurity (ROP)
Record '4' if other reason for surgery and specify
- d. **Hernia surgery?**
- e. **Gastrostomy tube placed?**
Record YES ('Y') for placement or removal.
- f. **Fundoplication (Nissen)?**
Record YES ('Y') if fundoplication was used.
- g. **Shunt for hydrocephalus?**
Record YES ('Y') if shunt was placed or revised.
- h. **Reanastomosis of large or small intestine?**
- i. **Stricture repair/lysis of adhesions?**
- j. **Bowel lengthening surgery?**
 - J1. Specify type (i.e., STEP, Bianchi)**
- k. **Other bowel surgery (specify)?**
- l. **Bronchoscopy?**
- m. **Other (specify)?**
Specify any other operations other than those listed above that the child had.

10.1.3 Section B. Form Completion

1. Where was interview conducted:

Record '1' if interview was conducted at the clinic, '2' if at the child's home, '3' if by telephone, '4' in a hospital or chronic care facility, or '9' if another setting.

2. Date when Medical History obtained:

Record the date when the Medical History information was obtained.

3. Initials of person administering Medical History Form:

Record the initials of person administering the Medical History Form. Record the first, middle, and last initial.

10.2 Readmission Form (NF04A) (rev 4/1/2011)

This form should be completed by the follow-up nurse, practitioner or designee using the best available information. If the medical chart is available, this information should be used along with history reported from the caretaker. This form is to be completed for readmissions to any hospital since discharge to home or chronic care **that required at least one overnight stay**.

The interview with the caretaker should be conducted in person, if possible. If this is not possible, a telephone interview may be conducted.

The Generic Data Base Study (GDB) includes information from date of admission to initial transfer > 7 days/discharge. The 22-26 month follow-up should include all illnesses, procedures, surgeries and follow-up needs following the **initial** transfer/discharge. There have been some questions about the use of the term "at-home" as some children have not been discharged out of the hospital or remain in long-term care facilities. When answering questions on the NF04 and NF04A consider the time period after initial transfer/discharge from the NICU.

10.2.1 Heading

Information for the heading should be obtained from the **Base Form (NF00)**. If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the Base Form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

10.2.2 Section A. Hospitalizations

This form should be completed **ONLY** for children that have been re-hospitalized, **at least one overnight stay**, since discharge to home or to chronic care.

1. Date of discharge to home or chronic care:

Record the date of discharge to home or to chronic care. This question is meant to orient the interviewer and caregiver to hospitalizations that occur after this date.

2. Date of first birthday:

Record the date of the first birthday. (This refers to uncorrected age.) This question is meant to orient the interviewer and caregiver to whether hospitalizations occurred before or after this date which will be helpful for answering question A4 (Time period).

3. Readmission:

Record the readmission number for readmissions to any hospital since discharge to home or chronic care that required at least one overnight stay. If transferred from the initial Network center to another hospital before discharge home, consider the time interval since the child first went home.

4. Time Period:

For each readmission, record whether the readmission occurred prior to or on the first birthday (1) or after the first birthday (2).

5. Primary Cause:

Record the primary cause of the readmission. More than one primary codes may be used per rehospitalization.

'1'=Respiratory

Respiratory disease includes bronchiolitis, reactive airway disease.

'2'=Central Nervous System

CNS includes seizures, shunt malfunction.

'3'=Surgery

Surgery includes tracheostomy, gastrostomy, tympanostomy, hernias, etc.

'4'=Infection

Infection includes sepsis, fever, diarrhea and dehydration, shunt infection, and meningitis, pneumonia, Upper respiratory infection (URI)/Otitis, Respiratory syncytial virus (RSV).

'5'=Growth and Nutrition

This includes poor growth, failure to thrive.

'6'=Environmental

This category includes accidental ingestion of toxic or potentially toxic substances, neglect, abuse.

'7' =Other. Specify _____

If causes other than those listed in '1' through '14' contributed to rehospitalization, specify those conditions.

'8'=Apnea/Apparent life-threatening event (ALTE) brief resolved unexplained event (BRUE)

Apnea refers to events associated with cessation of breathing and/or frequent apnea monitor alarms.

Formerly referred to as ALTE, the American Academy of Pediatrics recommended transition to terminology of BRUE, which is described as a sudden episode having ≥ 1 of cyanosis or pallor, absent or decreased breathing, marked change in tone, or altered level of responsiveness (Tieder JS, et al. *Pediatrics* 2016; 137: e1-e32).

'9'=Reflux

Admission associated with gastroesophageal reflux disorder (GERD). Symptoms include spitting up, vomiting, discomfort with feeding, arching, crying and /or choking.

'11'=Trauma (Accidental)

Accidental injuries including fractures, head injury, burns and laceration requiring suturing.

'12' = Trauma (Non-accidental) Non-accidental includes trauma resulting from abuse, neglect, etc.

'13' = Vomiting/diarrhea/dehydration

'14' = Sleep Study

6. Length of hospital stay

For each readmission, record whether the length of hospital stay was '1' One week or less, or '2' More than one week.

7. Did the child spend any time in the ICU?

For each readmission, record whether or not the child spent any time in the intensive care unit (ICU) by circling the following: 'Y' YES, 'N' NO, or 'DK' Don't Know.

10.2.3 Section B. Form Completion

1. Where was interview conducted:

Record '1' if interview was conducted at the clinic, '2' if at the child's home, '3' if by telephone, '4' in a hospital or chronic care facility, or '9' if another setting.

2. Date when Readmission information obtained:

Record the date when the readmission information was obtained.

3. Initials of person administering the Readmission Form:

Record the initials of the person administering the Readmission Form. Record the first, middle, and last initial.

10.3 Examination Form (NF05) (rev 2022/12/14)

Portions of this form can be completed by study personnel including the: Study Coordinator, the Study Neuroexaminer, an experienced MD, Nurse Practitioner or the Study Bayley Examiner, usually a psychologist, psychometrist, or other certified developmental specialist. It is helpful to be in contact with the child's primary physician before and after the visit. If the child has any medical problems, make sure that the caretaker gets the necessary referrals and let her know that the primary physician will be contacted. Each center should have a standard summary report that includes the results of the medical exam and the Bayley Scores to give to the primary physician.

10.3.1 Heading

Information for the heading should be obtained from the **Base Form (NF00)**. If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the Base Form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

10.3.2 Section A - PHYSICAL EXAMINATION

1. Weight:

Child should be weighed naked. Record weight to the nearest hundredth of a kilogram.

2. Recumbent length:

Recumbent length should be obtained using Pediatric length board. Record the mean of three measurements to the nearest quarter of centimeters.

3. Occipital-frontal circumference:

Record the largest of three measurements in centimeters to the nearest quarter of a centimeter.

10.3.3 Section B - NEUROLOGIC EXAMINATION

The neurologic examination should be performed by a ***trained professional*** who has maintained his/her annual NRN neurologic exam certification.

1. Eye

Record separately for each eye, a-e; Record '1' Yes, if in the examiner's judgment the child has strabismus, nystagmus, or roving eye movements. Record '2' No, if the examiner's judgment the child does not have strabismus, nystagmus, or roving eye movements. Record '3' Suspect, if the findings are intermittent and not consistent for the eye in question. Record '4' if findings are untestable.

a. Strabismus (any kind):

Record Yes '1', if child has intermittent or persistent esotropia (in-turning) or exotropia (out-turning) resulting in ocular malalignment, esophoria or exophoria.

Assess the child's ability to move his eyes to the right, left, up, and down by moving a light from side to side, up and down in the midline, and diagonally across the bridge of the nose. The eyes should move in a smooth and unrestricted manner. Check for any of the following abnormal eye movements and record Yes '1'.

1. Esotropia or esophoria on the left: Left eye appears to deviate internally.
2. Esotropia or esophoria on the right: Right eye appears to deviate internally.
3. Alternating esotropia or esophoria: Child can fix with either eye, but the opposite eye deviates.
4. Exotropia or exophoria on the left: Left eye appears to deviate externally.
5. Exotropia or exophoria on the right: Right eye appears to deviate externally.
6. Alternating exotropia or exophoria: Child can fix with either eye but the opposite eye deviates.

b. Nystagmus

Persistent involuntary oscillation of eyes in any/all fields of gaze

c. Roving Eye Movements

Record Yes '1' for Random eye movements - appears unable to fix/follow.

d. Tracks 180° (Record as 1, 2 or 4)

Have the child follow a bright toy or light across 180° of the field of vision. Record YES '1' if child is successful in following 180° horizontally, else record NO '2' or '4' if the child is untestable.

e. Vision:

Record separately for each eye.

The examiner should question the caretaker about the child's vision. If the child is prescribed glasses or contact lenses, the examiner should ask the caretaker how well the child sees with the glasses or contact lenses. If more than one applies, score the highest.

Record '1' if vision appears normal.

Record '2' if child wears or was prescribed corrective lenses.

Record '3' if child has another abnormality affecting that eye other than a condition requiring corrective lenses, but the impairment is not severe enough for the child to be considered blind in that eye.

Record '4' if child is considered to be blind but has some functional vision. For example, a condition that requires the child to have an object held directly in front of his/her face in order to see it, would be considered blind with some functional vision. This is consistent with a refraction definition of < 20-200 (legally blind).

Record '5' if child has no useful vision in that eye. This is consistent with a refraction definition of < 20-200 (legally blind).

2. Hearing

a. Was a Follow-up audiologic assessment completed since initial discharge to home?

Record YES ('Y') or NO ('N'). If follow-up audiologic assessment since initial discharge home was completed, determine if the child is normal or abnormal. Information obtained by history that hearing assessment was done and that the child passed or failed is acceptable. However, it is preferable to have documentation on this information or have copy of hearing assessment. **This does not include the routine hearing screen done at time of discharge with Automated Auditory Brainstem Response (AABR) or Otoacoustic Emissions (OAE) or a re-screen with OAE or AABR.**

1. If NO, is consult pending for assessment?

Record YES ('Y') or NO ('N').

If YES, follow-up audiologic assessment completed, using a Visual Reinforcement Audiometry (VRA), Auditory Brainstem Response (ABR) or other type of hearing test specify the results of testing.

For the (a.) Right ear and (b.) Left ear, , if tested separately, or if not, (c.) Sound Field only , record '1' if the child passed, record '2' if the child failed the test, record '3' if equivocal or record '4' if unknown.

b. Hearing impaired (based on observation +/- history):

Record '1' if no apparent functional impairment **+/- amplification**.

Record '2' if impairment **+/- amplification**.

Where impairment is defined as a loss of organ function.

No functional Impairment: In many children with mild to moderate hearing loss, the loss is easily compensated with amplification and they are able to follow verbal directions given during the assessment.

Functional Impairment: Where impairment is defined as permanent hearing loss that does not permit the child to understand the directions of the examiner and communicate despite amplification. Children are more likely to have severe to profound hearing loss or auditory neuropathy.

A judgment call will be necessary on the part of the examiner to determine whether the child fails to respond to verbal directions because of behavioral problems, cognitive impairment, or due to hearing impairment.

1) Hearing aid requirement:

Based on formal testing. Record '0' if none, Record '1' if right ear only, Record '2' if left ear only and Record '3' if both ears.

2) Cochlear implant requirement:

Record '0' if none, Record '1' if right ear only, Record '2' if left ear only and Record '3' if both ears.

4. Nature of motor involvement with child in any comfortable position

a. Observed abnormal movements?

Record YES or NO. The child can be observed in either a quiet but awake state or with goal-directed movements. Goal-directed movements include a child who is crying or who is reaching for a toy or other object.

If YES abnormal,

1. Short-jerky?

Record YES or NO. Short-jerky (chorea) movements are movements with a fast and slow component are non-rhythmical and usually are proximal. If this is yes, then should consider final neuro diagnosis of dyskinesia/dystonia in 9d.

2. Slow-writhing?

Record YES or NO. Slow-writhing (athetosis) movements are distal distorted, twisted and low and have a rotational component. If this is yes, then should consider final neuro diagnosis of dyskinesia/dystonia in 9d.

3. Tremor?

Record YES or NO. Tremors are fast, rhythmical movements. They are distal and they are fine distal movement in opposition to clonus.

4. Ataxia?

Record YES or NO. Ataxia is defined as poor coordination of movement; gait may be wide based, uncoordinated and unsteady. There may be poor coordination of the upper extremities. If this is yes, and child found to have hypotonia in 4b below, then should consider final neuro diagnosis of hypotonia with +ataxia in 9d.

b. Passive Muscle Tone

Child should be awake for this assessment. Muscle tone will be assessed by passive resistance to externally imposed movement (passive stretch) by the examiner.

Record degree of muscle tone for the following: Record as 1-6, using the following codes: '1' Normal, '2' Suspect Increased, '3' Definite Increased, '4' Suspect Decreased, '5' Definite Decreased, '6' Varying tone (see below).

Varying tone indicates that tone fluctuates with "state," varying from normal or low tone to extreme hypertonia. The dystonia found in extrapyramidal CP is typically increased with activity, tension and emotions, but decreased with distraction, sleep, relaxation. In distinction to the increased tone of spastic CP, it is also velocity-independent (i.e., no clasp-knife phenomenon, no difference between slow and rapid movement) and lead-pipe in character (i.e., steady resistance to movement of given joint in either direction). It usually occurs in association with abnormal movements (choreoathetosis) in extrapyramidal CP.

2) Upper extremity passive muscle tone, (right and left sides)

Scarf sign or scarf maneuver should be symmetrical, and the opposite hand should very easily reach the acromion on the opposite shoulder without resistance. There should be minimal resistance to supination and pronation and range of motion at the elbow and at the wrist should be complete. This is normal. If during scarf sign there is resistance and the elbow gets to midline or just past midline this is recorded as suspect.

If there is increased resistance and elbow does not reach midline, this is recorded as definite increased.

Some guidance (i.e., HINE exam) would classify the scarf sign as decreased tone if the examiner can pull the elbow all the way over to the contralateral anterior axillary line, and similarly would classify no resistance with extension of arm above head as decreased tone.

3) Lower extremity passive muscle tone, (right and left sides)

Record '1' if YES, within normal range, record '2' if suspect increased, record '3' if definite increased, record '4' if suspect decreased, record '5' if definite decreased and record '6' if varying tone.

The heel-to-ear maneuver: While child is lying flat lift the leg (extended at the knee) as far as possible towards the head while keeping the pelvis flat on the table.

Abductor Angle: While the child is lying flat, legs fully extended at the knee are slowly abducted simultaneously.

Popliteal angle: While the child is lying flat, flex the thigh at the hip to with knee-chest position, lift the lower segment of the legs and observe the angle formed with the thigh while maintaining the pelvis flat on the table.

Ankle dorsiflexion (slow maneuver): While the examiner's hand is on the knee to keep leg straight, the foot is flexed with light pressure.

Guidelines for the normal and abnormal angles for the lower extremities expected at this age are shown in the Table 10.1 below. . It is acknowledged that classifications overlap by one degree; it is expected that examiners will attempt to make their best estimate to categorize findings according to the ranges shown in the table.

Angles are to be taken at point of resistance (not furthest point).

- a) "Hip: Abduction and Knee", "Use the assessment in Table 10.1.
- b) For coding the Ankle, use the Ankle Dorsiflexion assessment in Table 10.1
- c) Knees: Popliteal use the assessment in Table 10.1
- d) Hips: Heel Ear use the assessment in Table 10.1

Table 10.1 Angle Classification of lower extremities.

Classification	Hip: Heel Ear	Hip: Abduction	Knee: Popliteal	Ankle: Dorsiflexion
1 = Normal	120° - 160°	120° - 160°	120° - 160°	40° - 70°
2 = Suspect Increased	90° - 120°	90° - 120°	90° - 120°	70° - 90°
3 = Definite Increased	< 90°	< 90°	< 90°	> 90°
4 = Suspect Decreased	160° - 170°	160° - 170°	160° - 170°	20° - 40°
5 = Definite Decreased	170° - 180°	170° - 180°	170° - 180°	< 20°
6 = Varying				

5. Is there scissoring of the legs on vertical suspension (see figure 10.1, below)

Record YES ('Y') if there is scissoring on vertical suspension of the legs

Figure 10.1 Scissoring of the legs



6. Gross Motor Function Level

Describe current gross motor function, refer to algorithm of the NF05A form.

The same NF05 form will be used for wrapping up 18-22-month visits and rolling out the 22-26-month visits, which will facilitate a smooth transition to the new follow-up window for the examiners, keyers, and analysts. Once all the 18-22-month visits have been completed, the 18-22-month GMFCS descriptions will be removed from the NF05 form. Complete Question 6 for all children. Examiners check one level (to the left), according to the child's age (18 months – 21 months 29 days OR 22-26 months). Keyers key the corresponding EDC Code listed to the right.

As noted in the level descriptions below, assessments related to “sitting” should be done by observation sitting either on the floor or exam table (legs/feet should not hang over

edge). Consistent “W sitting” is an adaptive mechanism used by children with hypertonicity of the lower extremities to maintain sitting balance.

Complete the following for children 18 months to 21 months 29 days.

<u>18 Months – 21 Months 29 Days</u>	<u>EDC Code</u>
___ Normal (Walks 10 steps independently and fluently)	=1
___ Possible Level I (Walks 10 steps independently but not fluently; child exhibits toe walking or asymmetric walking)	=2
___ Level I (Moves in/out of sitting and floor-sit with both hands free to manipulate objects. Infants creep or crawl on hands and knees, pull to stand and take steps holding onto furniture. Infants walk between 18 months and 2 years without holding on)	=3
___ Level II (Maintains floor sitting but may need to use hands for support to maintain balance. Creeps on stomach or crawls on hands and knees. May pull to stand and take steps holding onto furniture)	=4
___ Level III (Maintains floor sitting when the low back is supported. Rolls and creeps forward on stomach)	=5
___ Level IV (Has head control but trunk support is required for floor sitting. Can roll to supine and may roll to prone)	=6
___ Level V (Unable to maintain anti-gravity head and trunk postures in prone or sitting; little or no voluntary movement)	=7

Complete the following for children 22 – 26 months. The child must be able to accomplish each motor task listed for a level, with documentation either by direct observation or using best clinical judgment.

<u>22 – 26 Months</u>	<u>EDC Code</u>
___ Level “0” (Walks independently, normal and fluent gait)	=1
___ Level I (Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk 10 steps independently, with hands free, but with some gait abnormalities – includes persistent and predominant toe walking, asymmetric walking, wide based gait with coordination or ataxic gait.)	=3
___ Level II (Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees with reciprocal leg movement. Infants may pull to stand and take steps holding on to furniture.)	=4
___ Level III (Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs or may crawl with or without reciprocal leg movements.)	=5
___ Level IV (Infants have head control, but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.)	=6

- ___ **Level V** (Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.) =7

Also, complete question 6a for children > 24 months

<u>>24 Months</u>	<u>EDC Code</u>
___ Level "0" (Walks independently, normal and fluent gait)	=1
___ Level I (Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.) Note: Palisano does not consider AF0s or SMOs as assistive mobility devices, but only external assistive devices such as walkers or gait trainers.	=3
___ Level II (Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.)	=4
___ Level III (Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.)	=5
___ Level IV (Children floor sit when placed but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.	=6
___ Level V (Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.)	=7

Description of Current Gross Motor Function

The Gross Motor Function Classification system developed by Palisano et al. focuses on children's functional achievements rather than on their limitations. The emphasis is on the child's ordinary performance (not best capacity) in the home or community setting and should not include judgments about prognosis. Thus, as a general principle, an attempt should be made to determine what level

best represents the child's present abilities and limitations in gross motor function.

The descriptions of the 5 levels of function are broad and it may not be possible to describe the exact function of every child within each level. For example, an infant with hemiplegia, who is unable to crawl on hands and knees, but otherwise fits the description of level I (e.g., can sit with both hands free, can creep (commando crawl) or bottom shuffle and pull to stand), would be classified accordingly as being in level I. In contrast, another child with hemisindrome who can sit but needs to use hands to maintain floor sitting and can creep and pull to stand would be classified as level II. The distinction between these two examples is the ability of the former child to sit with both hands free. The scale is ordinal, with no intent that the distance between levels be considered equal. The functional abilities and limitations for each age interval are intended to serve as guidelines and are not comprehensive and are not norms. Distinctions between levels of gross motor function are based on functional limitations, the need for assistive technology including mobility devices (such as walkers and wheeled mobility), and to a much lesser extent the quality of movements. Level I represents the continuum of children with neuromotor impairments whose functional limitations are less than what is typically associated with cerebral palsy, or who have CP of minimal severity (such as "functional" children with hemisindromes). The distinction between levels I and II, therefore, are not as pronounced as the distinctions between other levels, particularly for infants who are 1 to 2 years of age. Assistive mobility devices which may be considered in distinguishing between levels II and III in older children are generally not used in children who are under 2 years of age.

To determine the level of gross motor function of the infant, follow the Palisano et al.¹ algorithm shown on the Gross Motor Function Work Sheet (Form NF05A). The algorithm starts with normal function and progresses to increasing levels of functional limitations.

The gross motor function of children who cannot perform the functions of a particular level will likely be classified *below* that level. Select the level that *most closely* resembles your judgment of the child's gross motor function. Record the level on Form NF05 - Section B. Question 6 (*Gross Motor Function Level*), using the appropriate code. The work sheet (Form NF05A) does not have to be entered into the data base.

7. Hand Preference

Record '1' if no preference
Record '2' if exaggerated right
Record '3' if exaggerated left
Record '4' if untestable

If the child is presented an object on his or her right side and s/he grabs it with his or her left hand, this is considered "exaggerated left. An "exaggerated right"

¹ Palisano et al, *Med Child Neurol*, 1997;39:214-233. Algorithm adapted from above by Rosenbaum P and Saigal S for TIPP Trial.

is when the child is presented an object on the left side and s/he grabs it with his or her right hand.

10.3.4 Section C. REFLEXES / MOTOR SKILLS / DIAGNOSES

For postural protective reactions to be classified as abnormal, any of the anterior, lateral, or parachute reflexes must be abnormal. Abnormal postural reactions would qualify this category as abnormal. Normal in these categories means that all reflexes and reactions are normal.

1. Protective reactions (anterior, lateral and parachute)

Record '1' if present and symmetric

Record '2' if present and asymmetric

Record '3' if not present.

2. Limb movement for both

a. Upper limbs and

b. Lower limbs

Record '1' if more symmetrical

Record '2' if more on right

Record '3' if more on left

For questions C.3-5, use the following codes:

Record '1' if reflexes are normal (1 to 3+)

Record '2' if reflexes are absent (0)

Record '3' if reflexes are hyperactive (4+)

Note: to define a 4+, there must be persistence of clonus, diffusion of reflex, or increased reflexogenic zone.

3. Deep tendon reflexes, for both right and left upper extremities

4. Deep tendon reflexes, for both right and left knees

5. Deep tendon reflexes, for both right and left ankles

6. Ankle clonus

Clonus is an elicited movement resulting in short, rhythmic, jerky distal movements. Abnormal clonus would be 5 or more consecutive jerks

Record '1', if None (≤ 4 beats)

Record '2', if Present (> 4 beats)

Record '3', if Sustained

7. Plantar reflexes

Record '1', for the flexor plantar response

Record '2', for the extensor plantar response

Record '3', for spontaneous extension \pm fanning

Record '4', for inconsistent results

Record '5' if absent

8. Functional gross motor skills

a) Axis-head and neck:

Record '1' if normal head control. Head remains midline and stable in every plane.

Record '2' if abnormal but can hold head up for extended period of time (≥ 5 min.). In this scale, the child is able to achieve midline position when upright but cannot maintain position when planes are shifted.

Record '3' if poor head control but can hold head up for short period of time. Code this when the child can achieve midline position but cannot maintain midline position even when the body is kept in an upright position.

Record '4' if no obvious head control. Code this when the child cannot achieve any head control and cannot maintain it at all in the midline position.

b) Axis-trunk:

This should be evaluated with child sitting on a stool or chair. It is to be performed with child seated with feet on floor and no back support.

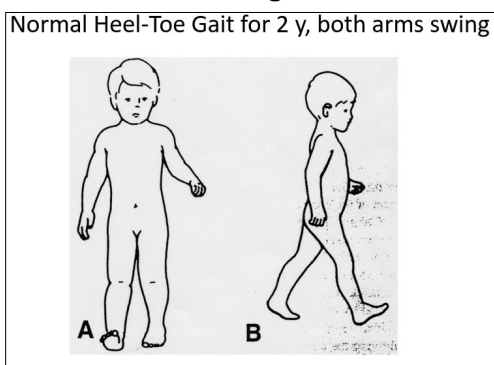
Record '1' if child has no apparent problem.

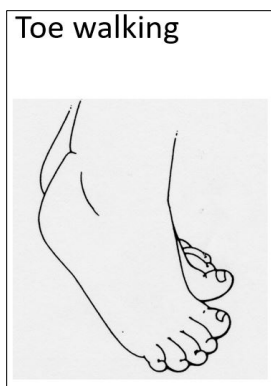
Record '2' if child can sit unsupported but less secure and stable than a normal child of same age.

Record '3' if child cannot be left in sitting position unless self-supported. Sits tripod (uses hand and/or forearms for support).

Record '4' if severe impairment as evidenced by difficulty to place or maintain in sitting position.

c) Lower limb function-gait:





Record '1' if no significant problem with gait; Walks fluently (heel strike followed by toe strike, i.e., no toe-walking, and no asymmetric or clumsy walking) for > 10 steps.

Note: If lower limb function-gait is coded as 1 then the Gross Motor Function Level should also be coded as 1 (Normal, i.e., Level 0). -

Record '2' if gait functional but Non-fluent walking (toe-walking, asymmetric or clumsy walking) for > 10 steps. No assistive device required. An "assistive device" includes "walkers, ankle-foot orthoses (AFO's), or hand(s) held. Cruising is the equivalent of use of an assistive device." This corresponds to Level I (code 2 for GMFCS)

Record '3' if gait functional, Non-fluent walking and requires assistive device (toe-walking, asymmetric or clumsy walking) for > 10 steps and requires assistive device. An "assistive device" includes "walkers, ankle-foot orthoses (AFO's), or hand(s) held. Cruising is the equivalent of use of an assistive device." This corresponds to Level I (code 2 for GMFCS)

Record Code '4' if no independent walking even with device or hand(s) held.

d) Upper limb function:

Record '1' if no apparent problem with bimanual tasks. This means that the child is able to manipulate small toys and small objects with both hands and transfer from one hand to the other with both hands in midline position.

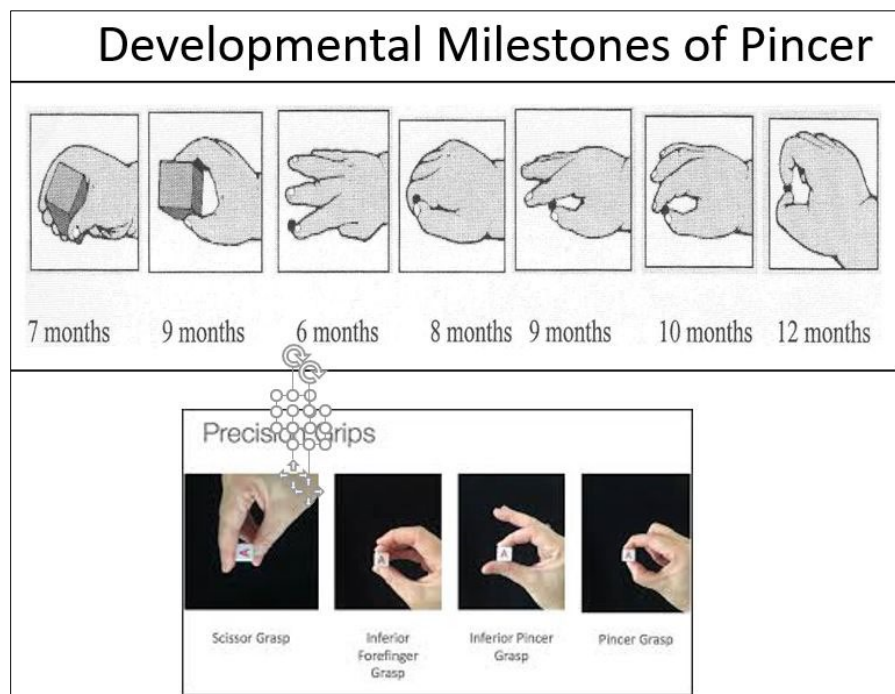
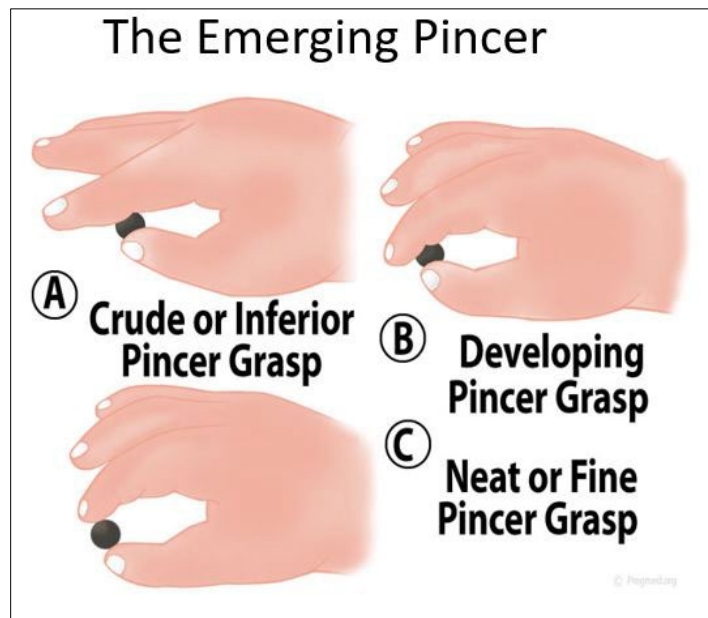
Record '2' if some difficulty using both hands together. Code this if the child is able to perform the above task but with a typical variation with limitation and difficulty in the midline position on bimanual transfer or freely using both hands easily to transfer.

Record '3' if no functional bimanual task.

e) Hand function for 1) Right and 2) Left

Optimally assessed with child sitting comfortably with hands free at a table at waist-level. A small item such as a Cheerio should be presented to child one at a time on the table, or on another flat, firm surface.

A consistent raking grasp alone (unilaterally or bilaterally) is considered Suspect if the examiner feels the child has displayed best effort



Refined pincer grasp (record "1")
Offer 1 Cheerio at a time

NOTE: Surface should be positioned LOWER (or child higher) than shown in this image!



Pick up with distal thumb and index finger

Rake grasp (record "3")



More than finger-thumb grasp; objects raked into palm with other fingers

Record '1' if fine pincer grasp. Fine pincer grasp would be manifested by the child picking up a small item like a Cheerio with the tip of his index finger and thumb.

Record '2' for a Finger-Thumb grasp

Record '3' if More than one finger-thumb (rake) grasp

Record '4' if tries but unable to grasp

Record '5' if he or she does not attempt to grasp

Record '6' if refusal

Record '7' if you, the interviewer, cannot assess. (e.g. the child has no fingers).

Cerebral palsy

For study purposes, the definition of cerebral palsy is based on the positive findings in both area 1 and 2: In addition, use algorithm in Figure 5.

- a) Definite abnormalities observed in the classical neuromotor exam – The classical neuromotor exam includes measurement of tone, deep tendon reflexes, coordination and movement (not including eye movements). Any one definite abnormality in the classical neuromotor exam, as defined, except for isolated low tone (hypotonia) or toe walking without tight ankles is sufficient.
- b) A delay in motor milestones with a disorder of motor function must be present. This may or may not be reflected in a Motor Quotient less than 70. In mild cases, there may be a subtle difference in hand functioning with a fine pincer grasp in one hand and a raking grasp in the other hand. Some disorder of motor function must be present. At least one abnormality must be identified in Question 8 in a-e.
- c) Aberrations in primitive reflexes and postural reactions may be present.

9. Neurological Diagnoses: Neurologic/Motor disorder

Note that **only one** of 9.a, 9.b, 9.c, or 9.d should be selected.

The following edits are in place in the EDC for question C9:

If C.9.a is YES (or a keyed missing code) then no response is allowed for C.9.b, C.9.c, or C.9.d

If C.9.a is NO then a response is expected for C.9.b

If C.9.a is NO and C.9.b is YES (or a keyed missing code) then no response is allowed for C.9.c or C.9.d

If C.9.a is NO and C.9.b is NO and there is a response entered for C.9.c (1, 2, or 3) then no response is allowed for C.9.d

If C.9.a is NO and C.9.b is NO and there is a response entered for C.9.d (1 through 9) then no response is allowed for C.9.c

a) Is the neurological exam Normal?

Record YES ('Y') if no abnormality is observed at the examination. Otherwise, record NO ('N').

If YES (Neurologic exam is normal), skip to question C10 (*Does the child have CP?*) and code NO.

If NO, go to C.9.b

- b) **Is the neurologic exam SUSPECT** (suspect or definite increased or decreased tone or isolated abnormal deep tendon reflexes [absent or 4+] with no functional impairment)? Note that abnormal or suspect findings on pincer grasp alone will not be included in “Suspect” for the purposes of the Follow Up Study.

A consistent raking grasp alone (unilaterally or bilaterally) is considered Suspect if the examiner feels the child has displayed best effort

For children who are 18-22 months corrected age, “possible Level 1” should be considered **functional impairment**, thus would *not* be included in the “Suspect” category.

Record YES (‘Y’) or NO (‘N’).

If YES, skip to question C10 (*Does the child have CP?*) and code NO.

If NO, go to either C.9.c or C.9.d

- c) **If Neuro Abnormal (other than cerebral palsy). Finding is associated with mild, moderate or severe gross motor functional impairment:** Choose only one code (code 1 or 3 below) and enter code to the space to the right. Then, skip to question C10 (*Does the child have CP?*) and code NO.

Because a primary purpose of the NRN neurologic exam is to assess *functional* status, those without definite tone or reflex abnormalities but with definite gross motor functional impairment will be classified in this category.

1=Hypotonia

Record if there is definite decreased tone in the trunk or extremities, often associated with joint laxity and wide angles. Isolated hypotonia with normal reflexes and without ataxia is not cerebral palsy.

3=Other diagnosis other than cerebral palsy or generalized hypotonia

If coded as Other, describe:

Persistent and predominant toe walking with normal angles and tone is classified as ‘Other’ as this would be consistent with functional impairment per NRN FU study group discussions.

- d) **If Neuro ABNORMAL (CEREBRAL PALSY), and child meets study definition of cerebral palsy on page 10-23 and Decision Tree, Figure 5. Choose only one and enter code in the space to the right.**

1=Spastic diplegia

Record if there is increased tone with muscle weakness in both lower extremities. Tight Achilles (90 degrees or greater) secondary to increased tone on full leg extension with toe walking would be classified as mild diplegia (cerebral palsy), Children may have scissoring,

hyperreflexia and ankle clonus. Infants have more subtle involvement with upper extremities, including gross and/or fine motor involvement.

2=Spastic hemiplegia - right

Record if there is increased tone with muscle weakness in the right upper extremity and the right lower extremity. Infants may have an abnormal gait. The diagnosis is supported by either subtle or exaggerated hand preference.

3=Spastic hemiplegia - left

Record if there is increased tone with muscle weakness in the left upper extremity and the left lower extremity. Infants may have an abnormal gait. The diagnosis is supported by either subtle or exaggerated hand preference.

4=Spastic quadriplegia

Record if there is significantly increased tone in both upper and lower extremities and there may be associated muscle weakness in all four extremities.

6= Dyskinesia/dystonia with varying tone

Non-spastic or extrapyramidal CP is a hyperkinetic movement disorder characterized by involuntary, sustained, or intermittent muscles contractions that cause twisting and repetitive movements, abnormal postures, or both, causing difficulty in performing movements smoothly. If involuntary movements (as described above in 4a1-2 on page 10-12) are present, they should be coded in either 4a1 or 4a2 on NF05; and if variable tone indicative of dystonia (as described above in 4b on page 10-13) is present, then it should be coded as 6 on either 4b2 or 4b3 on NF05. Note the algorithm in Figure 5 includes both dystonic CP and choreoathetotic CP under the umbrella diagnosis of “dyskinetic CP,” though dystonia may be present without associated dyskinesia..

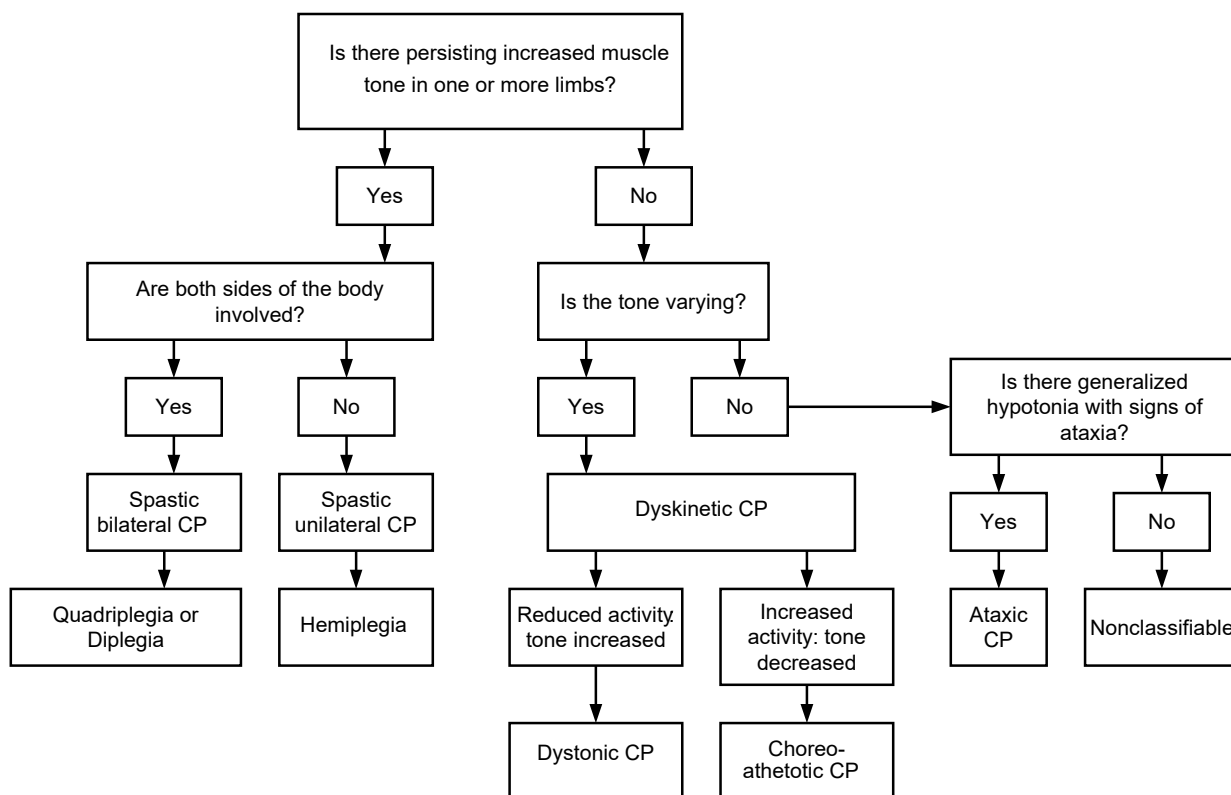
7=Hypotonic with ataxia

Ataxia is defined as poor coordination of movement; gait may be wide based, uncoordinated and unsteady. There may be poor coordination of the upper extremities. For this diagnosis, 4a4 should be coded Yes and at least one angle in 4b should be coded 4 or 5 (decreased tone). Hypotonia without ataxia is NOT cerebral palsy.

9=Mixed cerebral palsy

This includes a combination of spastic cerebral palsy with dystonia/dyskinesia. If mixed CP, identify 2 categories from answer codes 1-8 above that reflect findings in order of prominence.

Figure 5. Hierarchical Classification Tree of Cerebral Palsy Sub-Types:



10. Does this Child have Cerebral Palsy?

If YES (child has cerebral palsy), classification of cerebral palsy:

Record '1' mild cerebral palsy, if child is in GMF classification system a “Level 1” in Question 6, the Gross Motor Function Level.

Record '2' moderate cerebral palsy, if child is in GMF classification system a “Level 2” or “Level 3” in Question 6, the Gross Motor Function Level.

Record '3' severe cerebral palsy if child is in GMF classification system a “Level 4” or “Level 5” in Question 6, the Gross Motor Function Level.

11. Congenital and/or other abnormalities present?

Answer this question YES ('Y') if the child has congenital (i.e., Down syndrome) and/or acquired abnormalities (i.e., child abuse). Otherwise record NO ('N') — The examiner must make this judgment.

11a. If YES, enter birth defect codes from Appendix D or describe in free text field:

Include conditions that are identified before or after NICU discharge, such as congenital malformations, child abuse, trauma, secondary shunt

complications (e.g. shunt malfunction/infection), seizure disorders, hypoxic encephalopathy, post-natal illnesses resulting in brain injury, pediatric AIDS, Fetal Alcohol Syndrome, or facial palsy, vocal cord paralysis, or other problems.”

11b. If YES, does the abnormality affect neurodevelopmental assessment?

Answer this question YES ('Y') or NO ('N').

10.3.5 Section D - FORM COMPLETION

1. Where was exam completed:

Record '1' if interview was conducted at the clinic, '2' if at the child's home, '3' if at a clinic other than the follow-up clinic, '4' in a hospital or chronic care facility, or '9' if another setting.

2. Quality of the exam:

Record '1' if the overall exam was good, '2' if fair and '3' if poor

If Fair ('2') or Poor ('3'), factors affecting exam:

Record the primary factor that affected the quality of the exam (if exam was “fair” or “poor” in question 2 above):

'1' if child had an illness at time of exam (e.g., flu); '2' if an interpreter was not available for a child that spoke a language other than English; '3' if there were behavior problems; '4' if the child is severely developmentally delayed plus may have a sensory impairment (record a Bayley score of 49); '5' if the sensory impairment appears mild or moderately delayed for age; '6' if there is a sensory impairment, but child appears normal for age '9' if there was another factor affecting exam (record reason).

3. Date exam completed:

Record the date infant examination was completed.

4. Initials of person administering Infant Examination

Record the first middle, and last initials of the person giving the infant examination.

10.3.6 Certification for the Neurological Exam

Certification procedures are the following:

- Each site's primary neurologic exam trainer will submit a recording of themselves performing the exam (and score sheets) to NRN Gold Standards, Drs. Vohr and Hintz, every summer, score/key the exams included on the annual certification recording using the NF05C form), and attend an annual certification meeting in the fall, organized by the NICHD Program Scientist and the Follow Up chair. The site primary neurologic examiners will certify additional examiners (i.e., other site developmentalists) annually as per the deadline agreed to at the fall annual certification meeting by asking examiners to view/score the exams included on the annual certification recording and discussing their results with them using the corresponding Gold Standard NF05C score sheets made

available on the NRN website. The last exam on the annual certification recording is typically used as the additional examiners' inter-rater agreement exercise.

In addition, sites are encouraged to make their own recordings of controversial neurologic findings for central scoring by Drs. Vohr and Hintz and to share recordings of interesting neurologic findings for training and consultation purposes.

See the private gateway of the NRN website for a current listing of edit checks.

Chapter 11. CHILD BEHAVIOR CHECKLIST (CBCL)

11.1 Child Behavior Checklist

The Child Behavior Checklist [CBCL (ages 1.5-5 yrs.)] includes 99 items that describe specific kinds of behavioral, emotional, and social problems that characterize preschool children. Items are scored on syndrome scales designated as Emotionally Reactive; Anxious/ Depressed; Somatic Complaints; Withdrawn; Attention Problems; Aggressive Behavior, and Sleep Problems. Items are also scored on DSM-oriented scales designated as Affective Problems, Anxiety Problems, Pervasive Developmental Problems, Attention Deficit/Hyperactivity Problems, and Oppositional Defiant Problems. Estimated time to administer the CBCL is 10-15 minutes.

11.1.1 Procedural Guidelines

The following is a list of procedural and scoring guidelines.

1. Primary Caretaker

The primary caretaker should complete the CBCL prior to or at some point during the Follow-up visit. If the primary caretaker is not present, the coordinator should attempt to complete this interview by phone at a time separate from the Follow-up visit with the child.

3. Translation

The CBCL is available in a variety of different languages at <http://www.aseba.org>. If the caretaker's primary language is Spanish, the Spanish version should be completed by the caregiver. If the caregiver is having difficulty completing the CBCL and the interviewer is not fluent in the caretaker's language, an interpreter may be used to complete this interview.

4. Administration and Scoring

The CBCL will only be administered at the 22-26-month follow-up visit for infants less than or equal to 26 completed weeks GA (up to and including 26 6/7 weeks). For the purposes of this study, the CBCL should be completed by the primary caretaker using the blue CBCL paper form available from ASEBA (<http://www.aseba.org/>). The CBCL is designed to be self-administered so caregivers can complete the form themselves. The coordinator can administer the CBCL if the caregiver is having difficulty. In this situation, it is important that interviewers read questions verbatim and refrain from offering assistance (i.e., explaining the meaning of questions or interpreting questions). Centers will use the CBCL scoring software (ASEBA-PC v1.9.0) and summary scores will be recorded on the CBCL Summary Score Sheet (NF16) and transmitted to RTI.

If the child is low functioning/severely developmentally delayed, the CBCL should not be administered.

All 99 questions should be answered (pages 1-2). You do NOT need to complete the open-ended questions at the end of the CBCL (page 2) and you do NOT need to complete the Language Development Survey, located on pages 3-4 of the CBCL form. You may remove pages 3 and 4 and cross out the open-ended questions at the bottom of page 2 to avoid confusion.

The CBCL can be completed by the primary caregiver prior to the Follow-up visit. If this is done, it is optimal to send the CBCL form to the primary caregiver in advance and ask the family to bring the completed form to the Follow-up visit. The coordinator will need to review the completed form to make sure the 99 main questions were answered. In other words, make sure the caregiver did not accidentally skip a question. You may remove pages 3 and 4 and cross out the open-ended questions at the bottom of page 2 so that caregivers do not spend time completing unnecessary questions.

5. Preferred Order

The CBCL can be completed by the primary caregiver prior to the Follow-up visit or at any time during the Follow-up visit. It is recommended that the Bayley 4 be administered as early as possible in the visit so most likely the CBCL will be completed after that time.

11.1.2 Completing the CBCL Summary Scores Form (NF16) (7/12/2019)

This form should be completed for all children at the 22-26 month Follow-up visit who are less than or equal to 26 completed weeks GA (up to and including 26 6/7 weeks).

11.1.2.1 Section A. IDENTIFICATION

1. Date CBCL Administered

Record the date that the CBCL was administered in the MM/DD/YYYY format.

2. Relationship of respondent to child

Record the three-digit relationship code to the child on the line provided. (See Relationship Codes App B—if biological mother, code is 001)

3. Child's sex

Record "M" for Male, or "F" for Female

4. How was CBCL administered

Record "1" for Self-administered during visit, record "2" for Self-administered prior to/after visit, or "3" for Administered by clinic staff during visit, or "4" for Administered by clinic staff by phone.

5. Language CBCL was administered

Record "1" for English, "2" for Spanish, or "3" for Other. If Other specify on the line provided.

6. Initials of person completing Summary Score Sheet

Record the first, middle and last initials of the person completing this form.

11.1.2.2 Section B. SYNDROME SCALE SCORES

Complete the table for questions 1-3. Record the score for columns (a-g) **Emotionally Reactive, Anxious/Depressed, Somatic Complaints, Withdrawn, Sleep Problems, Attention Problems, and Aggressive Behavior.**

For percentile scores >97, record 98. For percentile scores ≤50, record 49.

1. Total Score

2. T Score
3. Percentile

11.1.2.3 Section C. INTERNALIZING, EXTERNALIZING, AND TOTAL PROBLEMS

Complete the table for questions 1-3. Record the score for columns (a-c) **Internalizing Problems, Externalizing Problems, and Total Problems.**

For percentile scores >97, record 98. For percentile scores ≤50, record 49.

1. Total Score
2. T Score
3. Percentile

11.1.2.4 Section D. DSM-ORIENTED SCALES

Complete the table for questions 1-3. Record the score for columns (a-e) **Depressive Problems, Anxiety Problems, Autism Spectrum Problems, Attention Deficit/Hyperactivity Problems, and Oppositional Defiant Problems.**

For percentile scores >97, record 98. For percentile scores ≤50, record 49.

1. Total Score
2. T Score
3. Percentile

Chapter 12. BAYLEY SCALES OF INFANT DEVELOPMENT

12.1 Bayley 4

The Bayley Scales of Infant and Toddler Development 4 (Bayley-4) will be administered at the 22-26-month visit. The Bayley-4 consists of three domains: Cognitive, Language and Motor. Estimated time to administer the Bayley-4 for this age level is 80 – 100 minutes, although administration may be faster with examiners who are very familiar with the Bayley 4 or may be somewhat longer with children with very advanced developmental skills. Pearson Assessments is responsible for technical support and distribution of the test materials and forms.

<https://www.pearsonassessments.com/store/usassessments/en/Store/Professional-Assessments/Cognition-%26-Neuro/Bayley-Scales-of-Infant-and-Toddler-Development-%7C-Fourth-Edition/p/100001996.html>

12.1.1 Reliability and Certification

Each NRN Bayley examiner must be certified annually. Examiner certification will be determined by the successful completion of a video of their administration demonstrating accurate administration and scoring the Bayley Scales on approximately 22-26-month-old children. NRN Gold Standard reviewers for this project (see list below) will review the certification videos and provide feedback.

NRN Gold Standard Bayley-4 Examiners

Katie Gustafson (katie.gustafson@duke.edu): Duke, Stanford, Cincinnati

Jean Lowe (JLowe@salud.unm.edu): New Mexico, Penn/CHOP, Utah, Emory

Vicki Watson (vwatson@wihri.org): Brown, Nationwide, Iowa, Alabama

Elizabeth Roth (Elizabeth.Roth@UHhospitals.org): Case Western, Rochester, Houston, Dallas

It is strongly preferred and recommended that a child within the study age window is used for the certification video, although children aged 18 to 30 months would be acceptable, if necessary to facilitate finding a child to video. *It is important that examiners demonstrate reliability with study age test items.* **Start point L or M should be used for certification, depending on age of child. If using an older out-of-study-age range child, begin at start point M. If using a younger out of study age range child, begin at correct start point (start point K for children 18-20 months)**

If an examiner needs to broaden the age range to facilitate finding a child to film, then the preference is to go slightly younger, particularly if using a term-born child. The children in the NRN cohort are more likely to be delayed than to be advanced, so submitting a video with a much older child is problematic given those items are rarely used in NRN network studies. Also, administering the earlier items with a much-older, typically developing children can be problematic because it increases the length of an

already very lengthy assessment and because children become quickly bored (and behavior can deteriorate) or they don't respond to items in the same way an appropriately aged child would. Seeing a child much outside of the study age window does not give a good representation of the NRN cohort and the typical patterns of responses/behaviors one would expect at 24 months.

A minimum of 85% reliability for administration *and* scoring is required per subscale in order to be certified on that subscale.

Examiners with very high administration and scoring reliability (90% or higher) on their first yearly video submission for all 5 subscales for TWO years in a row, may be approved for a two-year video review. Sole discretion for determining qualification for two-year video review resides with the Gold Standard examiners.

12.1.2 User Qualifications

University psychology departments can be helpful for identifying qualified psychologists to administer the Bayley-4. Contacting local school departments or Early Intervention programs to locate psychologists experienced in early childhood administration are other options. When considering whether a staff member has the appropriate training and experience to administer the Bayley-4 for the Follow-up visit, complete and submit the NRN Bayley-4 Examiner Qualifications Questionnaire to the NRN Bayley Gold Standard examiners prior to submitting a video for certification. This questionnaire collects information such as educational background, how the examiner was trained on the Bayley-4, experience in working with toddler age children, and experience administering the Bayley-4.

As stated in the User Responsibilities section of the Bayley-4 Manual on page 7:

““Because of the complexities of test administration, interpretation, and diagnosis, the Bayley-4 should **only be administered by examiners with graduate-level of professional training in the administration and interpretation of standardized clinical instruments**. Such training should consist of an overview of assessment principles, including establishing and maintaining rapport, eliciting optimum performance, following standardized administration procedures, understanding psychometric statistics, scoring and interpreting tests, and maintaining test security. Although a trained technician or a research assistant can administer the Bayley-4 and score the responses *under supervision* the test results should only be interpreted by those who have appropriate graduate or professional training in assessment.”

“Those using the Bayley-4 should also have experience with or training in, testing children whose ages; linguistic backgrounds ; and clinical, cultural, or educational histories are similar to individuals they will be evaluating. Examiners should also be familiar with the *Standards for Educational and Psychological Testing (Standards: AERA et al., 2014)*.

Pearson has classified the Bayley-4 as a Qualification Level B assessment instrument. Qualification Level B includes individuals with:

- A master's degree in psychology, education, speech language pathology, occupational therapy, social work, counseling, or in a field closely related to the intended use of the

assessment, and formal training in the ethical administration, scoring, and interpretation of clinical assessments.

OR

- Certification by or full active membership in a professional organization (such as ASHA, AOTA, AERA, ACA, AMA, CEC, AEA, AAA, EAA, NAEYC, NBCC) that requires training and experience in the relevant area of assessment.

OR

- A degree or license to practice in the healthcare or allied healthcare field.

OR

- Formal, supervised mental health, speech/language, occupational therapy, social work, counseling, and/or educational training specific to assessing children, or in infant and child development, and formal training in the ethical administration, scoring, and interpretation of clinical assessments.

Prior to submitting a certification video, examiners should complete and submit the NRN Bayley-4 Examiner Qualifications Questionnaire (see page 2 of Follow-up Technical Memo #53) to their NRN Bayley Gold Standard examiner and RTI Follow-up Study Coordinator (lpalberg@rti.org) by email prior to submitting a video for certification. This questionnaire has been developed to ensure all NRN examiners meet the User Qualifications for administering the Bayley as specified in the Bayley-4 Manual. The questionnaire collects information such as educational background, how the examiner was trained on the Bayley-4, and experience in working with toddler age children.

12.1.3 Procedural Guidelines

The following is a list of procedural and scoring guidelines. The references made in 1 to 10 below refer to the Bayley Scales manual.

1. Primary Caretaker

The primary caretaker should accompany the child during the administration of the Bayley-4. If the primary caretaker is not present, the adult who brought the infant to the clinic should stay with the child. Given the use of caregiver questions on the Bayley-4, it is essential that the adult present with the child be very familiar with the child's developmental skills.

2. Masking of Examiners

Examiners must be masked to the birth weight and gestational age of the child and to clinically significant family and developmental history. If the examiner becomes unmasked during the exam, report "unmasked".

In order to ensure blinding for this and other studies, the Bayley examiner should complete the Bayley Summary Score form (NF09B4) AFTER the assessment and the scores are calculated, OR a study coordinator or other research staff should complete the form.

Prior to the assessment and recording of findings, Bayley examiners should not look at the medical records and should not have seen the child for the preceding six (preferably twelve) months. Adjustment for gestational age should be completed by center staff other than the Bayley examiner, and Bayley examiners provided only with the adjusted age for determining the start point on the Bayley-4.

3. Non-English Speaking Children

It is preferable to perform the test in the child's preferred language. Non-English speaking families may require that the examiner arrange translation. If a translator is needed, inform the translator to translate instructions verbatim, not repeating instructions unless permitted by the examiner. The Spanish examiners should assemble a list of correct and incorrect responses encountered during training and certification. If more than 2 items are spoiled by the translator, the test is not scorable.

4. Priority of the Bayley-4 during the Clinic Visit

The Bayley-4 should be administered early in the clinic visit before medical procedures or interviews, as possible. Best performance is compromised if the child is tired, hungry, or upset. Try to have snacks available (or have parent bring snacks) so the child can take a snack break as needed. Try not to assess a very tired or very hungry child – schedule accordingly as much as possible.

5. Persons Present During the Assessment:

According to the Bayley-4 Manual, keep the number of individuals in the assessment room to a minimum. Ideally, only one (or both) parents, the child, and the examiner should be present. Do not attempt to assess the child with other persons present in the assessment room. Siblings should not be present as they may serve as a distraction or may spoil test items. If siblings accompany family to the visit, and there is no one available who can monitor/entertain the siblings outside the assessment room, the sibling must remain in the back of the room, behind the child, engaged in a very quiet activity. In addition, additional medical providers or staff beyond the examiner should never be present in the assessment room.

6. Interruption of Administration

If the examiner must stop the test and resume later during the visit or at another session (preferably within two weeks), complete the test and score in the usual way. You should not repeat items that the child failed in the first administration. However, if the child did not attend or attempt an item, you may repeat it. Leave that item blank to indicate that it can be repeated. The administration for scales not completed can be administered, if it is determined that the child was not making his/her best effort at the first visit, such as in the case where the child was too ill. If at the time of the second testing the child enters into another age category for testing, administer the Bayley Exam for the older age category. If the test is repeated, it should be administered within the visit window (22-26 months corrected age). Both the Receptive and Expressive Communication subtests should be completed in one visit. The Receptive scale should be administered prior to the Expressive scale.

This serves as a basic guideline if the administration of the Bayley-4 is interrupted. For any unique cases that require further clarification, send a description of the scenario to the

center PI, Dr. Susan Hintz (Follow Up PI), the Gold Standard Bayley examiners, and the DCC Study Coordinator.

7. Scoring

Examiners should use the child's **corrected** age to select the correct start point (L or M). Administer the Cognitive, Language and Motor Subset Scales adhering to the basal and ceiling rules. (p.27-30 of BAYLEY-4 Manual) Scaled scores will be determined from the raw score and both will be entered on the Bayley-4 Record Form. Cognitive, Language and Motor Composite Scores will also be calculated and entered on the front of the Record Form. Record the child's score directly on the testing form rather than making notes on cue sheets and transferring to the record form after the exam.

8. Data Entry

The adjusted age in months, the Cognitive raw score, scaled score and composite score are recorded. Receptive and Expressive Communication raw scores and scaled scores are entered. The Receptive and Expressive Communication scaled scores are then summed, and a Language composite score is obtained. Fine Motor and Gross Motor raw scores and scaled scores are entered. The Fine Motor and Gross Motor scaled scores are then summed and a Motor composite score is obtained.

9. Incomplete Exams

For each scale, if more than two items are omitted then the scale is not valid, and no score can be derived. Any part of the exam that is completed (Cognitive, Receptive and Expressive Communication, Fine and Gross Motor) should be scored and data entered.

10. Sensory Impairment:

Please make sure children who wear glasses or hearing aids bring these assistive devices to the research visit and that they are worn during the assessment. An attempt should be made to administer Bayley-4 items to the majority of children with a sensory impairment. There are exceptions.

1. Legally blind (< 20/200 with glasses). If parent reports child perceives only shadows or shapes, it is unlikely the child can be tested.
2. Hearing impaired (Mild, moderate, severe or profound). Inquire of parent if child has amplification? Is the child wearing the hearing aids? If not, you will need to reschedule when the child has the aids. Can the child follow simple one step directions when amplified? The majority of children with mild to severe hearing loss who are wearing their hearing aids can be tested. If the child has a profound hearing loss and is awaiting a cochlear implant or uses sign language the child will not be able to be tested.
3. Child is both vision and hearing impaired (Deaf/Blind). These children cannot be tested with the Bayley.

12.1.4 Administration

If possible, the Bayley assessment should take place in a clinical setting. If this is not possible, the Bayley assessment can be performed in other settings, such as in a hospital, or at the child's home. Assessments must be administered by a Bayley examiner certified for the Follow-up Study. The child may sit on the caretaker's lap or in a youth/highchair with the caretaker nearby.

Examiners should use the child's **corrected** age to select the correct start point (L or M). The examiner must follow the item administration recommended by the Bayley-4 Manual. The following should be adhered to for performing all subtests:

- Use exact language or scripts from the manual for instructions and avoid paraphrasing.
- Time appropriate items with a stopwatch. Although some timers display to the hundredths place, score and record time based on **whole** seconds. **Do not round up.** (e.g. 16.81 seconds is considered 16 seconds). Timers on a watch or smart phone are permitted as long as the examiner demonstrates competence using this application and can start and stop the timer quickly and appropriately.
- Adhere to the Basal and Ceiling rules (p.27-30 of Bayley-4 Manual)
- When included for a particular item, examiner must use **demonstration items** (items demonstrated by examiner), **sample items** (items that have practice items with corrective feedback) and **multiple trial** items (items that require multiple responses for scoring) NOTE: For multiple trial items, it is permitted to discontinue an item once the child has passed at the highest criteria (2 points) or when he/she has failed sufficient trials (0 points) so that it is clear they cannot pass at the 1 point level. This can save precious time on this lengthy assessment.

Additional recommendations include:

- Reference the manual as needed during administration, but the examiner should know the items well enough not to break the flow of the exam.
- Use enclosed scripts to avoid caretaker input into the assessment.
- Encourage the child without over-repetition of instructions restricted by the manual (e.g. "Good job", "OK"), rather than comments linked to success.
- Be willing to accept failures. Do not repeat item just because a child failed or provided incorrect response.
- Organize test materials to be nearby but out of sight of the child. We encourage the examiner to use plastic bins to hold materials that tend to go together, for example puzzle pieces, pegs, and spoon, comb and baby doll, to reduce time spent searching for materials. Set up materials before child arrives (e.g. pegs in pegboard, assemble pink board, open stimuli book to cognitive item 54 – Matches pictures).
- Keep test materials, test booklet, and stopwatch off the table to avoid distracting the child.
- The examiner does not review the subject's chart prior to the exam in order to stay masked to the neonatal history of the child and the results of previous developmental tests. If the examiner becomes unmasked to either information, report "unmasked" on the study form (NF09B4). Observation made at the assessment that the child has had particular medical conditions or knowledge that the child had been referred at a previous clinic visit does not count as unmasking.
- Data Entry: The identification information and age at the time of the exam are entered into the database. The raw score, scaled score and composite score for Cognitive as well as the raw score, scaled scores, summed Language and Motor scores and composite scores are also entered into the database. These values are recorded on the cover of the Record Form. Additional variables include whether the examiner was

unmasked; whether the exam was conducted in English and if not, whether an interpreter was used.

- Double scoring – Given how easy it is to make counting or scoring errors on the Bayley-4, it is required that another individual double check the totaling of scores and the use of tables to derive scores. This individual can be anyone who is trained to do so, including the study coordinator. This person confirms accuracy of scores and adds their initials to the NF09B4 form.

12.1.4.1 Home Visits

The Bayley examination can be done at a home visit. If the home does not have a proper sized staircase, the two stair items (#39 & 41) will be omitted, potentially reducing validity of gross motor subscale scores. If no stairs are available, it is essential that no other items in the Gross Motor subscale are omitted. (#52 & 54 potentially could be omitted if a child got that far which would make the exam invalid having 4 items omitted)

12.1.5 Scripts

Scripts to be used with parents before testing starts.

"Thanks for coming in today. I want to explain what I will be doing with _____ (child's name). I am going to show your child different toys and see how he/she responds to them. I will be giving him/her items at a range of age levels, so I don't expect him/her to know how to do every item today. Some tasks may be quite easy, and some may be more difficult, but that is true for all children.

I have to present the items in a certain way, with specific instructions, so I will ask that you not repeat the instructions or show him/her what to do. It is necessary that we administer this assessment in the exact same way with every child, so we have to adhere to specific ways of administering each item and use specific wording. Even though you do lots of teaching with your child at home, today we need to see what he/she can do all by himself/herself. There will be several items, however, for which I will need your input and for which I will ask you about his/her skills at home.

Also, all the toys are cleaned between children and are a safe size so it's OK if your child puts these toys in their mouth."

Note to examiners: It also helps to give reminders to parents before bringing out certain items. Examples:

- For COG44 Relational play: Others – Tell parent that they may not tell the child what to do with the different objects, such as the spoon, comb, ball, and tissue.
- For picture book items and toys that you want child to label say, *"I don't want you to say the names of these"*.

Give gentle reminders as necessary to an over-involved parent, as it is crucial that parents do not spoil assessment items.

12.1.6 Heading

Information for the heading should be obtained from the Base Form (NF00). If any changes have occurred since the Base Form was completed, the information should still match the Base Form. For example, if the mother has changed her name, use the initials that are on the base form. These initials refer to the biological mother. Even if the biological mother is not the caretaker, the initials should still match those of the biological mother that are given on the Base Form.

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. For centers with confidentiality issues, this may be omitted to meet their particular needs.

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

12.1.7 Section A. Bayley Information

The Bayley-4 Summary Scores Form (NF09B4) should be completed by the Bayley examiner. Only a certified Bayley-4 examiner can administer and score the Bayley test. However, in circumstances when either the child has been previously evaluated to be severely to profoundly impaired, or it is readily apparent that the child is severely to profoundly impaired, and the Bayley examiner is not available, the neuro examiner may assign a composite score of 54 for Cognitive, 44 for Language, and 44 for Motor on the NF09B4 form.

If a subtest was not successfully performed, questions A.1.a.1, A.1.b.1, A.1.c.1, A.1.d.1, A.1.e.1 use the following codes for reasons not successfully tested:

Record '1' if not successfully tested due to acute illness, such as acute infection, fever, vomiting, etc.

Record '2' if language other than English is spoken and not successfully tested because an interpreter was not available.

Record '3' if child had severe behavioral problems. Examples include willful defiance of examiner/parent; uncooperativeness and refusal and/or throwing of

items; extreme distractibility and/or inattention to tasks. Also included in this category are children who are so shy or withdrawn that they are not willing to attempt any items.

If, however, the child is distractible, difficult or shy, but with perseverance adequate items are successfully administered, scores are to be reported.

If behavior was considered unique to the test day, an attempt should be made to reschedule and retest the child at another visit, if possible.

Record '4' if the child was truly severely developmentally delayed and could not be tested (e.g. Microcephaly). Children with sensory impairment AND/OR who are also severely developmentally delayed are included in this category. Assign a composite score of 54 for Cognitive and 44 for Language and/or Motor subtests.

Record '5' if physically unable to complete task i.e., severe cerebral palsy.

Record '6' Anatomic abnormalities of hands/feet i.e., club feet, dislocated hips, arthrogryposis

Record '9' if other. Examples include children who are in a body cast and cannot perform motor items, or children who are absent extremities.

This category also includes children who were tested but the exam was invalid for reasons other than for reasons given under codes 1 to 6.

1. Was child successfully tested for the following:

a. Cognitive Subtest

Code YES if a valid Cognitive score was obtained. Otherwise, record NO.

1. If NO, reason not successfully tested:

Record the reason not successfully tested, codes 1-6, or 9 from above.

a. If 9) Other, specify reason:

Specify reason if other than codes 1 to 6.

b. Language Receptive Communication Subtest

Code YES if a valid Lang RC score was obtained. Otherwise, record NO.

1. If NO, reason not successfully tested:

Record the reason not successfully tested, codes 1-6, or 9 from above.

a. If 9) Other, specify reason:

Specify reason if other than codes 1 to 6.

c. Language Expressive Communication Subtest

Code YES if a valid Lang EC score was obtained. Otherwise, record NO.

1. If NO, reason not successfully tested:

Record the reason not successfully tested, codes 1-6, or 9 from above.

a. If 9) Other, specify reason:

Specify reason if other than codes 1 to 6 given.

d. Motor (Fine) Subtest

Code YES if a valid score was obtained. Otherwise, record NO.

1. If NO, reason not successfully tested:

Record the reason not successfully tested, codes 1-6, or 9 from above.

a. If 9) Other, specify reason:

Specify reason if other than codes 1 to 6 given

d. Motor (Gross) Subtest

Code YES if a valid score was obtained. Otherwise, record NO.

1. If NO, reason not successfully tested:

Record the reason not successfully tested, codes 1-6, or 9 from above.

a. If 9) Other, specify reason:

Specify reason if other than codes 1 to 6 given

Complete items f-i, if successfully tested or severely developmentally delayed (Code 4).

f. Adjusted age:

Prior to the administration of the Bayley-4, the child's adjusted age on the day of the visit will be calculated, using the adjusted age calculator found on the NRN software by pressing the F10 key. The examiner will be given the child's adjusted age, and this is the age that should be used to determine the start point for scoring purposes. The adjusted age should be recorded on the NF09B4 and should match the adjusted age as recorded on the SES at Follow-up (NF03), if all components of the Follow-up visit occur on the same day. **Do NOT calculate adjusted age as described in manual. Always use NRN adjusted age calculator.**

When recording the adjusted age on the NF09B4 for each subtest, the examiner should round up or down to the nearest whole month. The examiner should round down if the number of days in the child's adjusted age, as calculated by the NRN adjusted age calculator, is **15** or fewer. For example, if the child's adjusted age is 22 months, 13 days, the adjusted age should be entered on the NF09B4 as 22 months. If the number of days in the adjusted age is **16** or more, the examiner should round up to the next month. For example, if the child's adjusted age is 22 months, 17 days, the adjusted age should be entered on the NF09B4 as 23 months.

1. Record Adjusted age for Cognitive subtest in Months
2. Record Adjusted age for Receptive Communication in Months
3. Record Adjusted age for Expressive Communication Months
4. Record Adjusted age for Fine Motor subtest in Months
5. Record Adjusted age for Gross Motor subtest in Months

g. Bayley Scales of Infant and Toddler Development- 4

Record the Cognitive, Receptive Communication, Expressive Communication, Fine Motor and Gross Motor raw and scaled scores for adjusted age onto the summary sheet.

Record the summed Language score for adjusted age onto the summary sheet.
(Scaled Receptive + Scaled Expressive)

Record the summed Motor scores for adjusted age onto the summary sheet (Scaled Fine Motor + Gross Motor) .

Record Cognitive, Language, and Motor Composite Scores

For children who **cannot be tested with the Bayley-4** because of severe neurologic impairment and/or developmental delay, assign the following scores (which are one point lower than the lowest score):

Cognitive: 54

Language: 44

Motor: 44

Blind children

Blind children without any functional vision are to be listed as not successfully tested and no score is given. Blind children with functional vision may be scored. **Blind children who are ALSO severely multi-handicapped are to be given a score one point below lowest score for each scale, as described above (54 for Cognitive, 44 for Language, 44 for Motor and coded as "4 = Severely developmentally delayed and/or legally blind and/or profound hearing loss.**

Deaf children

If the child has been fitted with hearing aids, the Bayley subscales can be attempted. A child with profound hearing loss, who cannot respond, should be categorized as not successfully tested. **Deaf children who are ALSO severely multi-handicapped are to be given a score one point below lowest score for each scale, as described above (54 for Cognitive, 44 for Language, 44 for Motor and coded as "4 = Severely developmentally delayed and/or legally blind and/or profound hearing loss.**

h. Was Bayley-4 Exam conducted in English?

Record YES if Bayley Exam was conducted in English or NO if it was conducted in any other language.

1. If NO, was interpreter required?

Record YES if an interpreter was required or the caretaker served as the translator. Record NO, if a certified Bayley Examiner conducted the exam in another language.

i. Was the Bayley-4 examiner masked to the child's medical history?

Record YES or NO. If the mother happens to mention a medical problem the child is having or had, record NO. If results of previous testing are known, record NO. Do not include the following examples as unmasking.

- The examiner assumes the child is a low birth weight child.
- The examiner knows the child wears glasses or a hearing aid.
- Observations made during the Bayley exam that the child has had particular medical conditions or knowledge that the child had been referred at a previous clinic visit.

12.1.8 Section B. Form Completion

1. Where was Bayley Exam conducted?

Record '1' if the Bayley-4 exam was conducted at the clinic, Record '2' if conducted at the child's home, Record '3' if conducted at a clinic other than the designated follow-up clinic, Record '4' if conducted at another hospital or institution, or Record '9' if conducted in another setting.

2. Date Bayley-4 Exam:

Record the date the Bayley-4 exam was completed.

3. Initials of the person administering the Bayley-4 Exam:

Record the first, middle and last initials of person who has responsibility for this form.

4. Initials of the person verifying the Bayley-4 scores:

Record the first, middle and last initials of person who checked the calculation of each raw score and looked up the scaled scores associated with those raw scores in the table for the corrected age of the child. Sum of scaled scores and subsequent looking up of the composite scores in the appropriate table should be checked as well.

Chapter 13. STATUS OF CHILD

13.1 Status Form (NF10) (rev 1/18/2017)

The Status Form should be completed for all infants eligible for the Follow-up Study when the final status is known. If the child comes to the follow-up visit, then complete at the time the visit is completed. If the child died after initial discharge to home, then complete when this information is available. If the child is lost to follow-up, complete when this information is known. All information should be completed by the end of the 22-26-month interval at the latest.

If an infant is never discharged and dies before 1 year, or at 1 year, this should be noted on the NG05 (Late Clinical Outcome Form) and the infant is not expected for follow-up. If an infant dies **after** 1 year of age but was never discharged, this should be noted on the NF10 with the status code of **3=Died after GDB status**.

For transfer patients (i.e., if the child went to a center at the Follow-up visit other than the center where the child was enrolled in the Generic Study), **both the originating center and the new (transfer) center should complete an NF10 form.**

13.1.1 Heading

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc. based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. For centers with confidentiality issues, this may be omitted to meet their particular needs.

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base for the first time, the computer assigns this unique identifier.

13.1.2 Section A. Status Information

1. Date of birth:

Record the date of birth.

2. Final status of child:

Record '1' if the Follow-up visit was completed. This indicates that, in the ideal (standard) situation, the child was seen, anthropometrics and questionnaires were completed, and (1) the neurologic exam (NF05); (2) the Palisano* (NF05 question B6 Gross Motor Function Level); (3) the Bayley 4 (NF09B4 Form - Cognitive, Receptive Communication, Expressive Communication, and Motor) were completed.

The following elements must be completed for center's Official Follow-Up Rate (refer to section 1.7)

- Child seen
- Anthropometrics completed
- Questionnaires completed
- Bayley 4 Score (NF09B4 Form - Successfully completed Cognitive and Language or coded as 4 if unsuccessfully completed; successfully completed Motor or coded as 4 or 5 if unsuccessfully completed)
- The Neurologic exam (NF05 form)
 - Palisano (NF05 question B6 Gross Motor Function Level)
- If not possible, to obtain a complete Follow Up visit, the following is requested for a Partial Follow Up visit:
 - The Bayley and Palisano OR
 - A Neurologic exam and Palisano
 - Complete the NF10A, key and submit to RTI via weekly data transmission.

*Follow forms/directions for the Neonatal Research Network Palisano form (differs from BEAM study directions)

Record '3' if the child died after GDB status.

Record '4' if the child was lost to follow-up, or ASQ-3 (NF19) was completed, or could not be examined within the 22-26-month window.

If coded as lost to follow-up, complete the Lost-to-Follow-up questionnaire (NF12). If you are in contact with the family, complete the ASQ-3 (NF19) if the family is willing. The ASQ-3 (NF19) is part of the Lost-to-Follow-up package so completion of the NF19 does not constitute an incomplete visit.

Record '5' if the child went to a center at the Follow-up visit other than the center where the child was enrolled in the Generic Study. '5' should ONLY be recorded by the originating (GDB) center. For example, if the visit was completed at the new (transfer) center, then the new (transfer) center should record '1' (Child seen, Follow-up visit completed).

Record '6' if the Follow-up visit was incomplete. This indicates that at least part of the Follow-up assessment was obtained for the child within the 22-26-month window, but not all of the assessments could be performed. Indicate the completed assessments on the NF11. For a “complete” or “incomplete” visit the child must be seen by the developmentalist or psychologist. If code 6 “child seen, but incomplete visit” is recorded on the NF10, complete the NF10A and submit to RTI via weekly data transmission.

Complete SUMMARY FORM NF11.

a. If final status is died after GDB status (3)

8. Date of death:

b. If final status is lost to follow-up (recorded as '4' in question A.2 of this form) give reason lost to follow-up:

Record '1' if the child was adopted and the family is not willing to come in.

Record '2' if the child is now out of the area and the family is not willing to come in.

Record '3' if the child is lost to the center.

Record '4' if the family refused informed consent for follow-up

Record '5' if the family was non-compliant.

Record '6' if the child is in foster care and the family is not willing to come in.

13.1.3 Section B. Form Completion

1. Date form completed:

Record the date the form was completed.

2. Center number of where the child was seen.

03 = Case Western Reserve University

04 = University of Texas - Dallas

05 = Wayne State University

09 = Emory University

11 = University of Cincinnati

12 = Indiana University

14 = Brown University

15 = Stanford University

16 = University of Alabama

18 = University of Texas - Houston

19 = Duke University

22 = University of California at San Diego

24 = University of Iowa

25 = University of Utah

26 = University of New Mexico

27 = University of Pennsylvania/CHOP

28 = University of Rochester

29 = University of California-Los Angeles

30 = Nationwide

31 = Children's Mercy

3. Initials of person completing this form:

Record the first, middle and last initials of person completing this form.

13.2 Status Form (NF10A) (rev 4/1/2011)

The NF10A should be completed, keyed into the EDC, and transmitted to RTI for visits where the child was seen but the visit was not completed.

In other words, for each visit with an NF10 Final Status code of 6 “child seen, but incomplete visit” an accompanying NF10A should be keyed. This form is for administrative purposes to determine compensation for the incomplete visit. For each missing item on the NF05 (Infant Examination Form) or NF09B4 (Bayley 4) indicate the reason in the space provided. Only complete reason for incomplete items, leave other items blank.

A new section (Section D. NDI Assessment) was added to the NF10A form on April 1, 2011 to determine whether components of neurodevelopmental impairment (NDI) can be determined for children with incomplete visits. The preference for all primary outcome data is for an assessment to be performed by a certified examiner. However, there are unusual circumstances where a child cannot be formally assessed but the primary outcome data could be extracted from another source of medical documentation. This section was developed for the severely impaired child who may not be available for the Follow-up evaluation, or part of the evaluation, but the severity of the neurologic condition is clearly documented in the medical record by other providers. Following are instructions for completing this section:

For questions 1a-e use the following Clinical judgment codes and Source codes for each component of NDI. Comments can be added by hitting the F5 key while keying the data into the EDC.

Clinical judgment codes: ‘1’ Yes, ‘2’ No, ‘3’ Suspect, ‘4’ Can’t be determined

Source codes: ‘1’ Chart review, ‘2’ Physician report, ‘3’ Caretaker interview

1. In your best clinical judgment would you classify the child as:

a. Moderate to severe CP with GMFCS level ≥ 2

Code as ‘1’ Yes, ‘2’ No, ‘3’ Suspect, or ‘4’ Can’t be determined along with the source code. An example of when this component of NDI could be determined is when it is clearly documented in the child’s medical record by other providers that he/she has moderate to severe CP with GMFCS level ≥ 2 . If this component of NDI cannot be determined, then code as ‘4’ (Can’t be determined).

b. Bayley 4 Motor score <70 (Severe/Profound NDI*)

Code as ‘1’ Yes, ‘2’ No, ‘3’ Suspect, or ‘4’ Can’t be determined along with the source code. Severely impaired children seen for a Bayley 4 but deemed untestable should be noted as such on the NF09B4 form. If this component of NDI cannot be determined, then code as ‘4’ (Can’t be determined).

c. Bayley 4 Cognitive score <70 (Severe/Profound NDI*)

Code as ‘1’ Yes, ‘2’ No, ‘3’ Suspect, or ‘4’ Can’t be determined along with the source code. This item should not be used to speculate on level of cognitive functioning for children who are uncooperative with Bayley testing. Severely impaired children seen for a Bayley4 but

deemed untestable should be noted as such on the NF09B4 form. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

d. Bilateral blindness (<20-200) († Given lack of granularity of vision and hearing data, “levels” of vision and hearing are not assigned to these categories.)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. A child with bilateral blindness that is clearly noted in the child's medical chart is an example of when this component of NDI could be determined. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

e. Hearing impaired +/- amplification († Given lack of granularity of vision and hearing data, “levels” of vision and hearing are not assigned to these categories.)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. An example of when this component of NDI could be determined is when a child with deafness or cochlear implants who is followed by a pediatric ENT with this information clearly noted in the child's medical chart. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

As of March 2023, we assume the cut points for Bayley III and Bayley 4 are comparable. Therefore, we will leave the current NDI definitions with Bayley III reference in the 22-26 Month Follow Up Manual of Procedures, with the understanding this may be amended at a later time upon the collection of additional data.

The following definition of NDI was voted on by the Follow-up PIs and agreed upon by the Steering Committee during the July 20, 2018 meeting. It is acknowledged and understood that there are no perfect “definitions”, and that “NDI” should not be considered the outcome of choice for all analyses or trials. But as the Follow-up and Steering Committees have discussed at length, it is important to clarify some basic definitions.

1) “Binary” definition of moderate-severe NDI: Bayley III Cognitive < 85, Bayley III Motor <85, GMFCS 2 or greater, or bilateral “blind” despite corrective lenses (NF05 B.1.e = 4 OR 5 in both eyes) or bilateral no functional hearing with or without amplification.

2) Severity levels:

Domain	“Normal, at risk or mild”	Moderate NDI	Severe/Profound NDI*
Bayley III Cognitive	>=85	70-84	<70 / <=54
Bayley III Motor	>=85	70-84	<70 / <=46
GMFCS	Level “0” or I	Level II or III	Level IV or V
Vision	†	†	Bilateral “legally blind” NF05 B.1.e = 4 <u>OR</u> 5 in both eyes
Hearing	†	†	Bilateral hearing impaired +/- amplification

† Given lack of granularity of vision and hearing data, “levels” of vision and hearing are not assigned to these categories.

* As relevant, consider reporting severe NDI as a secondary outcome

Chapter 14. SUMMARY OF FOLLOW-UP VISIT

14.1 Summary of Follow-up Visit (NF11) (rev 7/26/21)

The Summary of Follow-up Visit Form should be completed for all infants ELIGIBLE for the Follow-up Study when the Follow-up visit has been completed.

14.1.1 Heading

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. **For centers with confidentiality issues, this may be omitted.**

Follow-up Number

When the child's information has been entered into the Follow-up Study Data Base

14.1.2 Section A. Identification Information

1. Visit date(s):

a. Date of first visit:

Record the date of first visit.

b. Date of final visit when forms are complete:

Record the date of the final visit when as many forms as possible have been completed and no more assessments will be attempted.

14.1.3 Section B. Assessment Information

Record YES or NO for whether each of the following assessments was completed.

1. Identification Information (NF00)?
2. SES at Discharge (NF01)?
3. SES at Follow-up (NF03)?
4. Medical History Form (NF04)?

- a. Readmission Form (NF04A)?
- 5. Child Examination Form (NF05)?
- 7. Status Form (NF10)?
- 8. Lost to Follow-up Form (NF12)?
- 9. Bayley III Scales Summary Score Sheet (NF09A)?
- 10. Child Behavior Checklist (CBCL) Summary Score Sheet (NF16)?
- 11. Bayley 4 Summary Score Sheet (NF09B4)?
- 12. Ages and Stages (ASQ-3) Summary Scores Form (NF19)?

14.1.4 Section C. Form Completion

1. Date form completed:

Record the date the form was completed.

2. Initials of person completing this form:

Record the first, middle and last initials of person who has responsibility for this form.

Chapter 15. LOST TO FOLLOW-UP

15.1 Lost to Follow-up Questionnaire (NF12) (7/26/2021)

In September 1997, the Lost to Follow-up Questionnaire (NF12) was added to the Follow-up Study. This form is to be completed for all those who were not assessed within the 22-26-month window. In August 2021 the Neonatal Research Network (NRN) NICHD leadership approved integrating the **Ages and Stages Questionnaire, Third Edition (ASQ-3)** into the Lost to Follow Up package.

Background

- Due to the COVID-19 pandemic, there is an increase of situations when a child cannot be seen for the 22–26-month Follow-up visit but the NRN Center is still in contact with the family.
- To capture as much data as possible on these children, the NRN Follow Up Study will include the ASQ-3 as part of the Lost to Follow Up package.

Eligibility, roll-out, training, and certification

- The ASQ-3 Working group led a **1-hour ASQ-3 training webinar** on **September 20th, 2021, at 2pm EST** (*in place of the standing NRN Follow Up call*). Materials available on the NRN private website here: [Protocols](#) > [Active Protocols](#) > [Follow-up](#) > [Training](#) > [ASQ-3](#)
[ASQ-3 Manual of Procedures](#)
[ASQ-3 Training Webinar Slide Presentation \(09/20/2021\)](#)
[ASQ-3 Training Webinar Notes and Zoom Recording Link \(09/20/2021\)](#) After viewing the training webinar and informing the RTI Follow-up Study Coordinators (lparrlberg@rti.org and newman@rti.org), staff members will be considered trained and certified on the ASQ-3.
- Trained NRN Center staff may then administer the ASQ-3 to caregivers of children who are not seen for the 22-26-month Follow up visit.

Administration and scoring

- The ASQ-3 should be administered to the caregiver by a trained NRN Center staff member using the manufacturer's form.
- Trained NRN Center staff will score the ASQ-3. The summary scores will be recorded on the **ASQ-3 Summary Scores Form (NF19)** dated 7/26/21 and keyed into the NRN Follow-up Study electronic data capture (EDC) system.

Purchasing

- The NRN DCC at RTI International centrally purchased and distributed the ASQ-3 materials to the NRN sites. On 7/27/2021, the NRN DCC asked the Follow Up PIs and Coordinators to complete the ASQ-3 Purchase Form, indicating items needed and shipping contact information.

There are three sections to the NF12 LTFU form:

A. Source of Information and Vital Status

Information on deaths that occurred after the expiration of the follow-up visit window will be recorded. (If a death occurs before the expiration of the follow-up visit window, record the death information on Form NF10).

B. Caretaker Questionnaire

The questionnaire should be administered to a person with a significant caretaking role and should be undertaken for a child who is 22 to 30 months corrected age.

C. Chart Review Information or Report from Physician

Information from the chart that includes 22 to 30 months corrected age will be recorded if this information was not obtained by the caretaker questionnaire.

15.1.1 Heading

Center Number

Refer to page 5.2 for your institution's center number

Site Number

Network Number

This is the Generic Network Number for the child, found on 6.a of the NF00

Birth Number

This number refers to the birth order given to patients. The code is used to uniquely identify patients. For a single birth code '1', for multiple births, code the patients '1', '2', '3', etc based on the order they were born.

Mother's Initials

Record the mother's first, middle, and last initial. For centers with confidentiality issues, this may be omitted to meet their particular needs.

Follow-up Number

When the patient information has been entered in the database for the first time, the computer assigns this unique identifier.

15.1.2 Lost to Follow-up Indicator

Indicate in Question 2 of NF12 whether or not any information is available for the child from indirect sources (e.g. caretaker interview; chart review) by choosing YES or NO. If yes, available information (Question 3 and succeeding questions) should be completed. If No, identifying information, date of last contact, if known, and date of forms should be completed.

15.1.3 Section A. Source of Information and Vital Status

If chart review information is not available and the questionnaire is not administered, this section can still be completed if known.

1. Name (First):

Fill in first name of child. This information will not be keyed into the computer.

2. Is information available for this child from indirect sources (e.g. caretaker interview; chart review).

IF YES, GO TO QUESTION 3

IF NO

a. Record the date of last contact.

Record month, day and year

b. Date form completed.

Record month, day and year

3. Is child alive?

Record YES ('Y') if child is known to be alive at 22 months corrected age. Record NO ('N') if information on the death of the child has been obtained.

a. If YES, corrected age when last known to be alive?

Record corrected age when child was last known to be alive.

b. If NO, date of death

Record date of death if known.

IF CHILD IS DECEASED STOP HERE (Fill in initials to complete form page 2 of form, C.5)

4. Caretaker interview:

Record YES ('Y') if caretaker interview was administered.

a. If YES, date of interview:

Record the date the interview was actually conducted.

b. If YES, corrected age of child at the time of the interview

Record the corrected age of the child at the time of the interview. The interview should only be conducted if the child is between 22 to 30 months corrected age.

5. Were any questions completed from chart review or report from physician?

Record YES ('Y') if a medical chart/physician report was reviewed and information that was not obtained by interview was recorded.

a. If YES, date of chart review or physician report:

Record the date that the chart or physician report was actually reviewed.

b. If YES, age of child at the time of the review

Record the corrected age of the child at the time information on the chart/physician report was collected. The age of the child should be between 22 to 30 months corrected age only.

15.1.4 Section B. Caretaker Questionnaire

This questionnaire should be administered only to a person with a significant caretaking role. (e.g. primary caretaker, grandmother, father, mother (if not primary caretaker but has a significant caretaking role)).

1. How would you describe (child's name) _____'s health?

Ask caretaker this question and read the possible responses.

Record '1' for Poor health

Record '2' for Fair health

Record '3' for Good health

Record '4' for Very Good health

Record '5' for Excellent health

2. Is (name) _____ walking alone (without holding on)?

a. If YES, age (name) _____ started walking independently?

Record chronological age.

b. If NO, is (name) _____ sitting alone without support?

Record YES or NO.

c. If NO, does (name) _____ have head control?

Record YES or NO.

3. Can (name) _____ see?

4. Has (name) _____ had an eye exam since initial discharge?

5. Does (name) _____ need or wear glasses?

6. Does (name) _____ hear?

7. Has (name) _____ had a hearing exam since initial discharge?

8. Does (name) _____ need or wear a hearing aid (s)?

8a. Does (name) _____ need or wear a cochlear implant (s)?

9. What is the estimated number of words in (name) _____'s vocabulary?

10. Can (name) _____ combine 2 words?

11. Can (name) _____ combine 3 words?

12. Has a doctor ever said that (name) _____ has

a. Hydrocephalus treated with a shunt?

b. Cerebral palsy?

c. Developmental delay?

This is defined as a Bayley score < 70.

d. Language delay?

e. Poor weight gain?

f. Seizures since discharge?

g. Blindness (legally blind)?

Record YES if child is blind in both eyes, without any useful vision.

h. Other behavior problems? If Yes, describe.

i. Other major medical problems? If yes, describe.

j. Other neurodevelopmental problem? If Yes, describe.

Record any problems affecting neurodevelopment.

k. Deafness? Record Yes or No

l. Gross Motor Function Level from caretaker interview

The same NF12 form will be used for wrapping up 18-22-month visits and rolling out the 22-26-month visits, which will facilitate a smooth transition to the new follow-up window for the examiners, keyers, and analysts. Once all the 18-22-month visits have been completed, the 18-22 month GMFCS descriptions will be removed from the NF12 form.

Complete **Question B.12.I** for all children with caretaker a questionnaire completed. Interviewers check one level (to the left), according to the child's age (22-26 months). Keyers key the corresponding EDC Code listed to the right.

Complete the following for children 18 months to 21 months 29 days.

<u>18 Months – 21 Months 29 Days</u>	<u>EDC Code</u>
<input type="checkbox"/> Normal (Walks 10 steps independently and fluently)	=1
<input type="checkbox"/> Possible Level I (Walks 10 steps independently but not fluently; child exhibits toe walking or asymmetric walking)	=2
<input type="checkbox"/> Level I (Moves in/out of sitting and floor-sit with both hands free to manipulate objects. Infants creep or crawl on hands and knees, pull to stand and take steps holding onto furniture. Infants walk between 18 mo. and 2 years without holding on)	=3
<input type="checkbox"/> Level II (Maintains floor sitting but may need to use hands for support to maintain balance. Creeps on stomach or crawls on hands and knees. May pull to stand and take steps holding onto furniture)	=4
<input type="checkbox"/> Level III (Maintains floor sitting when the low back is supported. Rolls and creeps forward on stomach)	=5
<input type="checkbox"/> Level IV (Has head control but trunk support is required for floor sitting. Can roll to supine and may roll to prone)	=6
<input type="checkbox"/> Level V (Unable to maintain anti-gravity head and trunk postures in prone or sitting; little or no voluntary movement)	=7

Complete the following for children 22 – 26 months.

<u>22 – 26 Months</u>	<u>EDC Code</u>
<input type="checkbox"/> Level "0" (Walks independently, normal and fluent gait)	=1
<input type="checkbox"/> Level I (Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk 10 steps independently, with hands free, but with some gait abnormalities – includes toe walking, asymmetric walking, wide based gait with coordination or ataxic gait.)	=3
<input type="checkbox"/> Level II (Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees with reciprocal leg movement. Infants may pull to stand and take steps holding on to furniture.)	=4
<input type="checkbox"/> Level III (Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs or may crawl with or without reciprocal leg movements.)	=5
<input type="checkbox"/> Level IV (Infants have head control, but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.)	=6
<input type="checkbox"/> Level V (Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.)	=7

Also complete question B.12.I.1 for children > 24 months

<u>>24 Months</u>	<u>EDC Code</u>
___ Level "0" (Walks independently, normal and fluent gait)	=1
___ Level I (Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.)	=3
___ Level II (Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.)	=4
___ Level III (Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.)	=5
___ Level IV (Children floor sit when placed but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.)	=6
___ Level V (Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.)	=7

13. Initials of interviewer

Record the first, middle and last initials of interviewer.

With permission of interviewee complete the Medical History Form (NF04), Readmission Form (NF04A), and SES Form at Follow-up (NF03) and the Ages and Stages (ASQ) – Form (NF19).

15.1.5 Section C. Chart Review Information or Report from Physician

Complete this section if items were not obtained by interview and the child was between 22- and 30-months corrected age at the time that the chart information was recorded.

1. Has the child had an eye exam since initial discharge?

Record YES or NO.

2. Has the child had a hearing exam since initial discharge?

Record YES or NO.

3. Does the child need or wear a hearing aid(s)?

Record YES or NO.

4. Does the child have any of the following based on chart review?

a. Hydrocephalus treated with a shunt?

b. Cerebral Palsy?

c. Developmental delay?

This is defined as a Bayley score < 70.

d. Language delay?

e. Poor weight gain?

f. Seizures since discharge?

g. Blindness (legally blind)

Record YES if child is blind in both eyes, without any useful vision.

h. Other behavior problems? If Yes, describe.

i. Other major medical problems? If yes, describe.

j. Other neurodevelopmental problem? If Yes, describe.

Record any problems affecting neurodevelopment.

k. Deafness? Record Yes or No

l. Gross Motor Function Level from chart review or report from physician.

The same NF12 form will be used for wrapping up 18-22-month visits and rolling out the 22-26-month visits, which will facilitate a smooth transition to the new follow-up window for the examiners, keyers, and analysts. Once all the 18-22-month visits have been completed, the 18-22-month GMFCS descriptions will be removed from the NF12 form.

Complete Question C.4.I for all children with caretaker a questionnaire completed.
Examiners check one level (to the left), according to the child's age (18 months – 21

months 29 days OR 22-26 months). Keyers key the corresponding EDC Code listed to the right.

Complete the following for children 18 months to 21 months 29 days.

<u>18 Months – 21 Months 29 Days</u>	<u>EDC Code</u>
___ Normal (Walks 10 steps independently and fluently)	=1
___ Possible Level I (Walks 10 steps independently but not fluently; child exhibits toe walking or asymmetric walking)	=2
___ Level I (Moves in/out of sitting and floor-sit with both hands free to manipulate objects. Infants creep or crawl on hands and knees, pull to stand and take steps holding onto furniture. Infants walk between 18 mo and 2 years without holding on)	=3
___ Level II (Maintains floor sitting but may need to use hands for support to maintain balance. Creeps on stomach or crawls on hands and knees. May pull to stand and take steps holding onto furniture)	=4
___ Level III (Maintains floor sitting when the low back is supported. Rolls and creeps forward on stomach)	=5
___ Level IV (Has head control but trunk support is required for floor sitting. Can roll to supine and may roll to prone)	=6
___ Level V (Unable to maintain anti-gravity head and trunk postures in prone or sitting; little or no voluntary movement)	=7

Complete the following for children 22 – 26 months.

<u>22 – 26 Months</u>	<u>EDC Code</u>
___ Level “0” (Walks independently, normal and fluent gait)	=1
___ Level I (Infants move in and out of sitting and floor sit with both hands free to manipulate objects. Infants crawl on hands and knees, pull to stand and take steps holding on to furniture. Infants walk 10 steps independently, with hands free, but with some gait abnormalities – includes toe walking, asymmetric walking, wide based gait with coordination or ataxic gait.)	=3
___ Level II (Infants maintain floor sitting but may need to use their hands for support to maintain balance. Infants creep on their stomach or crawl on hands and knees with reciprocal leg movement. Infants may pull to stand and take steps holding on to furniture.)	=4
___ Level III (Infants maintain floor sitting when the low back is supported. Infants roll and creep forward on their stomachs or may crawl with or without reciprocal leg movements.)	=5
___ Level IV (Infants have head control, but trunk support is required for floor sitting. Infants can roll to supine and may roll to prone.)	=6
___ Level V (Physical impairments limit voluntary control of movement. Infants are unable to maintain antigravity head and trunk postures in prone and sitting. Infants require adult assistance to roll.)	=7

Also complete question C.4.I.1 for children > 24 months

>24 Months	EDC Code
___ Level "0" (Walks independently, normal and fluent gait)	=1
___ Level I (Children floor sit with both hands free to manipulate objects. Movements in and out of floor sitting and standing are performed without adult assistance. Children walk as the preferred method of mobility without the need for any assistive mobility device.)	=3
___ Level II (Children floor sit but may have difficulty with balance when both hands are free to manipulate objects. Movements in and out of sitting are performed without adult assistance. Children pull to stand on a stable surface. Children crawl on hands and knees with a reciprocal pattern, cruise holding onto furniture and walk using an assistive mobility device as preferred methods of mobility.)	=4
___ Level III (Children maintain floor sitting often by "W-sitting" (sitting between flexed and internally rotated hips and knees) and may require adult assistance to assume sitting. Children creep on their stomach or crawl on hands and knees (often without reciprocal leg movements) as their primary methods of self-mobility. Children may pull to stand on a stable surface and cruise short distances. Children may walk short distances indoors using a hand-held mobility device (walker) and adult assistance for steering and turning.)	=5
___ Level IV (Children floor sit when placed but are unable to maintain alignment and balance without use of their hands for support. Children frequently require adaptive equipment for sitting and standing. Self-mobility for short distances (within a room) is achieved through rolling, creeping on stomach, or crawling on hands and knees without reciprocal leg movement.	=6
___ Level V (Physical impairments restrict voluntary control of movement and the ability to maintain antigravity head and trunk postures. All areas of motor function are limited. Functional limitations in sitting and standing are not fully compensated for through the use of adaptive equipment and assistive technology. At Level V, children have no means of independent movement and are transported. Some children achieve self-mobility using a powered wheelchair with extensive adaptations.)	=7

15.1.6 Section D. NDI Assessment

A new section (Section D. NDI Assessment) was added to the NF12 form on April 1, 2011 to determine whether components of neurodevelopmental impairment (NDI) can be determined for children who are lost-to-follow-up. The preference for all primary outcome data is for an assessment to be performed by a certified examiner. However, there are unusual circumstances where a child cannot be formally assessed but the primary outcome data could be extracted from another source of medical documentation. This section was developed for the severely impaired child who may not be available for the Follow-up evaluation, but the severity of the neurologic condition is clearly documented in the medical record by other providers. Following are instructions for completing this section:

For questions 1a-e use the following Clinical judgment codes and Source codes for each component of NDI. Comments can be added by hitting the F5 key while keying the data into the EDC.

Clinical judgment codes: '1' Yes, '2' No, '3' Suspect, '4' Can't be determined

Source codes: '1' Chart review, '2' Physician report, '3' Caretaker interview

1. In your best clinical judgment would you classify the child as:

a. Moderate to severe CP with GMFCS level ≥ 2

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. An example of when this component of NDI could be determined is when it is clearly documented in the child's medical record by other providers that he/she has moderate to severe CP with GMFCS level ≥ 2 . If this component of NDI cannot be determined, then code as '4' (Can't be determined).

b. Bayley 4 Motor score <70 / ≤ 46 (Severe/Profound NDI*)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. Severely impaired children seen for a Bayley 4 but deemed untestable should be noted as such on the NF09B4 form. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

c. Bayley 4 Cognitive score <70 / ≤ 54 (Severe/Profound NDI*)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. This item should not be used to speculate on level of cognitive functioning for children who are uncooperative with Bayley 4 testing. Severely impaired children seen for a Bayley 4 but deemed untestable should be noted as such on the NF09B4 form. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

d. Bilateral blindness (<20 - 200) Bilateral "legally blind" NF05 B.1.e = 4 OR 5 in both eyes († Given lack of granularity of vision and hearing data, "levels" of vision and hearing are not assigned to these categories.)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. A child with bilateral blindness that is clearly noted in the child's medical chart is an example of when this component of NDI could be determined. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

e. Bilateral Hearing impaired +/- amplification († Given lack of granularity of vision and hearing data, "levels" of vision and hearing are not assigned to these categories.)

Code as '1' Yes, '2' No, '3' Suspect, or '4' Can't be determined along with the source code. An example of when this component of NDI could be determined is when a child with deafness or cochlear implants who is followed by a pediatric ENT with this information clearly noted in the child's medical chart. If this component of NDI cannot be determined, then code as '4' (Can't be determined).

2. Initials of person completing this form:

Record the first, middle, and last initials of the person completing the chart review and/or this form.

As of March 2023, we must assume the cut points for Bayley III and Bayley 4 are comparable. Therefore, we will leave the current NDI definitions with Bayley III reference in the 22-26 Month

Follow Up Manual of Procedures, with the understanding this may be amended at a later time upon the collection of additional data.

The following definition of NDI was voted on by the Follow-up PIs and agreed upon by the Steering Committee during the July 20, 2018 meeting. It is acknowledged and understood that there are no perfect “definitions”, and that “NDI” should not be considered the outcome of choice for all analyses or trials. But as the Follow-up and Steering Committees have discussed at length, it is important to clarify some basic definitions.

1) “Binary” definition of moderate-severe NDI: Bayley III Cognitive < 85, Bayley III Motor <85, GMFCS 2 or greater, or bilateral “blind” despite corrective lenses (NF05 B.1.e = 4 OR 5 in both eyes) or bilateral no functional hearing with or without amplification.

2) Severity levels:

Domain	“Normal, at risk or mild”	Moderate NDI	Severe/Profound NDI*
Bayley III Cognitive	>=85	70-84	<70 / <=54
Bayley III Motor	>=85	70-84	<70 / <=46
GMFCS	Level “0” or I	Level II or III	Level IV or V
Vision	†	†	Bilateral “legally blind” NF05 B.1.e = 4 <u>OR</u> 5 in both eyes
Hearing	†	†	Bilateral hearing impaired +/- amplification

† Given lack of granularity of vision and hearing data, “levels” of vision and hearing are not assigned to these categories.

* As relevant, consider reporting severe NDI as a secondary outcome

15.2 Ages and Stages (ASQ-3) Summary

15.2.1 Introduction

To provide more quantitative information about children lost to follow up for the 22-26-month corrected age visit, the NRN Follow-Up PI group and Steering Committee added the Ages and Stages Questionnaire 3rd edition (ASQ-3) to the requested lost to follow up elements. The ASQ-3 is a screener but provides scores in five areas - Communication, Gross motor, Fine motor, Problem solving, and Personal-social. The ASQ-3 was developed as a parent/ primary caregiver questionnaire but can also be administered by phone. It is also available in several languages including Spanish.

Below is an overview of ASQ-3 key points for questionnaire selection, administration, and scoring. Also refer to ASQ-3 User’s Guide (particularly Chapter 6, Chapter 8, and Appendix E) for further information.

15.2.2 When to obtain the ASQ-3

- The age range encompassed by the ASQ-3 is 1-66 months. It is understood that all sites go to great measures to get children and families in for a full NRN follow up exam and acknowledged that Bayley may be given to 42 months 15 days corrected age.

- It is **strongly encouraged to obtain ASQ-3 and other lost to follow up data at 34-38 months corrected age (1 year after 22-26 month corrected age follow up window)** if not already obtained by that time.
- Each NRN site follow up team will have best information and insights about the children and families they are following, therefore it is recognized that flexibility in timing of “declaring” lost to follow up will be needed.

15.2.3 Questionnaire selection and administration

15.2.3.1 Selection of appropriate ASQ-3 age interval questionnaire:

- ASQ-3 kits include paper masters of the 21 age-based questionnaires and scoring sheets as well as CD-ROM with printable PDF questionnaires. To obtain accurate scores, the correct age interval questionnaire must be used as the questions individually tailored to relate to age-based skill acquisition.
 - For the purposes of the NRN, **corrected age should be used in selection of questionnaires.**
- The following (partial) table will guide selection of appropriate ASQ-3 questionnaire (see ASQ-3 User’s Guide, page 67, Table 6.1 for complete information):

Child’s corrected age	ASQ-3 questionnaire
28 months 16 days through 31 months 15 days	30 month
31 months 16 days through 34 months 15 days	33 33 month
39 months 16 days through 38 months 30 days	36 month
39 months 0 days through 44 months 30 days	42 month

15.2.3.2 Administration

- The ASQ-3 can be administered by sending the questionnaire to parent/ primary caregiver by mail or by phone administration or by telehealth visit. It is understood that the NRN follow up teams will have the best insight as to challenges and approaches for their site and for individual families.
 - However, the questionnaires have diagrams that facilitate parent’s understanding of items and therefore it is preferred if family has a copy of form in front of them during phone interview. If this is not possible, examiner will need to describe diagrams.
 - Some parents/primary caregivers may have challenges with literacy. NRN teams may already be aware of these issues for specific patients’ families, but teams may need to further explore.
 - Because of the complexities of some of the questions - which include pictures or pictorial descriptions (see below) - the **ideal administration strategy for a phone administration** would include 1) an initial call to introduce the questionnaire, discuss specific questions and materials that may be needed for skills assessment, 2) sending the appropriate age-based questionnaire to the parent/caregiver so they may try the skills, including a stamped self-addressed envelope , and 3) a follow up call/ telehealth to review the responses.
 - **However, it is understood that the “ideal” is often not possible.**
 - Thus, the ASQ-3 responses may need to be obtained on **an initial call or telehealth visit** if the if the parent/ primary caregiver is unable or unwilling to review and/or complete a mailed questionnaire and/or unable or unwilling to schedule a follow up call or telehealth visit. If

- only one call is possible, encourage the parent to try items with the child while on the phone/ telehealth if the parent is unclear whether the skill is something the child can do.
- If no follow up call or telehealth visit is possible, the parent/ primary caregiver may mail back a **completed questionnaire**. For this reason, a stamped, self-addressed envelope should be included when sending to the parent/ primary caregiver.
 - Of note, emailing blank forms is prohibited by the publisher for copyright reasons. However, some NRN sites are utilizing an ASQ-3 publisher-approved “online” administration version, which do allow for form transmission to parent/ primary caregiver.
 - If the NRN team feels that the parent/ primary caregiver has **literacy challenges**, a phone call and/or telehealth visit may be the best and only option to obtain ASQ-3 responses.
- Only scores from the five areas will be obtained for NRN purposes. **Therefore, the “Overall” section at the end of the questionnaires will NOT need to be administered.** The site may however wish to obtain that information for their own site-specific clinical information.
 - The **ASQ-3 has a total of 30 questions (6 questions in each of the 5 areas) and takes 10-15 minutes to complete.** The research team should introduce both the general purpose of the questionnaire and response options to the parent/ primary caregiver. Below are possible points to include:
 - *“This is a screening questionnaire that provides a quick check of things your child may be doing in areas of development including language and understanding; playing, moving and coordination of arms and legs and hands and fingers; problem-solving and how they play with toys; and interacting with others and doing things for themselves.”*
 - *There are five developmental areas that we will discuss, and each area has 6 questions that go from easier to more challenging. Your child may be able to do some but not all of the skills*
 - *“Each question has 3 possible responses: “yes” means your child is performing the skill consistently or most of the time; “sometimes” means your child might just be learning to do it or only do it on occasion; and “no” means that your child doesn’t yet do that activity or hasn’t yet learned that skill.”*
 - *“There are no right or wrong answers. Every child is an individual – every child learns new skills at different times.”*
 - The parent/ primary caregiver should also be advised that some skills asked about may include activities with certain toys or equipment – like playing with balls (throwing, kicking) and blocks, stringing beads or similar, looking at drawings or making them, looking at a picture book, walking up stairs, etc. **Because some of these skills may not be routine to the parent/family, the research team should advise the parent to try activities with the child before answering (see materials list below).**
 - In the case of a **phone interview**, ideally there will be an opportunity for the research staff to have discussed specific questions with the parent/ caregiver in advance, and the parent would have been sent the questionnaire to try the skills with the child. However, it is also understood that the initial call may be the only opportunity to obtain ASQ-3 responses, and therefore description of the scoring criteria diagrams would be necessary.

- The site and parent/ caregiver may be able to accommodate a **telehealth or zoom visit on the initial and/or follow up engagement**, which would allow for the site interviewer to “show” the descriptive pictures.
-
- Materials that **may** be needed during assessment (Also refer to ASQ-3 User’s Guide Appendix E, pages 199-200):
 - Children’s book (if none available, a magazine can be used that includes pictures of people or animals engaging in common actions, such as eating, drinking, running, etc.)
 - Mirror (can be wall mirror)
 - Ball, ideally small enough for child to hold and throw; large enough to kick (if not available, can crumple up paper into a ball shape)
 - Pencil, Pen, or Crayon and paper
 - Shoelace and beads or dried pasta with holes (penne, wagon wheels, etc.)(for stringing)
 - 4 or 5 small blocks (can be plastic or wooden blocks or MegaBlocks, Duplos, large Legos)
 - Child safe scissors (if not available, and no prior experience w scissors, score as 0)
 - Child’s own stroller or a push toy (wagon; shopping cart, etc.)
 - Coat or jacket with zipper
 - 5-7 piece interlocking puzzle or full page photo from magazine cut into about 6 pieces

15.2.3.3 Scoring

- Scoring the ASQ-3 takes ~3-5 minutes.
- Each response to items on the questionnaire should be scored as follows: **“yes” = 10, “sometimes” = 5; “no” = 0**
- Add all scores within each developmental area to assign separate scores to each area Communication, Gross Motor, Fine Motor, Problem Solving, Personal-Social.
 - As there are 6 questions in each area, **the maximum total for each area = 60.**
- **Dealing with unanswered (“I don’t know”) responses:**
 - An area should NOT be scored if there are more than 2 unanswered responses in that area.
 - Area scores may be adjusted for missing items up to 2 items as per the **below table** (also see ASQ-3 User’s Guide, page 72, Table 6.2). Find the total score from COMPLETED items on the left hand column (“Area score”). Follow to the right to determine the adjusted score if 1 item or 2 items are unanswered.

Area score	Adjusted area score–1 item omitted	Adjusted area score–2 items omitted
50	60	–
45	54	–
40	48	60
35	42	52.5
30	36	45
25	30	37.5
20	24	30
15	18	22.5
10	12	15
5	6	7.5
0	0	0

- Differentiating “No” from “I don’t know” responses
 - “Not yet” or “No” (0-points) means child *has not yet achieved developmental skill* – not the same as the parent responding “I don’t know.”
 - If parent says “I don’t know”
 - Encourage parent to try skill with child
 - If the skill is clearly above child’s ability (e.g. jumping for a child not yet walking; using sentences for child with only a few words), score as “No” (= 0 points)
 - If the parent definitely has no idea if the child has learned the skill, and has not had the opportunity to try it, leave item blank and score will be adjusted (assuming fewer than 2 blank items per subscale as described above)

15.2.4 Completing the Ages and Stages (ASQ-3) Summary Scores Form (NF19) (v2/14/222)

Form Instructions: Complete this form for all children who are not seen for the Follow-up visit.

Section A. ASQ-3 ADMINISTRATION INFORMATION

1. Date ASQ was administered (MM/DD/YYYY)

Record the Month (two-digit) / Day (two-digit) / Year (four-digit)

2. Corrected Age of child when ASQ was administered (MM | DD)

Record the Months (two-digit) / Days (two-digits)

3. ASQ version administered

Record the two-digit version code in the space provided using the codes included below.

ASQ Version Codes

18 = 18-months	24 = 24-months	33= 33-months	48= 48-months
20 = 20-months	27 = 27-months	36 = 36-months	54= 54-months
22 = 22-months	30 = 30-months	42 =42-months	

4. Mode of ASQ Administration

Record the two-digit Administration code in the space provided using the codes include below.

ASQ Administration Codes

01 = In-person, via interview	04 = Telephone interview
02 = In-person, self-completed	05 = Telehealth/Video interview

03 = Mail-in; self-completed

06 = Online, self-completed (any platform)

07 = Other, specify

a. If 07, other, specify

If Administration code "07 Other", specify other mode of administration in the space provided.

5. Relationship of respondent to the child

Refer to the list included in Appendix A of the NRN Follow Up Manual for relationship codes. If biological mother, code is 001

Section B. ASQ-3 DOMAIN TOTAL SCORES

For Section B. Q1 - Q5 record the two-digit, **one decimal place** score for each domain.

- 1. Communication Total Score**
- 2. Gross Motor Total Score**
- 3. Fine Motor Total Score**
- 4. Problem-Solving Total Score**
- 5. Personal-Social Total Score**

6. ASQ Scored by

Initials of person who scored the ASQ. It is the responsibility of the examiner to 1) verify that the scoring has been calculated accurately and 2) ensure that another member of the research team has double checked the calculation of the scores. The examiner's initials in this field are an attestation that these quality checks have been executed.

7. ASQ Scores checked by

Initials of person double checking the scoring. It is the responsibility of an appropriately trained individual at the site to verify that the scores reported were calculated correctly. The reviewer's initials in this field are an attestation that these quality checks have been executed.

Section C. Form Completion

1. Date form completed:

Record the date the form was completed.

2. Initials of person completing this form:

Record the first, middle and last initials of person who has responsibility for this form

APPENDIX A.

APPROPRIATE RESPONDENT TO INTERVIEWS / QUESTIONNAIRES

Form No.	Form Name	Respondent
NF01	SES at Discharge	Caretaker or well-informed household member (Answer as much as possible if not caretaker)
NF03	SES at 18 + 4 Months	Caretaker or well-informed household member (Answer as much as possible if not caretaker)
NF04	Medical History Form	Caretaker only
NF04A	Readmission Form	Caretaker only
NF16	CBCL	Caretaker only
NF19	ASQ-3	Caretaker or well-informed household member (Answer as much as possible if not caretaker)

APPENDIX B. RELATIONSHIP CODES

The following codes are used to identify the primary caretaker.

- 001 - Mother of Child
- 002 - Father of Child
- 011 - Husband, Significant Other (SO) (if different from 002)
- 012 - Wife, Girlfriend (if different from 001)
- 021 - Maternal grandmother
- 022 - Paternal (SO) grandmother
- 031 - Maternal grandfather
- 032 - Paternal (SO) grandfather
- 041 - Maternal aunt
- 042 - Paternal (SO) aunt
- 051 - Maternal uncle
- 052 - Paternal (SO) uncle
- 061 - Brother
- 062 - Step Brother
- 071 - Sister
- 072 - Step Sister
- 081 - Maternal female cousin
- 082 - Paternal (SO) female cousin
- 091 - Maternal male cousin
- 092 - Paternal (SO) male cousin
- 101 - Other maternal relative
- 102 - Other paternal (SO) relative
- 201 - Foster mother
- 202 - Foster father
- 301 - Adoptive mother
- 302 - Adoptive father
- 401 - Other non-relative
- 402 - Social worker/case worker
- 501 - Staff in congregate care
- 502 - Still hospitalized
- 504 - Unknown

APPENDIX C. LIVING ARRANGEMENT CODES

The following codes are used to identify the patient's living arrangements. Select one arrangement that best describes the patient's planned or current living situation.

- 1 = Both biological parents
- 2 = Biological mother only
- 3 = Biological father only
- 4 = Both biological parents in extended family
- 5 = Biological mom in extended family
- 6 = Biological dad in extended family
- 7 = Maternal grandparent(s)
- 8 = Paternal grandparent(s)
- 9 = Other non-adoptive relative
- 10 = Relative adoptive parent
- 11 = Non-relative adoptive parent
- 12 = Friends of family
- 13 = Foster family home of relative
- 14 = Foster family home of non-relative
- 15 = Pre-adoptive home
- 16 = Chronic Care Facility
- 17 = Group home
- 18 = No stable caretaker
- 19 = Hospital
- 20 = Other
- 21 = Biological mother and significant other
- 23 = Biological father and significant other

When at least one biological parent is in the household, the following decision rules should be followed.

Both biological parents, biological mother only, or biological father only

"Both biological parents", "biological mother only", or "biological father only" should be selected if they are the only biological relatives living in the household, other than the child's siblings. Non-relatives may be living in the household. However, if the biological mother only or father only is sharing the home with a significant other (male or female), use codes 21-24 to describe the living arrangement for that household.

Biological parents in extended family

"Both biological parents in extended family" should be selected when the baby is living with both biological parents and grandparents or other relatives. Nonrelatives may also be living in the household.

Biological mom in extended family or biological dad in extended family

"Biological mom or biological dad in extended family" should be selected when the baby is living with one biological parent and grandparents or other relatives. Non-relatives and/or a spouse who is not the baby's biological or adoptive parent may also be living in the household.

When there are no biological parents in the household, the following decision rules should be followed.

Maternal/paternal grandparent

When there is (are) not biological parent(s) in the baby's household, but a maternal/paternal grandparent is in the household, record "maternal/paternal grandparent" even if other relatives or non-relatives are in the household. If the baby is living with a grandparent(s) who is also an official foster parent, record "foster family home of relative".

Other non-adoptive relative

When there is neither a biological parent nor grandparent in the household, but there is a non-adoptive adult relative such as an aunt/uncle, record the "non-adoptive relative" category. Non-relatives may also be living in the household.

Relative adoptive parent

If the baby is living with a relative who has legally adopted the child, record "relative adoptive parent(s)".

Friends of family

"Friends of family" should be recorded when the child is staying with non-relatives, not under the supervision of the State agency.

Foster family home of relative

"Foster family home of relative" should be recorded if this is an official foster care placement under the supervision of State agency, whether licensed or unlicensed and whether or not the foster parents are receiving a foster care maintenance payment on behalf of the child.

Foster family home of non-relative

"Foster family home of non-relative" should be recorded if this is an official foster home with a non-relative under the supervision of the State agency whether licensed or unlicensed and whether or not a foster care maintenance payment is being made on behalf of the child.

Pre-adoptive home

"Pre-adoptive home" should only be recorded if the baby is living with non-biological parents who have taken formal steps to adopt the baby. This does not include a step-parent who is living with the biological parent and is planning to adopt the child.

Institution

"Institution" should be recorded if the child is living in a child care facility operated by a public or private agency which provides 24-hour care and/or treatment for children who require separation from their parent/caretaker. Residential facility and institution are used interchangeably in this study.

Group home

"Group home" should be recorded if the child is living in a licensed or approved home providing 24-hour care for children in a small group setting that generally has from seven to twelve children.

No stable caretaker

This refers to no definable caretaker or household. This is a very unusual circumstance. However, occasionally children are kept in the child welfare agency offices or are moved almost on a daily basis among various foster care placement settings.

Biological mother and significant other

"Biological mother and significant other" should be selected if the biological mother is the only biological relative living in the household, other than the child's siblings and is sharing the home with a significant other.

Biological father and significant other

"Biological father and significant other" should be selected if the biological father is the only biological relative living in the household, other than the child's siblings and is sharing the home with a significant other.

APPENDIX D. BIRTH DEFECT CODES

CODE	TYPE OF DEFECT
Central Nervous System Defects - 100 Series	
101	Anencephaly
102	Meningomyelocele
103	Hydranencephaly
104	Congenital Hydrocephalus
105	Holoprosencephaly
106	Fetal Alcohol Syndrome
199	Other Central Nervous System Defects
Congenital Heart Defects - 200 Series	
201	Truncus Arteriosus
202	Transposition of the Great Vessels
203	Tetralogy of Fallot
204	Single Ventricle
205	Double Outlet Right Ventricle
206	Complete Atrio-Ventricular Canal
207	Pulmonary Atresia
208	Tricuspid Atresia
209	Hypoplastic Left Heart Syndrome
210	Interrupted Aortic Arch
211	Total Anomalous Pulmonary Venous Return
212	Patent Ductus Arteriosus-cardiac
299	Other Congenital Heart Defects
Gastrointestinal Defects - 300 Series	
301	Cleft Palate
302	Tracheo-Esophageal Fistula
303	Esophageal Atresia
304	Duodenal Atresia
305	Jejunal Atresia
306	Ileal Atresia
307	Atresia of large bowel or rectum
308	Imperforate anus
309	Omphalocele
310	Gastroschisis
399	Other Gastrointestinal Defects
Genitourinary Defects - 400 Series	
401	Bilateral Renal Agenesis
402	Bilateral polycystic, multicystic, or dysplastic kidneys
403	Obstructive Uropathy with Congenital Hydronephrosis
404	Exstrophy of the Urinary Bladder
405	Hypospadias
499	Other Genitourinary Defects

Chromosomal Abnormalities – 500 series

501	Trisomy 13
502	Trisomy 18
503	Trisomy 21
599	Other Chromosomal Abnormality (Describe with F5 Comment)

Other Birth Defects – 600 Series

601	Skeletal Dysplasia (DESCRIBE w/ Comment)
602	Congenital Diaphragmatic Hernia
605	Inborn Error of Metabolism (DESCRIBE w/ Comment)
699	Other Serious and/or Life-Threatening Birth Defect

Pulmonary - 700 Series

701	Cystic Adenomatoid Malformation (CAM)
702	Pulmonary Hypoplasia
799	Other Pulmonary

Endocrine - 800 Series

801	Hypothyroidism
899	Other Endocrine

Orthopedics – 900 Series

901	Club Feet
902	Congenital dislocation of the hips
903	Limb abnormalities
904	Syndactyly
999	Other Orthopedic

APPENDIX E. DATA FORMS

The following pages contain the data forms for the Follow-up Study.

NF00 Identification Information for Use with Base Record

NF01 SES at Discharge

NF02 Visit/ Log

NF03 SES at 18 + 4 Months

NF04 Medical History Form

NF04A Readmission Form

NF05 Child Examination Form

NF05A Gross Motor Function Work Sheet

NF09B4 Bayley 4 Summary Scores Form

NF10 Status Form

NF10A Status Form

NF11 Summary of 18 Month Visit

NF12 Lost-To-Follow-up Questionnaire

NF16 Child Behavior Checklist (CBCL) Summary Score Sheet

NF19 Ages and Stages (ASQ-3) Summary Scores Form (NF19)

REFERENCES

1. Stein, R.E.K. and Jessop, D.J "Manual for the FunctionalStatusII(R) Measure." PACTS Paper. Bronx, New York: Albert Einstein College of Medicine. 1991.
2. Stein, R.E.K. and Jessop, D.J "Functional Status II(R): A Measure of Child Health Status." Medical Care 28, 11 (November 1990): 1041-1055
3. Stein, R.E.K. and Jessop, D.J "Pediatric Ambulatory Care Treatment Study". PACTS Papers/AECOM. Bronx, New York: Albert Einstein College of Medicine. 1985.
4. Dunst, C.J., Trivette, C.M., and Deal, A.G.: Enabling and Empowering Families: Principles and Guidelines for Practice. Cambridge, MA: Brookline Books. 1988