



**Environmental influences on  
Child Health Outcomes  
(ECHO)–wide Cohort  
Data Collection Protocol**

**Manual of Operating Procedures**

**Chapter 3:  
Study Measurements and  
Procedures**

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## CHAPTER 3: STUDY MEASUREMENTS AND PROCEDURES

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**Table 1. Summary of Changes**

Version	Date	Summary of Changes
01.20	30Nov2018	Original document
2.0	19Mar2021	<p>Section 2 Contact Information – Clarified initial response from ECHO Help Desk within 1 business day</p> <p>Updates related to the remote administration of NIH Toolbox:</p> <ul style="list-style-type: none"> <li>• Added Section 6.2.5.1 Remote Administration Guidelines for NIH Toolbox</li> <li>• Updated Section 7.6.3 Researcher-administered Questionnaires</li> </ul> <p>Section 7.4 Abstracting Data from Medical Records</p> <p>Section 7.6.3 - Researcher-administered Questionnaires</p>
3.0	21Mar2022	<p>Table 3. Researcher-Administered Questionnaires, Section 6.2.6 NIH Toolbox Remote Administration, and Section 7.6.3 Researcher-Administered Questionnaires</p> <ul style="list-style-type: none"> <li>• Streamlined guidance to reference the materials on the ECHO SharePoint NIH Toolbox Resources page.</li> </ul> <p>Section 7.5 Understanding Physical Measurements</p> <ul style="list-style-type: none"> <li>• Updated the Notes box to include reference for Caregiver Measured Anthropometrics.</li> </ul> <p>Section 9. Translation Guidance</p> <ul style="list-style-type: none"> <li>• Removed reference to the Language and Acculturation- Pregnancy and Childhood forms.</li> </ul>

## CHAPTER 3: STUDY MEASUREMENTS AND PROCEDURES

### 1 INTRODUCTION

Chapter 3 of the ECHO-wide Cohort Data Collection Protocol Manual of Operating Procedures (MOP) provides detailed instructions, guidance, and best practices associated with study measurements and procedures.

This chapter includes:

- Description of the ECHO life stages, including guidance and age-specific considerations for research administrators
- Measurement types and modes of administration
- Use of measurement information sheets (MISs), data collection forms (DCFs), and proprietary measures
- Best practices and guidance

### 2 CONTACT INFORMATION

<b>Contact the ECHO Help Desk for all questions.</b>	
<b>Help Desk:</b>	<a href="https://echoportal.org/Home/HelpDesk">https://echoportal.org/Home/HelpDesk</a>
<b>Email:</b>	ECHO-DAC@rti.org
<b>Phone:</b>	877-225-0771
<b>Hours:</b>	Mon-Fri, 8 AM – 5 PM ET (Initial response within 1 business day)

<b>Components</b>	<b>Resource</b>
ECHO Coordinating Center (CC)	<a href="#">ECHO-wide Cohort Data Collection Protocol Materials</a>
ECHO Data Analysis Center (DAC)	<a href="#">ECHOPortal</a>
ECHO Person-Reported Outcome Core (PRO Core)	<a href="#">NIH Toolbox</a>

### 3 ABBREVIATIONS AND ACRONYMS

<b>Abbreviation or Acronym</b>	<b>Definition</b>
CAT	computer adaptive test
CC	Coordinating Center (ECHO)
DAC	Data Analysis Center (ECHO)
DCF	data collection form
ECHO	Environmental influences on Child Health Outcomes
FDA	Food and Drug Administration (US)
ID	identification
IRB	institutional review board
MIS	measurement information sheet

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Abbreviation or Acronym	Definition
MOP	Manual of Operating Procedures
PI	principal investigator
PRO	person-reported outcome

### 4 DETERMINING PRIMARY CAREGIVERS

ECHO will follow children and pregnant women for ECHO outcomes of interest, whereas primary caregivers (including the biological mother, who may have been enrolled as a pregnant woman in the prenatal life stage, and the biological father) will provide valuable exposure-/covariate-related data and biospecimens.

When scheduling an event, research administrators should make every effort to schedule the event with the primary caregiver following the prenatal life stage (when events should be scheduled with the pregnant woman).

The research administrator will assess caregiver status and document caregivers, according to cohort-specific procedures, in the consent process and at each study visit. The research administrators will document the caregiver providing information, e.g., biological mother, biological father, or other respondent, in the respondent section of the DCF header.

#### Primary Caregiver

A primary caregiver is an individual, such as a family member (biological or nonbiological) or guardian, who is responsible for the care of the index child. The primary caregiver is the adult caregiver who spends the most time with the child, has substantial responsibility for taking care of him/her on a daily basis, and is most knowledgeable about him/her. For ECHO, the primary caregiver is likely the biological mother, though the diversity of ECHO cohorts warrants nonbiological mothers as primary caregivers. Nonbiological-mother caregivers must be legal adults, i.e., must be 18 years of age or older.

Other considerations for determining the primary caregiver are as follows:

- For the purposes of the study, if 2 persons share equally the caretaking responsibilities for the child, the person filling out the forms both about themselves and the child would be considered the primary caregiver.
- The primary caregiver cannot be a babysitter or other childcare provider who receives money to care for the child.

### 5 LIFE STAGES

#### 5.1 Determining Participant Life Stage

Cohorts are expected to collect life-stage–specific measures at least once in each of the life stages that their cohort participants enter during their full participation in the ECHO-wide Cohort Data Collection Protocol (see [Table 2](#)).

For a participant with overlapping developmental life stages (e.g., a 5-year-old falls in both early childhood and middle childhood), each cohort will determine and document which data elements and associated measures it plans to collect during that window of observation.

“Collect Once” indicates that the collection of the data element is required at least once during ECHO-wide Cohort Data Collection Protocol participation. Cohorts may collect these elements in any appropriate life stage according to associated MISs.

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**Table 2. Life-Stage Definitions**

Life Stage	MOP Section	Age Span
Prenatal	n/a	Post-LMP to pre-birth (parental and fetal measures)
Perinatal	n/a	Birth (including presentation for delivery) through the end of 45 weeks post-LMP
Infancy (after birth)	5.2	46 weeks post-LMP to 11 months, 30 days
Early Childhood	5.3	12 months to 5 years 11 months, 30 days
Middle Childhood	5.5	5 years to 11 years, 11 months, 30 days
Adolescence	5.5	11 years to 20 years, 11 months, 30 days

LMP, last menstrual period; MOP, Manual of Operating Procedures; n/a, not applicable

To manage study visits and data-collection methods, study personnel must consider the following:

- Age of child
- Typical characteristics of a given age
- Language skills and development
- Level of physical development
- Attachments or alliances (with whom the children have affectional bonds)

The following sections provide guidelines on the developmental life stages and approaches by age. The childhood life course is organized across developmental life-stage categories.

### 5.2 Understanding Life Stages: Infancy

In order to obtain meaningful and valid assessments, direct assessment of young children in infancy requires the art of engagement. Infants develop rapidly, and the timing of that development can vary widely across babies of the same age. For example, children may start talking very early (before 12 months, i.e., during the ECHO infancy life stage) or much later (24 months, i.e., during the ECHO early-childhood life stage).

The following approaches can help facilitate data collection with infants (0-11 months, 30 days):

- Childproof the environment.
- Be careful of items left within the baby's reach.
- Have the caregiver within the baby's sight.
- Take your time and be patient.
- Use simple, concrete sentences.
- Use the baby's name often.
- Use toys to get attention and focus; however, keep in mind that toys that are too engaging may make transitions difficult.
- Use voice carefully, softer tone rather than loud.
- Use games such as peek-a-boo, showing toys, letting the baby see him/herself in a mirror.
- Give verbal encouragement and praise for cooperation.
- Monitor their attention and take short breaks when needed.

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### 5.3 Understanding Life Stages: Early Childhood

Due to lack of attention span, poor ability to follow directions, or overall level of cognitive development, many of the skills required to complete assessments at the older end of the early-childhood life stage may be beyond the ability of children at the younger end. Research administrators should be aware of and attuned to developmental differences.

The following approaches can help facilitate data collection during early childhood:

- Continue childproofing appropriate to the child's mobility level.
- Get on the child's level, not towering above them.
- Be patient and positive.
- Use toys to get attention and focus.
- Give simple, clear instructions.
- Give verbal encouragement and praise for cooperation.
- Allow the child to do as many things as possible by him/herself.
- If the child becomes defiant or oppositional, use redirection.
- Give the child simple options and allow them to make choices.
- Make tasks into games; children love to imitate adult behavior.
- Monitor attention and take short breaks when needed.
- Offer snacks, with the caregiver's permission.
- For more impaired children, consider tangible reinforcement with items that don't need to be returned (e.g., stickers and snacks).
- Establish simple and systematic reinforcement schedules with the child. For example:
  - Allow children to cross out each activity on the schedule as completed.
  - After completion of agreed number of subtests, allow for a break, snack, or special activity.
  - For more able, but behaviorally difficult children, dispense a fixed number of break, snack, or exercise cards or tokens at the beginning of the session (e.g., 2 or 3 for a battery of tests per hour of testing).
- For physically active children, allow them to leave the table between tests.
- To increase the child's sense of control, give simple choices (e.g., choice of 2 subtests to do next).
- Do not respond directly to occasional disruptive behaviors, redirect promptly.

#### 5.3.1 Set the Environment

- Prepare the testing room to minimize distractions.
- Ensure that the interview space is safe.
- The space should be comfortable and allow for flexibility and developmental judgment where appropriate (e.g., research administrator may administer a task while the child is seated in a highchair, on the caregiver's lap, or on the floor).
- Observing the administrator interact warmly with his/her caregiver can facilitate the young child's comfort level with the administrator and the research setting.

#### 5.3.2 Build Rapport during Assent and Consent Process

- Depending upon readiness, developmental capacity, and/or comfort level of the child, involve caregivers as needed. Caregivers often play a more active role with children at younger ages, whereas preschool-age (36-60 months) assessments may be conducted separately (e.g., caregiver interviewed, while the child is assessed in a nearby room).

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- When assessing preschoolers without their caregiver present, it is important to spend time building rapport before the separation occurs.
- Integrate “warm up” time at the start of an assessment to help young children adjust to the setting. Typically, after warmly greeting the caregiver and child, administrators allow the child to play with nonassessment toys while the administrator is consenting the caregiver and talking with him/her regarding expectations for the visit.
- As applicable, the research administrator should tell the caregiver and preschooler about where each will be during the visit. The research administrator should also show the child the room their caregiver will be in and tell them that they can ask to see their caregiver at any time.

### 5.3.3 Begin the Assessment

- Maintain a pace for the assessment that the young child can follow.
- Use behavior-management techniques to engage the child and maintain focus and enthusiasm.
- Balance the order of tasks. The assessment process should be a positive, fun experience for the child. Follow potentially frustrating or challenging tasks with pleasant, calming, and reinforcing activities (e.g., verbal encouragement, use of head nods, and smiles).
- Use engaging facial expressions and vocal tones (e.g., smiling, laughing).
- Provide regular verbal praise (e.g., “Good work”) as long as it is not distracting or overly stimulating.

### 5.3.4 Set Time Limits

- Set reasonable time limits on how long assessments last. Although there are no firm guidelines, a general rule of thumb for gauging what is feasible for direct child assessments is:
  - Young children (12-17 months): 1-1.5 hours
  - Older toddlers (18-35 months): 1.5-2 hours
  - Preschoolers (36-60 months): 2-3 hours
- The above timing guidelines assume research administrators provide frequent breaks, opportunities for interaction with the caregiver, and highly varied and engaging activities.
- Study personnel may need to implement additional customization for assessments of special populations (e.g., children with severe language delay or autism-spectrum disorder).

## 5.4 Caregivers as Partners in Infancy and Early Childhood Assessments

In these life stages, assessments will typically occur with a caregiver present or nearby. Infants and toddlers generally require a caregiver in the room, whereas some preschoolers can tolerate separation after becoming comfortable.

Refer to the DCF and associated MIS that specify when a caregiver completing the DCF needs to be a parent or a parent figure.

Make sure that caregivers are informed about, engaged in, and comfortable with all aspects of the study, especially if significant time has elapsed since they signed the informed consent form.

Topics to revisit using accessible terms may include:

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- Overall purpose of the research
- Length of the visit
- Types of activities that will engage the child
- What child and caretaker are expected to do during each assessment

Some assessments ask that the caregiver **refrain from “helping”** the child. In these cases, providing the caregiver with a distraction can help keep the caregiver and the child from interacting. For example, **have the caregiver complete paperwork on a clipboard in the corner of the room or listen to music on headphones**. If the caregiver does help the child when they are not supposed to be helping, gently remind them to refrain.

Other times, the research administrator may ask the caregiver to **engage** with the child, and ensure that the assessment is a comfortable and pleasant experience for the child. The research administrator can collaborate with the caregiver to find the best way to maintain the child’s comfort. Throughout the assessments, the research administrator should remain engaged with the caregiver, not just with the child. **The research administrator can comment on the child’s interests and positive behaviors** and, if the child is uninterested or noncompliant with some activities, reassure the caregiver by letting them know that young children do not always complete or participate in all activities.

It is important to be attentive to cultural diversity and personal values regarding parenting practices and child behavior. This includes beliefs related to tolerance for distress as well as expectations regarding independent functioning, compliance, and expression of emotions.

### 5.5 Understanding Life Stages: Middle Childhood and Adolescence

- Middle childhood (5 years-11 years, 11 months, 30 days)
- Adolescence (11 years-20 years, 11 months, 30 days)

Children make significant gains in attentional control, processing speed, capacities to mentally represent and manipulate information, planning, self-awareness, and self-regulation during middle childhood and adolescence. Youths’ developing cognitive capacities interact with assessment demands, including the measurement tools’ content and administration procedures, to influence data quality.

Some assessments require that the child be alone; others do not. The research administrator should use judgment and input from the caregiver when obtaining physical and anthropometric measurements on a child in the middle-childhood age range, keeping in mind that the child may be more compliant if the caregiver is present.

Adolescents may be more comfortable without the caregiver present when performing physical and anthropometric measurements.

The following general guidelines may help facilitate data collection during middle childhood and adolescence.

- **Introduce.** Before introducing the tasks, the research administrator should introduce himself or herself to the participant, and ask the participant to tell a little about themselves. If the examinee is shy or hesitant, the research administrator might ask a few simple questions to start conversation (examples are, “What kinds of things do you enjoy doing in your free time?” or, “Do you have any favorite movies or TV shows?”). The research administrator should use judgment in selecting a topic or 2 that might get the participant engaged in light conversation. During this time, it is important for the research

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administrator to be genuine, smile often, use a warm voice, and exhibit a positive demeanor.

- **Build trust.** Participants who feel comfortable and who have rapport and trust with the research administrator will be more likely to put forth their best effort, which in turn will maximize the validity of the information gleaned from the assessment. Participants younger than 11 or 12 may naturally feel motivated to perform well to please the research administrator or caregiver, while adolescent or young-adult participants will be more likely to engage in the assessment if they have some context and understanding of the overall purpose of the research. Make accommodations to help maintain compliance. Use adaptive materials used in school (e.g., specialized keyboards, large-font materials) during the interview.
- **Explain the goals of the study.** Tell the examinee that their participation is important and appreciated. Explain that while some of the assessments may seem similar to things the examinee may have done in school, the purpose of the assessments for this study is very different from tests that are given in school.
- **Describe tests and tasks that the participant will be asked to do.**
  - For performance measures, explain that some tasks will be very easy, while others might be very difficult. Let the participant know that it is OK if he or she doesn't know the answers to all the questions.
  - For person-reported-outcome (PRO) measures, remind the participant that the questionnaire is "not a test" and that there are no right or wrong answers.
- **Ensure privacy and explain confidentiality.** Describe how you will keep their responses private. If it is not necessary for you to view responses to items as they are administered, avoid looking at their responses (e.g., provide a cover sheet). Clearly identify any limits to confidentiality, consistent with the consent language, before the participant completes the measure.
- **Be aware of developmental differences across and within ages.** The research administrator will need to use judgment when deciding when to encourage the participant to continue, offer a break, move faster or slower through activities, or adjust the order of protocol. For participants with limited reading skills for whom items must be read aloud, be certain to read the item text verbatim, and avoid giving the participant an indication of how they should respond. Maintain a pace that keeps the participant engaged and interested but does not give them many chances to get off task.
- **When administering performance measures, balance order of tasks.** Follow difficult or challenging tasks with easier or less-challenging activities to minimize frustration. If possible, alternate the performance-assessment types within a single testing session to minimize boredom (for example, begin with a speeded measure of executive function and follow it with a measure of memory or vocabulary).
- **Let participant know how long a session will take,** and let them know they can ask for a break. If the testing session will be longer than 1 hour, schedule short breaks every 45 to 60 minutes or at logical points between, but not during, measures. During the break, allow the participant to get a drink, use the bathroom, have a snack, etc.
- **Provide encouragement and maintain rapport with the participant.** Praise the participant's effort ("I can tell you're doing your best work on this." "You've really stayed on-task, so we're almost done.") rather than his or her performance ("You did great on that last thing we did." "You're getting a lot of these questions right.").

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### 5.6 Administering Assessments with Flexibility and Judgment

Flexibility and real-time judgment are crucial when conducting assessments with young children. The conditions, timing, pace, and order of testing will vary—within the limits of standardized procedures—depending on the individual needs and developmental capacities of the child. For example, a child who is anxious or slow to warm may prefer to sit on the caregiver’s lap or hold a comfort object during assessment. Some children may do better with more structure, such as if buckled in a chair during assessment, whereas others may do better standing or sitting on the floor to complete a task.

In the infancy and early-childhood life stages, chronological age is a crude indicator of children’s capacities. All children will differ, and particularly if assessing selected populations, the research administrators will need to exert judgment when encouraging the child to continue, offering a break, moving faster or slower through activities, or adjusting the order of protocol.

Regardless of the child’s age, when young children become restless, irritable, tired, or hungry during the assessment, their responses may not be an accurate reflection of their ability. Preschoolers may use “I can’t” or “I don’t want to” as a way of indicating fatigue, anxiety, or boredom.

In general, younger children (<3 years) can engage in adult-directed activities for 20 to 30 minutes before needing a break or change of activity, while some preschool-aged children (3-5 years) may last up to an hour with rapid pacing, encouragement, and reinforcement. However, some children may need frequent movement breaks throughout testing, whereas others do better with fewer transitions.

The research administrator may vary the order of activities. For example, some children may need to complete nonlanguage-based activities to develop rapport before they engage with a research administrator.

### 5.7 Building Rapport

Good rapport with the participant helps to secure a successful set of complete measurements. The study personnel should maintain a warm demeanor and work at the participant’s level, whenever possible. Additionally, the research administrator should stay attuned to the participant’s affective state. If the participant becomes significantly distressed, the study personnel should stop the measurement and turn to another part of the visit. While taking measurements in a standard order is preferred, the research administrator should use his/her judgment in determining when breaks and/or changes in measurement sequence are best.

In all communications with participants, research administrators should convey respect and kindness. The goal is to create a trusting relationship between the study personnel and participants. To build strong rapport, study personnel should:

- Be sincere and honest.
- Be supportive.
- Listen with empathy.
- Be nonjudgmental.
- Value participants as people before research participants.
- Follow through on commitments made to the participants.
- Recognize and ease burdens when possible.
- Explain each staff member’s role in the research clinic and how the roles are different from standard clinical care.

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- Acknowledge participants' efforts with personal notes.
- Address travel time and care compensation.
- When feasible, share study milestones and results with participants.
- Give participants the site's contact information and encourage them to call or e-mail if questions arise.

### 5.8 Engaging the Participant

**Social and Concrete Reinforcements:** Young children generally respond well to frequent social reinforcements such as high-fives, clapping, exclamations such as "Wow!," "Look what you can do!," "Way to go! I really like how you listened! You followed my directions!," "You did it!," and "I know this is hard, and I can see that you are working really hard."

Avoid generic phrases, such as "You are so smart," as these may lead to a decrease in children's motivation during a frustrating task.

Many children need concrete reinforcements (e.g., bubbles, stress balls, stickers) throughout the visit in addition to social reinforcements. Research administrators should individualize reinforcements, if possible, to the child. Children can choose reinforcements based on a quick preference-assessment where the research administrator holds up 2 options and the child selects his or her favorite. Use this approach, however, with caution, as this may be overwhelming for some preschool children. Research administrators should give children reinforcement when they comply with a task, taking care to reinforce children for effort and participation, not for correct responses.

**Techniques:** To help children stay engaged during the assessments, research administrators can use the following techniques:

- Sit close to a child who is having trouble staying in their seat.
- Maintain eye contact with a distracted child, but less eye contact with a shy child.
- State expectations clearly rather than asking the child to do something.
- Let the child know what they can do rather than what they can't do.
- Offer choices when appropriate.
- Use visual cues if necessary (e.g., timers, stop signs, visual schedules).

To keep participants engaged in study participation, research administrators should:

- Sincerely ask how a participant is doing overall, not just with the study.
- Explain the study-visit schedules, procedures, and measures.
- Provide participants with a copy of the study-visit schedule.
- Give families extra time to ask questions.
- Provide face time with the principal investigator (PI).
- Make every contact meaningful.
- Let families know you are invested in their well-being.
- Use simple, consistent verbal acknowledgement.
- Conduct post visit check-in calls.
- Send newsletters, greeting cards, letters, and appreciation items.
- Be mindful of the challenges participants confront throughout the course of the study.
- Address stressors such as travel-related expenses.
- Be flexible with appointment scheduling.
- Provide appointment cards.
- Reinforce whom to contact among the study personnel.

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### 5.9 Responding to Frustration and Noncompliance

For other types of behavioral assessments, such as standardized clinical observations like the Autism Diagnostic Observation Schedule and the Disruptive Behavior Diagnostic Observation Schedule, the research administrator's behavior is scripted, but with latitude. The goal is to observe the child's behavior and regulatory capacities in response to challenges, not to maximize cooperation and performance. The research administrator assesses the levels of support needed for the child to maintain or regain regulation.

The aim is to allow the behavior to unfold regardless of whether the child completes the task. The research administrator needs to strike a balance between not stepping in too quickly, which can prevent learning about the range and abilities of the child, and not allowing the child to engage in excessive and highly inappropriate behavior, which would create an environment that does not feel safe for the child or caregiver.

Thus, the research administrator will present prompts or "presses" to the child, but avoid imposing structure or offering support at the onset. The research administrator should gradually increase structure and support if the child continues to escalate or lose control. Levels of support begin with a minimalist response designed to gently help the child get back on track and escalate to higher levels of support, as suggested in the MIS. For these methods, the research administrator's behavior is "scripted" as part of the procedures.

Young children's limited communication skills, short attention spans, and low frustration-tolerance may lead to noncompliance during the assessment. Additional issues may arise for children who are anxious about separations. As a result, it is common for young children to become fidgety, frustrated, fatigued, and/or uncooperative in response to the demands of testing. In more extreme cases, this may include prolonged tantrums, agitation, refusal to cooperate despite environmental support, and even destructive behaviors (e.g., throwing things).

To optimize assessment at these times, try the following:

**Use judgment in determining what is within his/her "bag of tricks" that will most effectively reengage the child.**

- Often a child will respond well to distraction or an empathic response (e.g., "Oh, that made you upset when I took that toy. Here is a cool toy for you to have.>").

**Avoid power struggles.**

- For younger toddlers, research administrators should ignore minor noncompliant behavior, or the research administrator can redirect the child's attention to some other aspect of the assessment.
- For older toddlers and preschoolers, the research administrator can respond to minor noncompliant behavior by restating expectations, offering encouragement, or using a contingency.
- If the child is persistently noncompliant, the research administrator can engage the child in a more preferred activity before transitioning back to the assessment tasks.
- If limits do need to be set, such as when a child is engaging in destructive or potentially harmful behavior, these limits should always be paired with labeling and reflection (e.g., "I know you want to get on the table, but I don't want you to hurt yourself.>").
- When setting limits or redirecting the child, the research administrator's facial expression should remain neutral and tone of voice firm but calm.

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- If distress escalates and does not diminish in response to the research administrator's efforts, the research administrator may need to make additional decisions on the nature of the assessment.
- In cases where the research administrator needs caregiver assistance and the child remains upset or noncompliant, the research administrator should work with the caregiver to determine whether and how the child may resume the activity.

### 5.10 Working with Distressed Participants

#### 5.10.1 Crying

It is not uncommon for a participant to cry or become upset during an assessment.

For distressed infants, toddlers, and young-children participants, it may be helpful to redirect, address fears, or adapt the situation.

For older children and adolescent participants, the research administrator may not need to say anything. Sometimes, just sitting with the participant can be a comfort. It is not necessary to try to distract them to get them to stop crying. Let the participant know that it is OK to cry and to take their time. Do not make them feel that you are rushed. Offer the participant a break.

#### 5.10.2 Anger

A participant may experience anger during an assessment. This may occur as feelings arise while answering a question or from the question that is being asked. It may take a few minutes for a participant to calm down after becoming angry.

Do not try to rationally engage angry people; give them time to calm down. Approaches that may be helpful:

- Let the person know that you understand that they are upset. Be specific so they know that you truly understand: "It seems like you are upset," or "I apologize if I said or asked something that made you upset or angry."
- Offer the participant a break.
- Keep the focus on the other person's emotions.
- Figure out what the person wants from you: "What is it that you need right now?" "How can I help you?"
- Offer what help you can, or clearly say what you cannot do: "Let me try to find out what the delay is."
- Calmly set limits on what is tolerated: "I am willing to listen to you, but let's take a minute so you can calm down first." "I can see that you are upset, but if you want me to help you resolve this, you can't threaten me." If the person will not stop the angry or threatening behavior, you may have to stop the conversation. If the person physically threatens you, leave the situation and get assistance.
- Maintain a calm demeanor. Losing your temper will escalate the situation.

## 6 MEASURE TYPES AND MODES OF ADMINISTRATION

### 6.1 Understanding Types of Measures and Modes of Administration

For the ECHO-wide Cohort Data Collection Protocol, information will be collected in a variety of ways: questions asked of caregivers and children (depending on the age of the child), extraction of medical records, direct measurement (such as anthropometrics), and performance-based assessments (such as cognitive-function tests).

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The ECHO-wide Cohort Data Collection Protocol includes 6 types of measures that you can administer in a variety of modalities (see below).

- **Measure type** specifies what kind of measurement tool is used to capture the data element being assessed.
- **Mode of administration** identifies how the measurement tool will be implemented.

In some cases, the type of measure drives the modality (e.g., the mode of administration for a wearable is via the wearable device itself), while in other cases, the type of measure can be implemented in multiple modalities at the discretion of the cohort. The MISs provide guidance on recommended modes of administration for each measure, based on extant empirical literature and measurement validation.

The types of measures used in the ECHO-wide Cohort Data Collection Protocol are as follows:

- **Medical-record abstractions:** Process of extracting information from a medical record and entering those data into discrete fields on a data-collection tool
- **Physical and anthropometric assessments:** Measurements of the size, shape, and composition of the human body (e.g., blood pressure, height or length, weight, head circumference)
- **Questionnaires:** Research tools consisting of a series of questions (or other types of prompts) for the purpose of gathering information from participants
- **Direct observations:** Watching and noting how a participant responds or behaves
- **Performance-based assessments:** Participants demonstrate knowledge and skills, including process by which they solve problems

### 6.2 Wearables: “Smart” electronic devices with microcontrollers that can be worn on the body with minimal burden Administering Modes and Measures

#### 6.2.1 Data Abstraction

Data abstraction involves information extracted from administrative data, such as medical records, or back-end data collected passively via technology (i.e., wearables).

As noted in the ECHO-wide Cohort Data Collection Protocol, medical records from the biological mother and child participants are the only essential data elements that require data abstraction.

Prior to performing data abstractions, study personnel must comply with the rules and regulations for data access (i.e., HIPAA) as set forth by clinic or hospital-records systems.

**NOTE:** For more information about forms for medical-record abstraction, see **Section 7.3**.

#### 6.2.2 Wearable-Device Data Abstraction

For recommended data elements regarding physical activity, wearable devices are the preferred mode. However, given variability in the types of wearables and the variability of data obtained from the different devices, cohorts may abstract data from the device output, at their discretion. Cohorts will work with the DAC to transfer these data and provide appropriate interpretation.

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### 6.2.3 Wearable-Device Administration

If a cohort is collecting accelerometer data, please contact the DAC to review details about the device in use, the available data, any deidentification requirements, and to obtain information regarding the transfer of the data.

When collecting physical-activity data elements using wearable devices, refer to the device or service's operating manual or user guide to ensure proper administration. The ECHO program also provides an MIS located on the [ECHO-wide Cohort Data Collection Protocol Materials](#) page on SharePoint for the recommended data elements that they can collect using wearables, e.g., accelerometers.

Due to the variability in the types of wearables that cohorts may have available, it is the cohort's responsibility to develop and follow site-specific protocols for the wearables they administer. Some general guidance related to the administration of wearable devices is as follows:

- Ensure your devices are set up and operating appropriately prior to administering them to participants.
- If the wearable you administer requires the participant to recharge the device, provide the participant a charger in working condition and instruct them how and when to charge the device. Some wearables, such as the ActiGraph, require device-specific charging cables to avoid device failure and risk of fire.
- Provide your participants with a padded return envelope if they will be unable to return their device in-person at the conclusion of their data-collection period.
- Train all cohort study coordinators on proper placement of the wearables. Refer to device manufacturer instructions for specific details.
- Tell participants explicitly when they are required to wear their device. Some devices should be worn 24 hours/day, including during sleep and while bathing. Participants should keep a diary to detail the specific time and duration that they remove a device during the data-collection period.
- During the academic school year, it may be helpful to provide a letter for participants who are attending school and instructed to wear their device during school hours. Give the letter to the participant's teachers in order to explain the purpose of the device and the participant's participation in ECHO, including whether or not you expect them to wear the device during physical-education class or sports practice.

### 6.2.4 Self-Administered Measures

Participants complete self-administered measures without help from anyone else, including research administrators. In ECHO, questionnaires are the only measure type that is self-administered (while participants must physically wear wearable devices, the data collected are abstracted from the device output).

Participants may complete self-administered measures in a variety of ways:

- **Remotely:** in his/her own setting on his/her own schedule
- **In-person:** in the presence of the research administrator at a designated time (in a research laboratory, clinic, or during a home visit)

Participants may enter information with or without electronics:

- **Online:** using a computer, tablet, or Smartphone

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- **Online, in-person:** Completed by the participant via a computer, tablet, or Smartphone in the presence of the research administrator at a specifically designated time (in a research laboratory, clinic, or during a home visit)
- **Online, remote:** Completed by the participant via a computer, tablet, or Smartphone not in the physical presence of the research administrator and not at a specifically designated time—participant completes in his/her own setting on his/her own schedule.
- **Offline:** using paper and pencil.

### 6.2.5 Researcher-Administered Measures

Depending on the type of measure, the modes will vary. Research administrators will complete the researcher-administered measures with the participant, according to [Table 3](#).

**Table 3. Researcher-Administered Measures**

Researcher- Administered Measure	Online (via digital device) or Offline	In-person or Remote
Questionnaire (interview format)	Online or offline	In-person or remote
Performance-based assessment	Online	In-person or remote (via Participant App or Zoom/Screenshare)
Direct observation	n/a	In-person only

### 6.2.6 NIH Toolbox Remote Administration

The PRO Core developed the NIH Toolbox Participant and Examiner Application to facilitate remote administration of the NIH Toolbox. Zoom/Screenshare may also be used for certain measures, if the Participant and Examiner Application is not available. Guidelines for remote administration of the NIH Toolbox were developed and approved for use in the ECHO-wide Cohort Data Collection Protocol to provide general guidelines for remote administration, identify which instruments can be administered remotely using the Participant and Examiner Application or Zoom/Screenshare and provide detailed instructions for remote administration of each applicable instrument. In addition, resources for the NIH Toolbox Participant and Examiner App were developed to provide detailed guidance on downloading, trouble-shooting and administering this remote assessment solution on ECHO. Refer to the COVID-19 Remote Administration Guidelines, and ECHO-wide Protocol Data Measures NIH Toolbox Remote spreadsheet and NIH Toolbox Participant and Examiner App reference materials located on the ECHO Training Corner, [NIH Toolbox Resources page on SharePoint](#).

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### 6.2.7 Questionnaire Recall

The majority of questionnaire measurement tools in the ECHO-wide Cohort Data Collection Protocol are intended for contemporaneous data collection during the designated life stage and not via recall after the life stage has passed. However, there are specific questionnaires that do require recall, and the DCF and associated MIS provide such guidance.

### 6.2.8 Computer Adaptive Testing

One can administer a subset of measurement instruments in the ECHO-wide Cohort Data Collection Protocol as computer-adaptive tests (CATs) in lieu of administering the full instrument. Such instruments were developed using item response theory, which allows assessments to be brief while maintaining precision and validity. CATs begin with a set of standard items that were calibrated using item response theory, and an algorithm is used to determine which item should be administered next based on the individual respondent's prior answers. Each respondent receives a unique set of items adapted to his/her individual level of the latent trait being measured.

The primary value of CATs is an increase in measurement precision at the individual level with minimal burden on participants. Instead of having to administer a fixed set of items to all participants, CATs enable completion of instruments in 4 to 6 items. However, while overall scores on CATs are comparable across participants, specific item-level data cannot be compared since each individual participant received a personalized set of items.

## 7 MEASUREMENTS AND PROCEDURES

### 7.1 Understanding the Measurement Information Sheets

MISs are available for each essential (preferred and acceptable) and recommended measure for the ECHO-wide Cohort Data Collection Protocol. MISs serve as guidance documents to facilitate implementation and consistency in data collection across cohorts.

MISs include the following information related to measurement administration:

- Life stages of administration
- Target participant (i.e., the target participant may be different from the participant completing the measure; e.g., biological mother, primary caregiver if not the biological mother)
- Person completing the measure (i.e., "reported by," e.g., biological mother, biological father, other caregiver)
- Mode of administration (e.g., questionnaire, self-administered or interviewer-administered, performance-based, or observation)
- Available translations
- Protocol measurement type (essential—preferred or acceptable, and recommended—preferred)
- Brief explanation of the measure
- Equipment and supplies required to administer the measure
- Estimated time to complete the measure
- Number of items (if applicable)
- Procedures and instructions
- Reference documents

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- Links to the DCFs

**NOTE:** MISs for essential and recommended measures are located on the [ECHO-wide Cohort Data Collection Protocol Materials](#) page on SharePoint.

MISs for proprietary measures requiring secure access are located on the [ECHOPortal](#) with the associated DCFs, as applicable.

### 7.2 Understanding Proprietary Measures

The ECHO program has identified multiple measures that are proprietary and require a licensing agreement for use under the ECHO-wide Cohort Data Collection Protocol. The CC is responsible for obtaining, maintaining, and enforcing licensing agreements for these essential and recommended proprietary measures for cohorts that have identified using such measures.

Cohorts identifying use of these essential and recommended proprietary measures may administer the measure following the publisher's manual or handbook, as available; instructions from the publisher and within the MIS; and licensing agreement with the CC. The DAC has created DCFs, REDCap forms, data dictionaries, and processes that vary depending on the measure, for data capture and processing consistent with licensing agreements. Cohorts can use the systems and processes from the DAC without additional effort. For cohorts that decide to use their own systems for data entry, the CC may need to provide screenshots to the publisher showing adherence to the licensing agreement. In addition, the CC may establish a memorandum of understanding with the cohort site PI specifying the conditions under the licensing agreement.

An MIS is available for each proprietary measure, describing the tool; location of materials; administration approach; and instructions for administration, options for data capture, and any data processing steps for submission to the DAC. Research administrators must also refer to the publisher manual or handbook when available, for further instructions.

Proprietary measure MISs are located on the [ECHOPortal](#), with the associated DCFs, as applicable.

The DAC will work with each cohort to obtain collected data and will monitor cohort- and site-level use of the proprietary measures throughout the course of the study. DAC data systems will follow all licensing requirements established with the CC.

The CC will report proprietary measure usage to the publisher according to agreed-upon frequency.

The PRO Core provides Apple gift cards for cohorts to purchase National Institutes of Health Toolbox licenses.

[Table 4](#) provides a list of proprietary measures (in alphabetical order).

**Table 4. Proprietary Measures**

Achenbach System of Empirically Based Assessment Adult Self Report (ASEBA ASR)
Ages & Stages Questionnaires (21 age-appropriate assessments covering 2 months-60 months)
Block Kids Food Frequency Questionnaire (FFQ) 2004 (ages 8-17)
Block Kids Questionnaire (ages 2-7)
Child Behavior Checklist for ages 1.5-5 years (ASEBA CBCL - Preschool)
Child Behavior Checklist for ages 6-18 years (ASEBA CBCL - School Age)

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Conflict-Tactics Scales (CTS2 - Revised)
Conners Kiddie Continuous Performance Test Second Edition (Conners K-CPT2)
Conners 3rd Edition Attention-Deficit/Hyperactivity Disorder Index Child Self-Report (Conners 3AI-Self Report)
Conners 3rd Edition Attention-Deficit/Hyperactivity Disorder Index Parent Report (Conners 3 AI-Parent)
Family Environment Scales (FES) – Cohesion Subscale
Family Environment Scales (FES) – Conflict Subscale
National Institutes of Health (NIH) Toolbox For Assessment of Neurological and Behavioral Function
Patient-Reported Outcomes Measurement Information System (PROMIS) Measures
Social Responsiveness Scale Second Edition (SRS-2) Preschool (18 months-4 years)
Social Responsiveness Scale Second Edition (SRS-2) School Age (4-18 years)
Social Responsiveness Scale Second Edition (SRS-2) Adult (Relative/Other Report)
Strengths and Difficulties Questionnaire (SDQ) for Ages 2-4 years
Strengths and Difficulties Questionnaire (SDQ) for Ages 4-10 years
Strengths and Difficulties Questionnaire (SDQ) for Ages 11-17 years
Strengths and Difficulties Questionnaire (SDQ) Self-report for Ages 11-17 years
Strengths and Difficulties Questionnaire (SDQ) Self-report for Ages 18+ years
Vineland Adaptive Behavior Scales Third Edition Comprehensive version

### 7.3 Understanding the Data-Collection Forms

The ECHO-wide DCFs capture a subset of the essential and recommended data elements using preferred and acceptable measures as listed in the ECHO-wide Cohort Data Collection Protocol. DCFs do not include any performance-based assessments or proprietary measures that have copyright restrictions on production of DCFs.

**NOTE:** Research administrators can print and share copies of nonproprietary DCFs via the [ECHO Portal Resource Library](#).

#### 7.3.1 Study Staff Instructions

Each DCF includes instructions for form-completion that states who should complete the form, the life stages for which the form should be completed, and the participant identification (ID) that should be used (pregnant woman's participant ID or child's participant ID). Each DCF has an accompanying MIS for measure-specific instructions.

#### 7.3.2 Data-Collection Form Completion Guidelines

Only designated study personnel with the following qualifications may administer the DCFs:

- Designated by the ECHO cohort site PI
- Completed measure-specific trainings via ECHO Learning Management System. Refer to **MOP Chapter 2: Training Requirements**.

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### Data-Collection Form Headers

Cohort site staff should complete the header section of the DCF (first and subsequent pages) when administering the form. Greyed-out text indicates that the item is not applicable for the particular form. Following are instructions for each item:

- Cohort ID—Record the 5-digit cohort ID of the cohort that completes the form.
- Site ID—Record the 4-digit site ID of the cohort site that completes the form.
- Participant ID—Record the participant ID of the participant (child or pregnant woman) for whom you are collecting the form data.

**NOTE:** While we refer to a pregnant woman as a participant, we assign a "participant ID" for each pregnancy where data will be contributed to the ECHO-wide cohort. It is this pregnancy ID that we use in the header.

- PIN—Record the participant ID confirmation number of the participant for whom you are collecting form data. Participants will get their personal identification number during participant registration.
- Cohort Visit ID—Record the cohort visit ID indicating when the form was completed.

**NOTE:** The Visit ID is a cohort-specified descriptor of "visits" or "measurement occasions." This information was originally provided by cohorts through the Cohort Measurement Identification Tool survey, but cohorts or cohort sites may have updated the visits and visit descriptors using the cohort visits tool during the data transform process. When completing this box, it is important that the information conveyed is enough to select the appropriate formal visit name within the data systems. Shorthand notation is acceptable as long as it will be clear what visit to select in the data system.

- Form Completed—Record the date the form was completed in month/day/year (mm/dd/yyyy) format.
- ECHO Life Stage—Mark the box corresponding to the life stage of the participant when the form was completed.
- Respondent—Mark the box corresponding to the source who provided the information about the participant specified in the "Participant ID" field. If the respondent is not the participant themselves, choose either biological mother, biological father, or "other respondent" for other caregivers.
- Respondent Code—if "other respondent" is selected, record the roster code that is associated with the particular respondent who is listed on the Respondent Roster and Relationship to Child form.

**NOTE:** Cohort study staff must maintain a unique Respondent Roster to document all caregivers who have consented to contribute information about a child enrolled in the ECHO-wide cohort. All caregivers are assigned a roster code that corresponds to the sequential order in which that person was added to the Respondent Roster and Relationship to Child form. The roster is not a static list of codes that define the relationship of the caregiver to the child participant. Instead, the relationship is collected for each caregiver on the Respondent Roster and Relationship to Child form as new primary caregivers are consented to participate in the study. For example, if a grandmother is providing responses during visit 1, and a different grandmother is doing so for visit 2 (for the same participant), study staff will use a different respondent code for each of these individuals.

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### 7.3.3 Completing Administrative Data-Collection Forms

Administrative DCFs are available for cohort site staff to document various actions and events that impact data collection for a participant. These include Participant Registration – Pregnancy, Participant Registration - Child, Enrollment and Consent, Respondent Roster for the Child, Reportable Events, and Study Withdrawal/End of Study forms. Study staff will develop additional administrative DCFs as needed.

**NOTE:** Administrative forms containing form-completion instructions are located on the [ECHO Portal Resource Library](#).

### 7.4 Abstracting Data from Medical Records

**Training:** Medical records vary among providers. Research administrators will become familiar with common language and verbiage used by providers. Research administrators will complete training on data-collection processes for medical records abstraction via an LMS Course to ensure that personnel across all sites are able to complete the medical-record abstraction forms correctly and consistently.

**Table 5. Abstraction Forms**

Abstraction Form	Participant	Action During Consent
Birth/Neonatal  Child	Child	<ul style="list-style-type: none"><li>• Ask parent or guardian, as applicable, to complete a medical-record release for the child for each of the healthcare providers who would have data on the ECHO measures.</li><li>• Collect names and addresses of all healthcare providers (e.g., pediatricians, well-child clinics).</li></ul>
Maternal	Biological Mother	<ul style="list-style-type: none"><li>• Ask participant to complete a medical-record release for each of the healthcare providers and specialists who would have data on the ECHO measures.</li><li>• Collect names and addresses of healthcare providers and specialists.</li></ul>

**Contacting healthcare providers:** When requesting medical records from healthcare providers or specialists, consider the following:

- **Be professional.** It is extremely important to maintain professionalism throughout the entire process. In all phone, fax, email, and in-person exchanges with providers, be friendly and accommodating of their busy schedules. Be sure that all emails are professionally written and include a signature with contact information on the bottom.
- **Be confident.** Providers may be unfamiliar with the practice of requesting health records for the purposes of a research study. To ease any concerns and build trust, it is crucial to understand the study and the data-security procedures in place to maintain confidentiality with these data. Be prepared to confidently explain the main purpose of the study and why we are collecting health records.
- **Be strategically persistent.** Providers are very busy and may not want to go out of their way to help get these records. Help troubleshoot solutions to issues that arise and assist the providers. Follow up once a week until you are able to get the records. When providers push back about consents, remind them that we have done due diligence by

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getting IRB and/or institutional ethics committee approval for accessing and protecting the confidentiality of these records.

- **Be organized.** The process of obtaining these records to the final step of converting them to useable data is tedious. There are a lot of moving pieces to keep track of to ensure success. Keep track of all progress, double-check that files are being stored correctly, and report your progress and any issues to your supervisors and/or PI.
- **Be prepared.** For ease of reference, have access to IRB approval letters, a general HIPAA authorization template, and a summary of the Health Information Technology for Economic and Clinical Health Act. While it is unlikely that providers will need this information, it is helpful to have these documents available as a backup.

**Completing the forms:** Confirm that the medical records belong to the correct participant by comparing the participant's name, date of birth, and/or other identifying information, to information on the contact form. This is important because many people have similar names and record numbers.

Consider completing an initial review of the medical records before completing the abstraction. This allows the data collector to become familiar with the various forms and their order. It is not necessary to read everything in the chart. Data collectors will find relevant data items throughout the medical records.

Complete each section of the medical-record abstraction form as much as possible before going on to a new section, but return to a section if you discover additional information later.

### 7.5 Understanding Physical Measurements

Physical-measurement assessments include anthropometric (e.g., weight, height, waist circumference) and biological physical functioning (e.g., blood pressure, heart rate). Since routine calibration of instruments ensures accurate results by the equipment, research administrators should consider the following when conducting physical-measurement assessments:

- Calibrate weighing scales, stadiometer, and skinfold tools regularly using standard weights, height rods, and skinfold calibration blocks.
- For scales, calibrate at multiple points across the range of expected measurements using a set of standard weights.
- Calibrate new equipment upon receipt and at weekly intervals.
- Each site should develop calibration procedures tailored for the specific equipment they will be using.
- Incorporate manufacturer's instructions for maintenance and calibration into general guidelines.
- Maintain calibration records.
- Remove all potentially injurious jewelry (e.g., rings, watches, bracelets).
- Be aware of pens, pencils, and long fingernails. The only time a pen or pencil should be in hand is when recording a measurement.
- Wash hands (or use hand sanitizer) before and after measuring the participant.
- Always tell the participant what to expect and be cognizant of any sensitivity related to having to undress a child.

**NOTE:** For more details on anthropometric measurements, refer to the **Child Anthropometry & Physical Examination MIS**. For more details on remote collection of height, weight, and waist circumference measurements, refer to the **Caregiver Measured Anthropometrics MIS**.

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### 7.6 Administering Questionnaires

PRO questionnaires are a special type of questionnaire focused on self- and proxy-report measures of global, mental, physical, and social health. Questionnaires elicit participant-reported measures, unfiltered by others to the maximum extent possible. When a person cannot serve as a reliable reporter (e.g., young children or those with cognitive impairment), make accommodations to collect the data while maintaining the respondent's unfiltered response, as the assessment goal.

**NOTE:** For instructions and more information regarding mode of administration (e.g., self vs. interviewer, in-person vs. remote) for specific questionnaires, refer to **Section 6** and the **related MIS**.

#### 7.6.1 General Guidelines for Questionnaires

Given the variability in how ECHO cohorts will administer questionnaires, the following guidelines provide best practices to ensure scientific rigor and, to the extent possible, standardization of measure administration across the ECHO program.

- Confirm the participant signed the consent form. For children (<18 years), parent or caregiver consent and child assent are required.
- Whether self-administered or researcher-administered (i.e., by interview), responses should come directly from the participants and not be influenced by suggestions, hints, or interpretations from others.
- Provide an appropriate setting for participants. To the extent possible, ensure participants have a quiet and private location to complete questionnaires, or for interviewer-administered questionnaires, ensure that others nearby cannot hear the dialogue.
- Do not alter the question and response options. If participants do not understand a term or concept, instruct them to answer as best they can, without attempting to provide synonyms or definitions; doing so can unintentionally change the meaning of the items.
- It may not be necessary to remind the participant of the response options after reading every statement. Participants may offer their response without prompting. However, be cautious for measures that **change** response options for different statements, as these responses will need to be stated if they are not the same as the previous ones.
- Remain neutral about the content of participant responses, but positive in reference to participant cooperation. Take care to control voice, facial expressions, and body language. Try not to react to the participant's answer with positive or negative judgments, as this can influence future responses. To maintain good rapport, provide frequent, polite, and positive reinforcement, with statements such as: "You're doing fine," "Thank you," and "We really appreciate your participation."
- Remind caregivers to let children answer for themselves. If a caregiver starts to answer for the child, gently remind the caregiver that these questionnaires are specifically for the child to answer by him/herself. The researcher can say, "We are interested in learning about your child's health, development, and family context from your point of view and that of your child. You will each have an opportunity to share this with us. We ask that you let your child answer for him/herself, as our goal is to get his/her perspective (even if it's different from yours)."

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- It may be necessary to separate caregivers from children to avoid prodding. One strategy to avoid too much caregiver interference is to ask caregivers and children to complete questionnaires simultaneously in separate rooms or different areas of the same room. If multiple study personnel are available, have one work with the child and one with the caregiver to help avoid caregiver interference. Separate rooms are ideal when research administrators administer questionnaires aloud or when they pertain to the child's relationships with family members, the home environment, or risky behaviors.
- If a participant hesitates or refuses to answer a question, repeat the question. Say, "Let me go over that again. If you don't want to answer, that's your choice; but I need to ask each of the questions." Add that the participant's feelings or opinions about the question are important. If the participant still refuses, accept the refusal graciously and go on to the next question. Where possible, document reasons for incomplete data collection and refusals.
- For all questions related to the household of the ECHO child participants:
  - In cases where children may live in more than 1 household (e.g., as may be the case with shared custody or other childcare arrangements), answer the questions for the 1 household where the child resides most of the time.
  - In cases where children spend equal time in 2 households, answer the questions with respect to the household of the caregiver who is responding to the questionnaire.

### 7.6.2 Self-administered Questionnaires

#### 7.6.2.1 Paper and Pencil vs. Online

Self-administered questionnaires can be completed with paper and pencil, online, or when available, via an iPad app.

Paper-and-pencil questionnaires bring extra burden to study personnel—forms must be securely stored and data must be manually entered into the data-capture system.

#### 7.6.2.2 Remote vs. In-person

Remote administration (via survey link or mailed paper forms):

- Participants may complete measures on their own schedule, reducing the in-person time for both participants and study personnel.
- So that participants can find an appropriate setting to complete the measure, provide information on the content and an estimate of how long it will take to complete the questionnaire.
- Provide the study personnel contact information in case questions or problems arise with the self-administered forms.

In-person administration:

- Having participants complete questionnaires in person ensures they do so without being influenced by others and may reduce follow-up burden for study personnel.
- Depending on the structure of in-person visits, self-administered questionnaires can be used to fill downtime (e.g., between pre- and post-bronchodilation), particularly for caregiver questionnaires that research

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administrators can administer while the child engages in physical measurements and direct assessments.

- Study personnel should be available to answer any questions.
- After the participant completes the DCF and before the participant leaves the study site, the research administrator should review the form for completeness. If clarification or information is required, obtain it while the participant is present.

### 7.6.2.3 Researcher-Recorded Responses

If a participant is unable to physically record an answer for him/herself, it is acceptable for study personnel to ask the participant to choose a response, which the study personnel then record on behalf of the participant. Note special circumstances on the DCF by checking “Staff-administered” for the Mode of Administration in the DCF footer.

### 7.6.3 Researcher-administered Questionnaires

**Prepare for remote participation.** When in-person participation is not feasible, send materials to participants ahead of time so that they can follow along as the research administrator reads the questions and responses over the telephone.

For NIH Toolbox, please refer to the COVID-19 Remote Administration Guidelines, ECHO-wide Protocol Data Measures NIH Toolbox Remote spreadsheet, and the NIH Toolbox Participant and Examiner App reference materials located on the [NIH Toolbox Resources page on SharePoint](#).

**Read questions as written.** For example, if items use first-person pronouns such as “My” and “I” (e.g., “In the past 7 days, I had a problem with **my** sleep”), the researcher should use the same first-person pronouns, explaining to the participant as necessary.

**Use reference aids to optimize validity.** As mentioned above, provide participants with a copy of the questionnaire to read along with the research administrator (handing out or mailing in advance).

**Consider providing a “response card” that indicates response choices.** This strategy is particularly useful in cases where response options are lengthy (e.g., a list of symptoms, a list of income sources) or with younger children. However, since ECHO-wide Cohort Data Collection Protocol questionnaires employ several different sets of response options, handing out, mailing, or otherwise sending the actual questionnaires might be more advisable.

#### 7.6.3.1 Paper Administration

Cohort sites must retain all original completed paper forms for the duration of the ECHO-wide Cohort Data Collection Protocol. The DAC will notify cohort sites when all queries are addressed and original source documentation is no longer needed. Cohort sites should follow their institutional policy and government regulations (see Code of Federal Regulations-Title 21 for additional guidance) for record retention.

#### 7.6.3.2 Electronic Administration

- For site-specific data-capture systems, the cohort data manager, or designee, must ensure that the system has an audit trail of all data entry and changes. For security reasons, give only a select number of users “administrator”-level rights to a data-

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capture system. To not inadvertently delete information or change previously submitted data, restrict other users.

- In situations where electronic form completion is not feasible, e.g., power or Wi-Fi outages, you may reschedule the visit, or, if a paper form is available, you may complete the paper form, and the research administrator may transcribe it electronically when electronic form completion is available.

### 7.6.4 Child Self-Report vs. Proxy

**Age is one factor, but not definitive.** Child self-report measures generally start at age 8, with parent proxy versions for younger children. Additional considerations, such as reading ability, comprehension, and cognitive ability may require parent proxy questionnaires at older ages. Similarly, children younger than 8 years may have the capacity to self-report. The ECHO PRO Core is working on a method to identify these children and allow them to report on their own behalf. Until this is ready, the position is to have parents serve as proxy for children under 8.

Having the child self-report is ideal, particularly as children reach the tween and teenage years (i.e., 12 years and older). If a child self-report option is available and developmentally appropriate for the cohort's specific study sample, cohorts should use the child self-report versions. The MIS and DCF will provide specific guidance on the age for which the measure is valid. This should be a guiding principle in determining whether the child or caregiver serves as the respondent.

## 8 VISIT CHOREOGRAPHY

Visit choreography describes the flow of activities throughout the data-collection event, which includes pre-assessment, assessment, and post-assessment procedures (outlined in more detail below). It is important to follow the visit choreography and guidelines associated with each event in order for the event to run smoothly, to minimize the burden to the participant, and to collect all data in an efficient and accurate manner.

### 8.1 Choreographing Pre-assessment Procedures

Prior to the data-collection event, the research administrator should:

- Review records of contact.
- Mail any event materials (questionnaires, self-collection kits, etc.).
- Confirm all event equipment, materials, and supplies, and place orders as necessary.
- Prepare any materials needed for the event.
- Tell the participant what will occur during the measurement.
- Instruct the participant and/or caregiver that trained study personnel will collect the measures.
- Inform the participant that all measurements obtained are part of a research study and do not represent a medical diagnosis.

### 8.2 Choreographing Assessment Procedures

Because of differences in collection and availability of study personnel, the order of assessment is cohort-specific.

At the time of the data-collection event, the research administrator should:

- Complete informed consent or assent activities.
- Administer performance-based assessments and questionnaires.

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- Collect samples and measures quickly, but not as to negatively affect the accuracy of the measurement.

When administering direct-observation measures, the research administrator should:

- Review and be familiar with the assessments prior to your first observation.
- Observe the participant for the time specified either in the MIS or on the measurement instrument.
- Be objective and record only what you see; do not infer, interpret, or translate information.
- Do not consider the caregiver report when rating. Derive data for observation measures from direct observation of the participant.
- So as to not influence the participant's behavior, keep your voice and facial expressions neutral. If the administrator reacts to the participant's actions or responses, the participant may change his/her behavior based on changes in the administrator's voice or facial expressions.

### 8.3 Choreographing Post-assessment Procedures

Directly following the data-collection event, the research team should:

- Provide incentive to the participant.
- Process forms, questionnaires, and sample collections.

### 8.4 Reducing Participant Burden

Stack event components in a way that allows for a productive use of any downtime. For example:

- If you need a urine specimen, offer participants water at the start of the visit to make sure they can provide a sample before the visit is over.
- If you need a saliva specimen, remind the participant early in the visit that they cannot have anything to drink 30 minutes before they provide the specimen. Collect the saliva after 30 minutes or more, after you have offered them a drink.
- If you need a resting blood pressure, this is a perfect time to complete some questionnaires and then obtain the blood pressure.
- If both the child and the caregiver need to complete questionnaires, allow each to complete their questionnaire at the same time or while one of them is doing something else, if possible.

**NOTE:** Prior to a study visit, gather the needed equipment and supplies. For each measure, refer to **Section 4 Life Stage Visit** and the associated **MISs**.

### 8.5 Considering the Flow of Activities

To assist study personnel in completing all required activities in the correct order, cohorts should create a site-specific visit checklist for each study visit. Here are some points to consider when creating the checklist:

- Given that fatigue affects performance, complete performance-based measures such as cognitive testing early in the visit, before anthropometric measurements, questionnaires, and biospecimen collection.
- To help the participant gain a sense of trust with the staff, move from least-invasive to more-invasive procedures (e.g., in order of weight, vital signs, body measurements, collection of biologic samples).

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- For interviews, move from assessments that collect less-personal information to assessments that collect more-personal information, and end on a “fun” or positive assessment. This gives the participant a chance to build trust and gain comfort with the interviewer.
- Before starting any procedure, explain it to the participant. The explanation should be appropriate to the age and language development of the participant. When dealing with children and adolescents, speak directly to them rather than to the caregiver. Answer questions honestly.
- With children, it may be helpful to provide them with their own “checklist” and give stickers or checkmarks for each task completed. Research administrators can present the checklists in the form of a roadmap, a treasure hunt, or some other fun activity.
- Schedule break times during the visit and have snacks available, if needed.

### 8.6 Retaining Participants

Participant retention is critical to the success of the ECHO-wide cohort program. Research administrators must strive to maintain relationships with caregivers and provide a flexible schedule in conducting follow-up data collection.

To keep participants in the study and available to contact, at every encounter:

- Be friendly and courteous.
- Update address, phone, email, and emergency-contact information.
- Remind participants when you will be calling again.

Participants may refuse to participate in any or all parts of the study procedures at any time and may continue participation at a future visit. For example, if a participant refuses to answer specific questions, accept the refusal graciously and go on to the next question.

Where possible, document reasons for incomplete data collection and refusals.

Each cohort site should establish procedures for the acceptable modes of contact that are best suited for their participants. To assist with locating participants who may be lost to follow-up, we suggest the following:

- Call participant-provided contacts during evening or weekend hours.
- Review available hospital medical records for treating-physician names.
- Call the treating physicians and the primary care physician for additional information.

Check the internet to find patients who may have moved.

#### 8.6.1 Relocation

If participants relocate to an area from which it is no longer feasible to travel, we will ask one of the ECHO cohort sites for continued in-person visits to continue participation in the study by:

- Completing questionnaires remotely (online, via telephone)
- Providing biospecimens remotely when possible (via self-collection kits)
- Providing access to medical records

#### 8.6.2 Study Withdrawal

Participants may withdraw at any time over the course of the study. This may occur officially by formal notification from the family or caregiver to the investigator, or unofficially when a participant cannot be reached via the usual methods of contact. Make

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every effort to acquire complete data on all participants. However, a participant may withdraw consent for use of his or her own or child's data at any time.

If the participant or caregiver withdraws consent at any time for any reason, the research administrator should encourage the participant to document the details of their withdrawal, and the administrator should address the following:

- Use of previously collected data and unused biospecimens
- Permission to gather new data from medical records without participant contact
- Permission for future contact for vital-status updates

### 8.6.3 End of Study

Study participation ends when a participant completes the study, withdraws consent, or dies. For all participants, collect as much data and biospecimens as possible for the duration of the study.

To assist with documenting information about a participant's death, we suggest the following:

- Check the National Death Index to determine if a participant has died.
- Check vital records and register of deeds to obtain and verify date and location of death.
- Check newspaper obituaries for death information (public libraries are a resource for newspaper searches).
- Check [Ancestry.com](https://www.ancestry.com) for death information.

**NOTE:** When a participant discontinues participation in the ECHO-wide Cohort Data Collection Protocol, the research administrator should communicate conditions of the participant's withdrawal to the DAC by submitting the **Study Withdrawal/End of Study form**.

**NOTE:** All **administrative DCFs** are maintained on the [ECHOPortal Resource Library](#).

## 9 TRANSLATION GUIDANCE

Standardized assessment tools that were not created by ECHO will be translated into Universal Spanish (i.e., 1 translation that can be used for individuals from any Spanish-speaking country) where needed. Some standardized instruments may also be made available in additional non-English languages and are noted as such in the MIS. We will make available ECHO-specific assessment tools in English and Universal Spanish.

There should be no on-site interpretation done of any ECHO-wide cohort DCFs. Contact the CC for guidance on what to do if a participant/family requires a form in a language that is not available. Study personnel who have been trained and certified as medical interpreters should contact the CC to determine if they are eligible to interpret DCFs for completion. Using personnel or family members as ad-hoc interpreters is not permitted.

### 9.1 Children

Obtaining the most reliable information from participants is of great importance when determining the language that young children are most comfortable with in their daily life. It is particularly important for young children for whom language skills are just developing and for whom the school environment may play less of a central role. Many children will be exposed to

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one language in their home and another language at day care or school. Some families may switch between languages in day-to-day communication and throughout life stages.

Research administrators should use a standardized approach to determine the most appropriate language to use in bilingual or multilingual children.

### 9.2 Bilingual or Non-English-Speaking Caregivers

In addition to assessing the language most familiar to the child, it is also important to determine the primary language that is spoken or read in the home. The Language and Acculturation—Pregnancy Language and Acculturation—Childhood forms provide standardized questions to assess the language-of-choice spoken in the home.

### 9.3 When to Use Translated Forms

Research administrators should make every attempt to provide the assessment tools in the participant's primary language. Check the MIS to determine available translations for each tool. The CC will provide translations in Universal Spanish for measures not currently translated when permitted by the author or publisher as well as for other related participant-facing materials.

It is not acceptable for a study staff member or family member who speaks the language of the participant to translate the measure to the participant and then record the answer. Research administrators translating "on the fly" cannot guarantee the accuracy of the questions and responses.

## 10 SENSITIVE TOPICS

Many of the measurement tools used in ECHO ask participants about sensitive topics. It is important to obtain all data even in situations that may be uncomfortable.

When asking questions about family or home life, keep in mind that the participant may come from a difficult or atypical situation. This is especially true when working with the child participant, as they may struggle to explain the situation or ask for assistance if they are unsure how to respond.

Here are a few tips to remember when asking about family or home life:

- When appropriate, ask about family composition rather than making assumptions. It may be helpful to keep a tracking form for this, such as noting deceased or incarcerated parents. Be aware of divorce, remarriage (step-parent), single parent, and same-sex-couple situations. Use inclusive language and be aware of these possibilities.
- Be aware that a seemingly simple survey question can be difficult for someone whose family does not fit the "normal" mold. For example, a divorced mother with shared custody may have difficulty answering a questionnaire about their child's second home. An adopted child may be unsure of whether to answer questions about their adoptive or biological parents.
- Unless an assessment or questionnaire contains explicit instructions on the topic, it is important to take your cues from how the participant defines their family or home. The research administrator should be specifically trained on surveys that could pose questions or problems about family situations. These would include questions about family composition, income and finances, parent/child relationships, etc.

Research administrators are required to complete measure-specific training prior to administering the measure. Research administrators should practice their documentation and data-collection techniques. Topics considered sensitive will vary by participant age, gender, ethnicity, and socioeconomic status. For each participant, the research administrator should determine the topics to approach with sensitivity.

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General guidelines and approaches for dealing with sensitive topics are as follows:

- Conduct assessments in a setting where the participant has privacy to provide answers (verbal or written). All questionnaires could be completed in person using an interview format, but for sensitive topics, participants may choose self-administration due to the personal nature of the topics.
- Establish rapport and trust with the participant prior to discussing sensitive topics.
- Acknowledge that some of the questions may be sensitive. If the participant shows signs of embarrassment or fear, reassure them that there is no need to be.
- Let the participant know there are no right or wrong answers and there no judgment being made on the answers.
- Let the participant know the reason for asking the information and remind them that the information is being collected for research purposes and their answers will be combined with all other participants'.
- Be honest in telling the participant the level of confidentiality that you are able to maintain.
- Explain the safeguards in place to protect the participant's personal information.
- Use a nonjudgmental and neutral approach. Do not let your reactions show, by taking care to control voice, facial expressions, and body language so as to not appear to be reacting to the participant's answer in a positive or negative manner. Do not appear to agree or disagree with or approve or disapprove of the participant's answers.

### 10.1 Dealing with Challenging Topics: Deceased Child or Caregiver

If a child or caregiver dies during study participation, it will be necessary to collect information regarding the circumstances of the death on the Study Withdrawal/End of Study form. Refer to **Section 7.3.3**. Note that when the primary caregiver dies, a new caregiver will need to be consented to the study, if they choose to continue participation.

Discussing the death of a child or a caregiver takes a great deal of sensitivity and skill. The family is dealing with the ultimate tragedy, and answering questions about the death may be difficult.

Approaches that may facilitate the conversation include:

- Ensure you have the appropriate authorizations in place to obtain any records related to the death of the child or caregiver.
- It is essential that a firm arrangement is in place to ensure that the caregiver or child will be offered a chance to discuss the child's or caregiver's death with someone.
- Allow the surviving caregiver or child to speak openly, and try to focus on just listening. Try to avoid making statements such as, "I know what you are feeling," but try to reassure them that you empathize with how they are feeling.
- Allow for moments of silence.

Cohorts should establish general guidelines and approaches for dealing with grieving participants.

### 10.2 Dealing with Challenging Topics: Finances

Discussion of an individual's finances is often perceived as too personal, and participants may be reluctant to answer questions. As with other sensitive topics, there may be embarrassment, stigma, and influence of cultural and religious beliefs that influence the participant's level of comfort to discuss their personal finances.

Approaches that may facilitate the conversation include:

- Reassure the participant that their financial situation will not affect their ability to be in the study.

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- Be flexible and sensitive to work schedules or any other financial impact to study participation (e.g., time to participate, commuting costs).
- Generalize the experience to the participant. Let the participant know that the study personnel meet with participants from varied financial backgrounds.

### 10.3 Dealing with Challenging Topics: Home Address

Although asking for a participant's home address may seem like a simple question, it may be a sensitive topic. Reasons that participants may be reluctant to give an address include:

- **Housing insecurity:** The participant or family may be homeless, living in a shelter, or living with friends or family.
- **Legal issues:** The participant or family may be undocumented and afraid they might be deported, they may have pending legal actions, or they may have a restraining order against someone they fear will get their address.
- **Embarrassment:** The participant or family may be living in a perceived "bad area" or in conditions that they feel are embarrassing (residence is dirty or in poor repair).

Approaches that may facilitate the conversation include:

- Explain that ECHO is collecting addresses to understand how neighborhood conditions may affect child health. These include things like air pollution, population density, water quality, and safety. Having an address allows researchers to link to other sources that can provide that information.
- Reassure the participant that their living situation will not affect their ability to be in the study.
- If home visits are part of the assessments for the study, reassure the participant that the study personnel will only visit to gather specific research information and not to pass judgment on the living situation.
- Generalize the experience to the participant. Let the participant know that the study personnel meet with participants who are facing many difficult housing situations.
- Assure participants that their addresses will not be shared with anyone outside of ECHO.

### 10.4 Dealing with Challenging Topics: Sex and Sexuality

ECHO includes measures that assess sexual behavior. Given the sensitive nature of the information asked of the participant, it is vital that the research administrator effectively manage the situation. Approaches that may facilitate the conversation include:

- Assess your own comfort discussing sexuality and identify any biases that you may have. If you are uncomfortable talking about sex and sexuality, the participant may become uncomfortable, too.
- Avoid making assumptions about the participant's sex or sexuality based on age, appearance, marital status, or any other factor. Unless you ask, you cannot know the participant's sexual orientation, behaviors, or gender identity.
- Ask the participant for their preferred personal pronouns or terminology when talking to a transgender participant. Use those pronouns and support the participant's current gender identity.
- Allow the participant to speak openly about his/her sexual concerns and try to focus on just listening.
- Use neutral and inclusive terms (e.g., "partner").
- Ensure a shared understanding of the terms being used to avoid confusion. If the participant uses an unfamiliar term, ask for an explanation.

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### 10.5 Dealing with Challenging Topics: Sexual Abuse

A minor participant may spontaneously report abuse. Research administrators must know the local laws regarding reporting of abuse and follow those laws.

Be honest in telling the participant the local reporting requirements. There is much variation in reporting sexual activity based on the participant's age and whether the act was nonconsensual or consensual.

### 10.6 Dealing with Challenging Topics: Substance Use and Abuse

ECHO includes measures that assess substance use. Be aware that mothers may be particularly sensitive to questions regarding substance abuse during pregnancy. For both the caregiver and the child, there may be multigenerational or cultural patterns of substance abuse that influence their choices and views regarding substance use and/or abuse.

Approaches that may facilitate the conversation include:

- Understand and challenge personal beliefs, attitudes, stigma, and myths about substance abuse.
- Keep a file of drug and alcohol referral agencies in case the participant asks about how to get help with substance abuse.

### 10.7 Dealing with Challenging Topics: Traumatic Life Events

Over the term of the study, participants may experience a myriad traumatic life events—death of loved ones, medical issues, financial upheaval, relationship issues, legal problems, being a victim of crime, car accidents, natural disasters, or other situations that bring unwanted life changes.

Approaches that may facilitate the conversation include:

- Recognize that the participant has been through a stressful event and may need time and space to deal with the event or the aftermath.
- If the participant is having problems staying on track, gently redirect the conversation back to interview questions.
- Acknowledge the participant's achievements in completing the assessments.
- Do not appear distracted or rushed. Allow breaks if the participant seems overly distressed or preoccupied.
- Avoid offering simple reassurances such as, "I know how you feel" or "It will all work out."
- Acknowledge the participant's situation with statements like, "This is a really tough time for you" or "Things like this can be very overwhelming."
- Acknowledge that you understand how difficult it is to participate in the interview and thank the participant for his/her willingness to share information. Let the participant know that the information will be an important contribution to the research.

### 10.8 Dealing with Challenging Topics: Suicidal Ideation

Suicidal Ideation is any self-reported thoughts of engaging in suicide-related behavior. Suicide is where there is evidence (either implicit or explicit) that the cause of death was self-inflicted and the person intended to kill him/herself.

The likelihood of a positive endorsement of a suicide item is extremely low at age 6. However, if the caregiver responds, "Somewhat or Sometimes True" or "Very True or Often True" to this question, the research administrator administering the questionnaire should immediately do the following:

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- Inform the psychologist and/or physician
- Follow the institution’s referral practice, which may include:
  - Contacting the psychologist and/or physician
  - Performing a clinical assessment for suicide risk
    - If the risk is real and imminent: make immediate referral to the emergency room or call 911
    - If the immediate risk is low: make referral to a mental health provider (outpatient psychiatrist, etc.) in the child’s hometown

Approaches that may facilitate the conversation include:

- Understand and challenge personal beliefs, attitudes, stigma, and myths about suicide.
- Use clear definitions to identify, classify, document, and discuss suicidal behaviors.
- Allow the participant to speak openly and try to focus on just listening.
- Avoid providing quick solutions, which may leave the participant feeling misunderstood or dismissed.
- Assess for signs of acute distress and ask if the participant has plans, intentions, and means to act on his/her thoughts. Based upon assessment findings, administrators will take appropriate action per the table below.

**Table 6. Guidance for Responding to Suicidal and Homicidal Thoughts**

Individual at Risk	Imminent Danger*	Action
Self	No	<ul style="list-style-type: none"> <li>• Continue study activities, depending on level of emotional distress.</li> <li>• Offer a healthcare referral.</li> <li>• Offer contact details to National Suicide Prevention Hotline.</li> </ul>
Self	Yes	<ul style="list-style-type: none"> <li>• End study activities.</li> <li>• Offer contact details for the National Suicide Prevention Hotline.</li> <li>• Call 911 if the participant declines referral to a hotline.</li> <li>• Escalate to study managers and investigators.</li> </ul>
Other	Yes	<ul style="list-style-type: none"> <li>• End study activities.</li> <li>• Call 911.</li> <li>• Escalate to study managers and investigators.</li> </ul>

\*Homicidal or suicidal thoughts combined with plans, intention, or means to act on thoughts. Document event according to established cohort and institutional procedures.

**NOTE:** Refer to **Section 7.3.3 Completing Administrative DCFs** and **Section 11 Return of Results** for additional guidance.

### 11 RETURN OF RESULTS

The following information provides guidance for immediate response to clinically evident abnormalities identified during a clinic visit that may require attention.

Each cohort is responsible for:

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- Following established cohort procedures, state and local regulations, and institutional policies for reporting results and immediate health and safety issues as identified in or by participants engaged in the ECHO-wide Cohort Data Collection Protocol.
- Following established cohort procedures for initiating healthcare referrals to medical or mental healthcare providers as necessary, considering need for free or reduced-cost services.

#### 11.1 Physical and Anthropometric Measurements

Research administrators should follow established cohort procedures when providing participant results of blood pressure, heart rate, height, weight, or other anthropometric or routine clinical data collected during the visit.

Cohort procedures should include the following:

- Provide a brief explanation of the measurement.
- Explain that the measurement will be analyzed as data are collected over time, but not as single-point measurements.
- Explain actions for specific issues, i.e., elevated blood pressure.

Cohort procedures for identification of elevated blood pressure may include:

- If the research administrator and/or cohort site PI believes the participant is in **imminent danger**, he or she should call 911 for medical assistance.
- If the research administrator and/or cohort site PI believes the participant is **at serious risk**, notify the participant of the results and the need to see a healthcare provider immediately.
- If the research administrator and/or cohort site PI believes the participant is **at moderate risk**, give a copy of the results to the participant and initiate healthcare follow-up or a referral to a healthcare provider as necessary.

**Table 7. Blood Pressure Values That May Require Further Evaluation**

Age	Blood Pressure, mmHg			
	Boys		Girls	
	Systolic	Diastolic	Systolic	Diastolic
1	98	52	98	54
2	100	55	101	58
3	101	58	102	60
4	102	60	103	62
5	103	63	104	64
6	105	66	105	67
7	106	68	106	68
8	107	69	107	69
9	107	70	108	71
10	108	72	109	72
11	110	74	111	74
12	113	75	114	75
>13	120	80	120	80

2017 Clinical Practice Guidelines, American Academy of Pediatrics Subcommittee on Screening and Management of High Blood Pressure in Children [*Pediatrics* Vol 140(3), September 2017].

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Table 8 provides guidance on immediate actions and referrals based on children’s blood pressure results.

**Table 8. Blood Pressure Guidance from the National Health and Nutrition Examination Survey**

Level	Medical Findings
Level I	Major medical findings, e.g., dangerously high blood pressure, emergencies, that warrant immediate attention by a healthcare provider.
Level II	Major medical findings that warrant attention by a healthcare provider in the next 2 weeks because they are expected to cause adverse effects within this time period.
Level III	Minor medical findings that an examinee and his or her physician already know about. Medical findings that do not require prompt attention by the medical provider.

### 11.2 Harm to Self or Others

Harm to self or others may be expressed verbally or in writing, e.g., depression, suicidality, or other sensitive indicators, such as posttraumatic stress disorder, attention-deficit and/or hyperactivity disorder, conduct disorder, psychotic disorders, mood disorders with psychotic features, or adjustment disorders. During a child neurodevelopmental health and functioning assessment, the research administrator may identify suicidal tendencies.

When harm to self or others is identified, the research administrator should do the following:

- Notify the participant’s healthcare provider or initiate a healthcare referral according to established cohort procedures.
- If it is not safe for the participant to leave the visit (i.e., unreported or unresolved mistreatment in the home where the adolescent is afraid of injury; suicidal crisis where the participant has a plan, access, and intent; or revealing a pregnancy has precipitated a crisis), contact the proper authorities to ensure the safety of the participant or others.

### 11.3 Legal Reporting Requirements

Cohorts must follow established cohort procedures and state and local regulations for reporting pregnancy in minors and abuse- and neglect-related findings.

### 11.4 Concerning Results Warranting Referrals

Behavioral problems, developmental delays, discovery of hearing deficits, or other concerns that do not immediately threaten the health of the participant should be communicated to the participant according to established cohort procedures.

**NOTE:** For additional guidance for returning results on other measures, please contact the [CC Cohort Advocacy Team \(CAT\) Representative](#) at [ECHOCC@dm.duke.edu](mailto:ECHOCC@dm.duke.edu).

## 12 REMUNERATION

Per protocol, ECHO cohorts may reimburse participants for their time to participate in the ECHO-wide Cohort Data Collection Protocol. The degree of participant reimbursement will be at the discretion of each ECHO cohort (and commensurate with participant burden). The plan for participant remuneration must be included in the consent form and approved by the IRB and/or institutional ethics committee of record. Food and Drug Administration (FDA) guidance (Payment to Research Subjects-Information Sheet, *Office of Good Clinical Practice, Updated Jan. 25, 2018*) states the following:

“Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. Payment to research subjects for participation in studies is not considered a benefit that

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would be part of the weighing of benefits or risks; it is a recruitment incentive. FDA recognizes that payment for participation may raise difficult questions that should be addressed by the IRB. For example, how much money research subjects should receive and what subjects should receive payment for, such as their time, inconvenience, discomfort, or some other consideration. In contrast to payment for participation, FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging, to raise issues regarding undue influence. Other than reimbursement for reasonable travel and lodging expenses, IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subject's ability to give voluntary informed consent. Payment for participation in research should be just and fair. Present the amount and schedule of all payments to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence [21 CFR 50.20].”