



**Airway microbiome and age 6-year asthma phenotypes  
in a healthy infant cohort**

**(MARC-43/CHIME Study)**

**SITE MANUAL OF PROCEDURES**

Last updated: March 19, 2018

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# GENERAL INFORMATION

## Study ID assignment

Sites will assign all children enrolled in the study a unique, 6-digit Study ID number. The Study ID number is made up of a 3-digit site number (assigned by the EMNet Coordinating Center) plus a 3-digit participant number.

If you are uncertain of your site number, please email [afsullivan@partners.org](mailto:afsullivan@partners.org). Participant numbers should be assigned sequentially based on enrollment date and time, starting in the 700s. For example, the 26th patient from site 098 should be listed as “098726.”

## Site Roster

The site PI should email the Project Coordinator ([afsullivan@partners.org](mailto:afsullivan@partners.org)) a roster of all study staff (including site-specific study coordinators) and their contact information. All study staff must be approved to work on the study by their local IRB.

## Form Completion Schedule

All fully enrolled participants will have the following forms completed by site study staff: Screening Form, Pre-Visit Interview, Scheduling Form, Enrollment Form, Contact Form, Specimen Checklist, and the Tracking Form.

## Site Communication Plan

The EMNet Coordinating Center website ([www.emnet-usa.org](http://www.emnet-usa.org)) has a section dedicated to MARC-43. This website has the study protocol, materials, and other relevant information available for viewing and download. All site PIs have a username and password that enables them to access password-protected materials.

Study-wide announcements will occur through email. Should all sites need to receive additional documents, we will alert site PIs and study coordinators via email and the documents will be made available on the EMNet website for viewing and download.

The EMNet Coordinating Center will schedule periodic calls with sites post-initiation to assess progress throughout the study.

## Documentation that may be considered for chart screening

Reviewers may use any documentation that occurred while the patient was in the hospital/clinic/PCP visit.

## Decision rules for conflicting results

In cases when there is conflicting documentation, reviewer should prioritize certain providers' documentation based on the following rules:

- An Attending Physician's documentation should be used over a Resident Physician's documentation.
- Resident Physician over a Physician Assistant (PA) or Nurse Practitioner (NP)
- PA or NP over a nurse
- Nurse over a medical student

## Miscellaneous

Times: Time notations should be made based on the 24-hour clock. Valid times should be recorded as 00:00 (midnight) to 23:59. Please note that 24:00 is not a valid time.



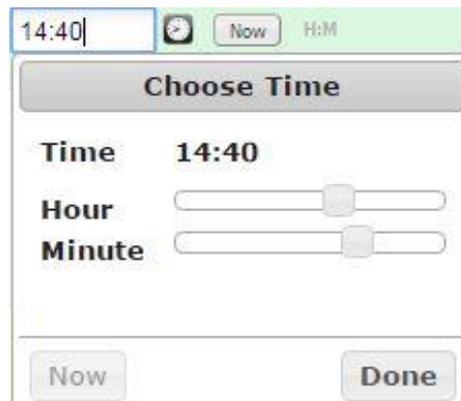
We recommend using the REDCap calendar feature to enter dates, rather than typing in dates. Click on the calendar function and click the date rather than typing the date. One also can click the “Today” button to enter the date on which the button is clicked.



Some questions require that the parent/legal guardian provide a date of an event (e.g., the date of a breathing problem). If they cannot remember the exact date and are not willing to provide an estimate, ask them in which month the event occurred. If they cannot identify the precise day in that month that the event occurred, enter the day as the 15<sup>th</sup> (i.e., the middle of the month).

#### *Times*

Click on the clock button to enter time. Another option is to click the “Now” button to insert the time at which the button is clicked. If you type the time, use military time format (HH:MM).



#### *Required Responses*

When saving a form, a pop-up screen will inform you if you have skipped any questions that are required. Please return to the skipped question(s) and provide a response. If one is unable to provide a response because the information is unavailable (e.g., not documented, question not answered by parent), leave the question blank. When one is ready to save the form as complete, initial the text box in the data confirmation section to communicate that responses to all blank questions are truly unavailable.

#### *Drop-down menus*

If an answer has been selected from the drop down menu but it needs to be changed to a different option, please type the answer in the box (making sure it's one of the available options) and it will be changed. Sometimes the drop-down menu options don't allow you to select a different option once one has already been selected. This can be corrected by simply typing the option (instead of trying to select it from the menu). For example, question 39 asks for the year of birth of the biological mother. If you selected "1984" but then wanted to change it to "1985", then you will need to type "1985" in the box so that the year appears.

### *Saving Data*

When saving each form, the form status must be categorized as "incomplete," "unverified," or "complete" as follows:

Click "Incomplete" if there are no data entered and you want to exit the form. You may also exit by clicking "cancel." The button for this form will remain red on the data entry event grid.

Click "Unverified" if any fields are pending responses (i.e., the form partially filled out). The button for this form will turn yellow on the data entry event grid.

Click "Complete" only if all fields have responses. The button for this form will turn green on the data entry event grid. Please do not mark a form with no data entered into it as "complete."

Remember to click the "Save" or "Save and Continue" button when you are done regardless of whether the form is complete or incomplete. REDCap is programmed to time-out after 30 minutes, please be sure to save data frequently.

In particular, save data before trying to move to any new screens or forms! Do not click on the back or forward arrows at the top left hand portion of the screen (the browser arrows). Any unsaved data will be lost.

# SPECIFIC FORM INSTRUCTIONS

## Screening Form

The screening form should be filled out for anyone screened.

### *Screening Form*

| <b>#</b> | <b>Question</b>                                    | <b>Instructions</b>   |
|----------|--|---|
|          | <b>Screening ID</b>                                | The Screening ID is a number automatically assigned by REDCap. Please note that this is NOT the Study ID.   |
|          | <b>Interviewer Initials</b>                        | Enter the initials of the person completing the Screening Form.<br><br>If the person does not have a middle name, use X for the middle initial.<br><br>Example:<br>Jane A. Jones: J A J<br>Sam Smith: S X S   |
|          | <b>Date</b>  | Enter the date of the screening in MM/DD/YYYY format.   |
|          | <b>Enter all patients screened via phone</b>       | Make sure you enter the data in REDCap for every participant you speak with over the phone and screen.  |
|          | <b>Does the patient have any of the following?</b> | Check ALL that apply<br><br>Check “Child <28 days old or ≥1 year old” if child is younger than 28 days or older than one year<br><br>Check “Child born more than 8 weeks early (<32 week pregnancy)” if child was born more than 8 weeks early (pregnancy that lasted less than 32 weeks)<br><br>Check “Child has known heart-lung disease, immunodeficiency, immunosuppression, or chronic gastrointestinal disorder (except for reflux and/or constipation)” if you identified one of these diseases while reviewing the child’s medical record<br><br>Check “Child has a documented previous episode of lower respiratory tract infection that resulted in a hospital admission” if you identify a previous episode of lower respiratory tract |



## Screening Form

| #  | Question  | Instructions   |
|----|---|--|
|    | <b>Call participant</b>   | <p>Use the following script to introduce the parent to the study:</p> <p>We are conducting a research study at [<i>site name</i>] on healthy children. Dr. _____ suggested your child, [<i>child</i>], would be a good candidate to participate [<i>insert description of any prior recruitment methods used – e.g., and you should have received a letter from his/her office</i>]. The goal of the study is to learn more about the normal bacteria that live in the nose, mouth, and intestine of healthy infants and how they relate to the health during childhood. May I tell you more about it?</p> <p><i>If No, stop here.</i><br/><i>If Yes, proceed to script in REDCap.</i></p> |
|    | <b>Does this sound like something you would be willing to do, and would be interested in learning more about?</b> | <p>Enter “Yes” if parent is interested in learning more about the study.</p> <p>Enter “No” if parent is not interested in learning more about the study.</p> <p><i>If No, stop here.</i></p> <p><i>If Yes,</i><br/>Thank you for your interest. Based on information from Dr. __, I believe [<i>child</i>] is eligible for this study, but before I tell you more about it, I am going to ask you some questions to make sure [<i>he/she</i>] is eligible.</p>   |
| 1. | <b>I would like to confirm that you are the parent or legal guardian of [<i>child</i>]. Is that correct?</b>      | <p>Enter “Yes” if person on the phone is the child’s parent or legal guardian.</p> <p>Enter “No” if person on the phone is not the child’s parent or legal guardian.</p> <p>You may continue with the rest of the questions only if the child’s parent or legal guardian is the one on the phone.</p>  |
| 2. | <b>Does [<i>child</i>] have any medical problems</b>  | <p>Enter “Yes” if the parent reports that the child has medical problem.</p> <p>Enter “No” if parent reports no medical problems.</p>  |

Screening Form

| #  | Question                  | Instructions  |
|----|---------------------------|---|
|    |                           | If the parent reports that the child has a medical problem, continue to question 2a to determine if the child is eligible to participate.   |
| 2a | <b>Medical Conditions</b> | <p>If “Yes” to question 2:</p> <p>Check “Chronic lung disease” if the child has bronchopulmonary dysplasia (BPD), cystic fibrosis (CF), or congenital lung malformation.</p> <p>Check “Congenital heart disease” if the child has a heart condition that causes shortness of breath, cyanosis, etc (i.e., heart disease that is hemodynamically significant and would complicate bronchiolitis management and/or result in cardiorespiratory problems during first 6 years of life). This includes congenital heart syndromes such as tetralogy of Fallot, transposition of the great arteries, valve anomalies, and truncus arteriosus, among others.</p> <p>Check “Immunodeficiency” if the child has any immunodeficiency. This includes primary immunodeficiencies like severe combined immunodeficiency disorder (SCID), Bruton’s a gammaglobulinemia, common variable immune deficiency (CVID), Wiskott-Aldrich, DiGeorge, Chediak-Higashi, among other syndromes. Select this option if the child has any other secondary or acquired immunodeficiencies such as AIDS.</p> <p>Check “Immunosuppression” if the child is taking any immunosuppressive medications such as glucocorticoids, methotrexate, azathioprine, interferons, ciclosporin among others.</p> <p>Check “chronic gastrointestinal disorder” if the child has a GI disorder. This includes celiac disease, short bowel syndrome, Hirschsprung, among others. Please do NOT include reflux and constipation as a “chronic gastrointestinal disorder.”</p> <p>If any of the above conditions are checked, the child is not eligible; however, continue to answer all of the questions on this form.</p> |

## Screening Form

| #  | Question  | Instructions   |
|----|---|--|
|    |   | <p>Check "Other" if there is another medical problem mentioned and describe the medical problem under "specify." If "Other" is checked, one must make a decision whether or not the condition identified is one that makes the child ineligible for the study.</p> <p>If there are no medical conditions, enter "No" for question 2 and continue with the screening form.</p>  |
| 3. | <p><b>Was [child] born more than 8 weeks before his/her due date (&lt;32 weeks of pregnancy)?</b></p> | <p>Enter "Yes" if child was born more than 8 weeks before his/her due date (a pregnancy lasting less than 32 weeks)</p> <p>Enter "No" if child was born at 32 weeks or after 32 weeks.</p>   |
| 4  | <p><b>Telephone Number</b></p>  | <p>Answer "Yes" if the parent has a telephone number that is always in service. This may be a cell phone or a land line.</p> <p>Answer "No" if the parent/legal guardian does not have a telephone number that is always in service.</p> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p>   |
| 5  | <p><b>Permanent address</b></p>   | <p>Answer "Yes" if the parent/legal guardian has a permanent address.</p> <p>Answer "No" if the parent/legal guardian lives at any of the following locations:</p> <ul style="list-style-type: none"> <li>• homeless shelter</li> <li>• half-way house</li> <li>• nursing home</li> <li>• psychiatric treatment facility</li> <li>• correctional facility</li> </ul> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p> |
| 6  | <p><b>Stay in Current Location</b></p>  | <p>Answer "Yes" if the parent/legal guardian plans to live at their current residence for the next 12 months. Consider this question as the parent's best estimate about whether or not they will stay in the same place.</p>  |

Screening Form

| # | Question                     | Instructions  |
|---|------------------------------|---|
|   |                              | <p>Answer "No" if the parent/legal guardian plans to move in the next 12 months.</p> <p>You may enroll parents who are <u>college students</u> even if they do not plan on staying at the same address for 12 months as long as they meet the other eligibility criteria. You also may enroll <u>military personnel</u> if they meet all other eligibility criteria and do not expect to be deployed in the next 12 months. You may also enroll families planning to move <u>locally</u> within the next 12 months. By a local move, we mean one that does not require a change in PCP.</p> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p> |
| 7 | <b>Email Address</b>         | <p>Answer "Yes" if the parent has an email address that he/she expects to use for the next 12 months.</p> <p>Answer "No" if the parent does not have an email address or one which he/she will not use for the next 12 months.</p> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p>  |
| 8 | <b>Primary Care Provider</b> | <p>Answer "Yes" if the child has a PCP, either a pediatrician, family doctor, or nurse practitioner that the parent expects to use for the next 12 months. By primary care, we mean coordinated, comprehensive, longitudinal care (including prevention). The PCP is usually one person but may be a clinic.</p> <p>Answer "No" if the child does not have a PCP at all or if the child has a PCP, but the parent does not expect to use this PCP in the next 12 months.</p> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p>  |

## Screening Form

| #  | Question  | Instructions   |
|----|---|--|
| 9  | <b>Willing to Provide Alternate Contact Information</b> | <p>Answer "Yes" if the parent is willing to give the phone number of an alternate contact to reach in case study personnel lose contact with the parent. The alternate contact information itself will be recorded at the enrollment visit on the Contact Form.</p> <p>Answer "No" if the parent is not willing to give an alternate contact's phone number.</p> <p>If "No," the child is not eligible; however, continue to answer all of the questions on this form.</p>   |
| 10 | <b>Admitted for a breathing problem</b>                 | <p>Enter "Yes" if the child was admitted overnight to a hospital because of a breathing problem. The child is not eligible; however, continue to answer all of the questions on this form.</p> <p>If the child was admitted never admitted overnight to a hospital because of a breathing problem, answer "No."</p> <p>If "Yes," the child is not eligible; however, continue to answer all of the questions on this form.</p>   |
| 11 | <b>Eligibility</b>                                      | <p>REDCap will provide a prompt to let you know if the child/parent/legal guardian is eligible. This is based on the following eligibility criteria:</p> <ul style="list-style-type: none"><li>• Child less than 1 year old</li><li>• Child has a gestational age <math>\geq</math> 32 weeks</li><li>• Child has none of the medical conditions specified</li><li>• Parent/legal guardian has a phone always in service</li><li>• Parent/legal guardian has a permanent address</li><li>• Parent/legal guardian plans to stay where they live for the next 12 months</li><li>• Parent/legal guardian has an email address they expect to use for the next 12 months</li><li>• Child has a PCP that parent/legal guardian plans to use for the next 12 months</li></ul> |

## Screening Form

| #  | Question                      | Instructions  |
|----|-------------------------------|---|
|    |                               | <ul style="list-style-type: none"> <li>• Parent/legal guardian willing to provide us with the contact information of an alternate contact</li> <li>• Child never admitted to a hospital because of a breathing problem</li> </ul> <p>If the potential participant is ineligible, the form is complete.</p> <p>If a potential participant is confirmed eligible after answering the Screening Form questions and the parent is interested in the study, proceed with an explanation of the study and the in-person visit.</p>  |
| 11 | <b>Diaper instructions</b>    | <p>Enter "Yes" if the parent/guardian would like to have the diaper instructions e-mailed or faxed.</p> <p>Enter "No" if the parent/guardian doesn't want the instructions e-mailed/faxed.</p> <p>If "Yes", select the preference from the drop down:</p> <ol style="list-style-type: none"> <li>1. email</li> <li>2. fax</li> </ol> <p>Enter the specific e-mail address/fax number of the parent.</p>   |
| 12 | <b>Willing to participate</b> | <p>Enter "Yes" if parent agrees to participate Proceed with scheduling the in-person visit (checking the date/time they have a scheduled visit to come into the practice/hospital).</p> <p>Enter "No" if parent is unwilling to participate in study.</p> <p>Check all the reasons why parent is unwilling to participate from the drop down (check all that apply):</p> <p>Check "Burdensome to collect and bring in child's diaper" if parent doesn't want to participate because they don't want to bring in a diaper.</p> <p>Check "Do not have time to do in-person interview" if parent doesn't want to come in for an in person visit due to time constraints.</p> |

## Screening Form

| #  | Question                  | Instructions   |
|----|---------------------------|--|
| 13 | <b>Questions</b>          | <p>Check "Other" for any other reason besides the ones listed above; please specify the reason.</p> <p>Enter "Yes" if parent has any questions and answer his/her question about study and visit logistics.</p>  |
| 14 | <b>Interview</b>          | <p>Enter "No" if parent has no questions.</p> <p>Enter "Yes" if parent is available to complete the phone interview now.</p> <p>Enter "No" if parent is unavailable to complete the phone interview at this time.</p> <p><u>If Yes</u>, proceed to enrollment telephone interview form.</p> <p><u>If No</u>, enter date parent would like you to call back and time preference, selecting from the drop down:</p> <ol style="list-style-type: none"><li>1. Morning</li><li>2. Afternoon</li><li>3. Evening</li><li>4. Specific time – enter the exact time.</li><li>5. Anytime</li></ol> <p>Enter any information that will help complete the call at a later time in the Comments section</p>   |
| 15 | <b>Was Child Enrolled</b> | <p>You will need to come back to the Screening Form if the parent signs the consent form. Complete this question after the parent has come to the enrollment in-person visit and signed a consent form. <b>Please leave this question blank until the participant signs a consent form during the enrollment visit.</b></p> <p>Answer "Yes" if the parent consented to participating in the main study and mark whether or not the parent consented to the genetics portion of the study. Assign a Study ID (see instructions below for details)</p> <p>Answer "No" if the parent decides not to participate in the study. Ask the parent if they will explain what made them decide not to participate in the study. If necessary, clarify that this is to better document the enrollment process, and that the parent does not have to</p> |

## Screening Form

| # | Question        | Instructions  |
|---|-----------------|---|
|   |                 | give a reason. Check the reason that is mentioned as the biggest factor in the parent's decision and specify any such reason that is not already listed on the form.  |
|   | <b>Study ID</b> | <p>If the child is enrolled in the study, manually enter the next available Study ID number. This is a unique study identification number used to identify participants throughout the study. The Study ID number is made up of a 3-digit site-specific number followed by a 3-digit study participant number, starting in the 700s, and continuing in sequential order based on enrollment date/time. For example, the 10th participant for site 098 will be 098710.</p> <p>If you are uncertain of the 3-digit site-specific number, email <a href="mailto:afsullivan@partners.org">afsullivan@partners.org</a>.</p> <p>To determine the next available Study ID, one can consult the Study ID numbers in REDCap, a list kept on-site, or use the next sheet of labels.</p> <p>Enter the Study ID number in the Screening Form. All participants who have a signed consent should be assigned a Study ID.</p> |
|   | <b>Comments</b> | Enter any important information regarding the screening call here.  |

## Enrollment Telephone Interview Form

This form should be completed for any eligible subject who agrees to complete the interview prior to the in-person visit. If the parent is screened and enrolled in person on the same visit, the enrollment telephone interview may be completed after the in-person visit.

### *Enrollment Telephone Interview Form*

| <b>#</b>                              | <b>Question</b>                    | <b>Instructions</b>   |
|---------------------------------------|------------------------------------|---|
|                                       | <b>Screening ID</b>                | The Screening ID is a number automatically assigned by REDCap. Please note that this is NOT the Study ID.   |
|                                       | <b>Interviewer Initials</b>        | <p>Enter the initials of the researcher completing the Visit Form.</p> <p>If the researcher does not have a middle name, use X for the middle initial.</p> <p>Example:<br/> Jane A. Jones: J A J<br/> Sam Smith: S X S</p>  |
|                                       | <b>Interview date</b>              | Enter the date of the Enrollment Telephone Interview in MM/DD/YYYY format.  |
|                                       | <b>Beginning of Time Interview</b> | Enter the time at which this Enrollment Telephone Interview began in military time format (HH:MM).  |
|                                       | <b>Who interviewed</b>             | <p>Enter "Mother (biological)" if the biological mother of the child participated in the enrollment interview.</p> <p>Enter "Mother (non-biological)" if the non-biological mother of the child participated in the enrollment interview.</p> <p>Enter "Father" if the father of the child participated in the follow-up interview.</p> <p>Enter "Legal Guardian" if the legal guardian completed the follow-up interview. Specify the relationship. Enter "Grandparent" if the grandparent is the legal guardian. Enter "Sibling" if a sibling is the legal guardian. Enter "Other" if the relationship of the legal guardian to the child is not presented. Specify the relationship.</p> |
| <i>Section A: General Information</i> |                                    |   |
| 1                                     | <b>Date of Birth</b>               | Enter the child's date of birth in a MM/DD/YYYY format.   |

*Enrollment Telephone Interview Form*

| <b>#</b> | <b>Question</b>        | <b>Instructions</b>   |
|----------|------------------------|---|
| 2        | <b>Age Check</b>       | <p>You must answer this question before continuing with the rest of the form. Questions later will appear or not appear depending on the answer to this question.</p> <p>Enter "Yes" if 6 months or more have passed since the child's date of birth.</p> <p>Enter "No" if less than 6 months have passed since the child's date of birth.</p>  |
| 3        | <b>Sex</b>             | <p>Enter male if the child is male.</p> <p>Enter female if the child is female.</p>   |
| 4        | <b>Hispanic Origin</b> | <p>Enter "Yes" if the child is of Hispanic, Latino, or Spanish origin.</p> <p>Hispanic refers to peoples having origins in Mexico, Puerto Rico, Cuba, Central America, South America, or any other Spanish-American culture or origin. Persons of Hispanic origin may be of any race.</p> <p>Enter "No" if the child is NOT of Hispanic or Latino origin.</p>   |
| 5        | <b>Race</b>            | <p>Check all options that apply for the child's stated race.</p> <p>If the child's race is "Other" please specify the race. Please do not list an ethnicity or nationality under this category.</p> <p>Check "Refused" if the parent refused to answer the question. Using the information available to you, enter the child's race, in your opinion, in the box provided. Use the medical record and all other clues available.</p> <p>Note: People of Hispanic/Latino origin may be of any race and should answer the question on race by selecting one or more race categories shown on the form (White, Black or African American, American Indian and Alaska Native, Asian, Native Hawaiian and Other Pacific Islander, or Other Race). Hispanics should indicate their ethnic origin in the Hispanic question, not in the race question, because in NIH and other federal agencies consider ethnic origin a separate concept from race.</p> |

*Enrollment Telephone Interview Form*

| # | Question         | Instructions   |
|---|------------------|--|
|   |                  | <p>If a subject reports that he/she is of Latino/Hispanic origin and their race is "other: Hispanic" or "other: Latino" please ask follow-up questions to determine the category of race (e.g., white Hispanic).</p> <p>Please refer to the following definitions:</p> <p>White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.</p> <p>Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian", "Caribbean", "West Indian", "African", or "Ethiopian" can be used in addition to "Black or African-American."</p> <p>Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)</p> <p>Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p> <p>American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.</p> |
| 6 | <b>Insurance</b> | <p>Enter the type of health insurance that covers the child.</p> <p>Enter "Public" if the child's health insurance is public (e.g., Medicaid, state children's health insurance program (CHIP)) and go to 6a.</p> <p>Enter "Private" if the child's health insurance is through a private company. This includes both HMO (Kaiser) and Non-HMO (Blue Cross/Blue Shield) health insurance. Other examples of health insurance companies are Unitedhealth and Aetna, Humana.</p> <p>Enter "None" if the child does not have health insurance.</p>  |

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| #                                  | Question                        | Instructions  |
|------------------------------------|---------------------------------|---|
|                                    |                                 | Enter "UKN" if the parent does not know the type of health insurance. Remember, please do not read UKN as an option.  |
| 6a                                 | <b>Type of public insurance</b> | If the parent answered Public to the type of health insurance in Q6, you need to specify the type of public insurance that the child has. Check all that apply. |
|                                    |                                 | Check "Medicaid" if the child is covered under Medicaid.  |
|                                    |                                 | Check "State children's health insurance program" if the child has this insurance program, also known as CHIP.  |
|                                    |                                 | Check "Other" if the insurance covering the child is another type of public insurance not listed and specify (e.g. Canadian national health insurance).         |
|                                    |                                 | Check "UKN" if the parent does not know the type of health insurance.   |
| <i>Section B: Child's Lifetime</i> |                                 |   |
| 7                                  | <b>Child's birth weight</b>     | Enter the child's weight at birth using the weight ranges provide. Weight in kilograms is provided in parentheses.  |
|                                    |                                 | Enter "UKN" if the person interviewed does not know the child's birth weight.   |
| 8                                  | <b>Gestational Age</b>          | Select option for number of weeks of pregnancy at which the child was born.   |
|                                    |                                 | Enter "UKN" if person interviewed does not know the child's gestational age.  |
|                                    |                                 | If more than 8 weeks early (<32 week pregnancy) the child is not eligible for study. Read the script on REDCap and end interview with the parent.               |
|                                    |                                 | Skip to section G and record that the patient was found to be ineligible.   |
| 9                                  | <b>Neonatal Acute Care</b>      | Enter "Yes" if the child was kept in an intensive care unit (ICU, NICU), premature nursery, or other special care facility when he/she was born.                |

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| #   | Question                           | Instructions   |
|-----|------------------------------------|--|
| 10  | <b>Immunizations</b>               | <p>Enter “No” if the child was NOT kept in an intensive care unit (ICU, NICU), premature nursery, or other special care facility when he/she was born. Also enter “No” if the child was kept in such a facility for a very short time (e.g., less than 2 hours).</p> <p>Enter “UKN” if the person interviewed does not recall if the child received any intensive or special care after delivery.</p>        |
| 11  | <b>Influenza vaccine</b>           | <p>Explain to the parent that the influenza vaccine is the flu shot.</p> <p>Enter “Yes” if the child has EVER received the influenza vaccine and go to Q11a.</p> <p>Enter “No” if the child has NEVER received the influenza vaccine.</p> <p>Enter “UKN” if the parent does not know if the child has received the influenza vaccine.</p>  |
| 11a | <b>Influenza vaccine doses</b>     | <p>Enter “1 dose” if the child received one dose of the influenza vaccine this season.</p> <p>Enter “2 doses” if the child received two doses of the vaccine this season.</p> <p>Enter “not applicable (zero doses this season)” if the child has not received a vaccine dose this season.</p> <p>Enter “UKN” if the parent cannot remember if the child received 1 or 2 doses of the influenza vaccine.</p> |
| 11b | <b>Last Influenza vaccine dose</b> | <p>Enter “&lt; 1 month ago” if the child received the last influenza vaccine dose less than 30 days ago.</p> <p>Enter “≥ 1 month ago this season” if the child received the last influenza vaccine dose more than a month ago, but during the current flu season.</p>  |

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| #   | Question                                    | Instructions  |
|-----|---|---|
|     |   | <p>Enter "Last season" if the child received his last influenza vaccine dose the previous flu season.</p> <p>Enter "UKN" if the parent is not sure when the child received the last influenza vaccine dose.</p>   |
| 12  | <b>Palivizumab (Synagis) use</b>            | <p>This is a monoclonal antibody used to specifically target the respiratory syncytial virus (RSV). Enter "Yes" if the child has <u>EVER</u> had an injection of palivizumab and go to Q12a.</p> <p>Enter "No" if the child has never had an injection of palivizumab.</p> <p>Enter "UKN" if the parent does not know if the child has ever had a shot of palivizumab.</p>                        |
| 12a | <b>Palivizumab (Synagis) Last dose</b>      | <p>Enter "&lt; 1 month ago" if the child received a palivizumab shot less than 30 days ago.</p> <p>Enter "≥ 1 month ago this season" if the child received a palivizumab shot more than a month ago.</p> <p>Enter "UKN" if the parent is not sure when the child received a Palivizumab dose.</p>   |
| 13  | <b>Overnight Admission</b>                  | <p>Enter "Yes" if the child has ever previously been admitted to the hospital overnight.</p> <p>Enter "No" if the child has NOT been previously admitted to the hospital overnight. Also enter "No" if the child has been previously admitted to the hospital, but not overnight.</p> <p>Do not count an overnight stay in a NICU or special care nursery at birth as an overnight admission.</p> |
| 14  | <b>Number of breathing problem episodes</b> | <p><u>Read the breathing problem definition before asking this question.</u></p> <p>Enter the number of times the child has had a breathing problem. Include this illness in the number of times the child has had a breathing problem (i.e., the answer will be at least 1).</p>   |
| 14a | <b>Admission for breathing problem</b>      | <p>Enter "Yes" if parent reports that child has been admitted to a hospital for a breathing problem in the past.</p>  |

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| #      | Question                                  | Instructions  |
|--------|---|---|
|        |   | Enter "No" if parent reports no admission to a hospital for a breathing problem.  |
|        |   | NOTE: If the answer to this question is different than the one given at the Screening Form, please describe the discrepancy in the Comment box at the end of the form. Do not change answers previously reported on the Screening Form. |
|        |   | If "Yes", child is not eligible to participate in study. Read script, end interview, and skip to section G.   |
| 15     | <b>Episode</b>                            | This section has a series of questions that will be answered for each episode.  |
| 15.1   | <b>Breathing Problem start</b>            | Enter the day in which the breathing problem of interest started. Use MM/DD/YYYY format.  |
| 15.2   | <b>Breathing Problem still ongoing</b>    | Enter "Yes" if the breathing problem being described is still ongoing.  |
|        |   | Enter "No" if the described problem is not still going on and go to Q15.2.1.  |
| 15.2.1 | <b>Breathing Problem duration</b>         | If the breathing problem is not ongoing, enter the total number of days that this breathing problem lasted.   |
|        |   | If the breathing problem lasted 1 day, please clarify with the parent if the breathing problem lasted "<1 day," "Exactly 1 day," or "Between 1-2 days" (if the breathing problem lasted more than one day, but less than two).          |
| 15.3   | <b>Breathing Problem affect sleep</b>     | Enter "Yes" if this breathing problem affected the child's sleep. This could mean that the breathing problem woke the child up from sleep or interfered with the child's ability to sleep his/her regular hours.                        |
|        |   | Enter "No" if this breathing problem did not affect the child's sleep.  |
| 15.4   | <b>Breathing Problem Infectious Cause</b> | Enter "Yes" if the parent believes that the breathing problem was caused all or in part by a cold or other acute respiratory infection.   |
|        |   | Enter "No" if the parent does not believe that the breathing problem was caused all or in part by a cold or other acute respiratory infection.  |

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| <b>#</b> | <b>Question</b>                                 | <b>Instructions</b>  |
|----------|---|--|
| 15.5     | <b>Visit to hospital or doctor's office</b>     | <p>Enter "Yes" if the child went to a hospital or visited a doctor's office or other healthcare provider to get care for this particular breathing problem.</p> <p>Enter "No" if the child did not visit a hospital or doctor's office or other healthcare provider to get care for this breathing problem.</p>  |
| 15.5.1   | <b>Type of Provider Seen</b>                    | <p>Indicate the type of care received for this breathing problem by checking the relevant boxes. If the child was seen by more than one type of provider, check all that apply. For example, if the child went to the emergency room and was then admitted, check "Emergency room visit" and "Admitted to a hospital".</p> <p>*NOTE: "Admitted to hospital" would make the child <u>ineligible</u>. If the type of facility is not listed (e.g., clinic) mark "Other." Please note that the primary care provider for a participant could be a clinic. In that case, you would always indicate this as the PCP and not in the "Other" category.</p> <p>We are interested only in visits prompted by the breathing problem. We are not interested in scheduled "well visits" or other healthcare visit where the child happened to have a breathing problem at the time of the visit, but the breathing problem was not the reason for the visit. However, if a parent reported a breathing problem where they <u>would have taken the child to the doctor</u> but did not because an appointment was already scheduled for the next day, etc., please count this.</p> <p>If child was admitted to a hospital, the participant is ineligible, end call and continue to section G.<br/>                     If child went to the emergency room, go to Q15.5.1a.<br/>                     If child visited a breathing specialist, go to Q15.5.2a.<br/>                     If child visited PCP, go to Q15.5.3a.<br/>                     If child went to another healthcare provider, go to Q15.5.4a.</p> |
| 15.5.1a  | <b>ER visit Frequency for breathing problem</b> | Enter the number of times that the child went to the emergency room for this breathing problem.  |
| 15.5.1a1 | <b>ER name &amp; Location</b>                   | For each ER visit, enter the hospital's name and the location.   |
| 15.5.1a2 | <b>ER visit Date</b>                            | Enter the date in which this ER visit took place using MM/DD/YYYY format.  |

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| <b>#</b> | <b>Question</b>                                | <b>Instructions</b>   |
|----------|--|---|
| 15.5.1a3 | <b>Doctor's Office visit before ED visit</b>   | Enter "Yes" if the child was seen at a doctor's office or clinic before going to an emergency room. Then, enter the office/clinic's name and the location.<br><br>Enter "No" if the child was not seen by a doctor at an office or clinic before going to the emergency room.   |
| 15.5.2a  | <b>Breathing Specialist Visit Frequency</b>    | Enter the number of times in which the child visited a breathing specialist for this breathing problem. A breathing specialist could be a pulmonologist or allergist. Do not include visits to breathing specialist that might have led to a hospital admission or ED visit that were discussed in previous questions.  |
| 15.5.2a1 | <b>Specialist Name/Location</b>                | For each specialist visit, enter the specialist's name and the location in which he/she practices.  |
| 15.5.2a2 | <b>Specialist Visit Date</b>                   | Enter the date in which this specialist visit took place using a MM/DD/YYYY format.   |
| 15.5.3a  | <b>Primary Care Provider Visit Frequency</b>   | Enter the number of times in which the child visited a primary care provider for this breathing problem. A PCP could be a family medicine physician, pediatrician, or nurse practitioner. The PCP is usually one person but may be a clinic.<br><br>Do not to include previous visits to the PCP that might have led to a hospital admission or ED visit, and were documented previously. |
| 15.5.3a1 | <b>PCP Name/Location</b>                       | For each PCP visit write the PCP's name and the location in which he/she practices.   |
| 15.5.3a2 | <b>PCP Visit Date</b>                          | Enter the date on which this PCP visit took place using a MM/DD/YYYY format.  |
| 15.5.4a  | <b>Other Visit Frequency</b>                   | Enter the number of times in which the child visited any other type of healthcare provider not already documented.  |
| 15.5.4a1 | <b>Other Healthcare Provider Name/Location</b> | For each other healthcare provider visit, write the provider's name and location in which he/she practices.   |
| 15.5.4a2 | <b>Other Healthcare Provider Visit Date</b>    | Enter the date on which this other healthcare provider visit took place using the MM/DD/YYYY format.  |

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| <b>#</b> | <b>Question</b>                                    | <b>Instructions</b>   |
|----------|--|---|
| 15.6     | <b>Inhaled Bronchodilator use</b>                  | <p>When reading this question, explain to the subject that an “inhaled bronchodilator” is a quick-relief puffer or nebulized treatment such as albuterol (Ventolin, Proventil) or levalbuterol (Xopenex). Patients may know inhaled bronchodilators as a “rescue medicine.”</p> <p>Enter “Yes” if the child used an inhaled bronchodilator at anytime before, during, or after this breathing problem and go to Q15.6.1. This includes use during healthcare visits.</p> <p>Enter “No” if the child did not use an inhaled bronchodilator at any point during the breathing problem and go to Q15.7.</p>  |
| 15.6.1   | <b>Number of times treated with bronchodilator</b> | <p>Enter the maximum number of times in which the <b>parent</b> treated the child with an inhaled bronchodilator in one day. This does <b>not</b> include treatment during healthcare visits by doctors/nurses/etc.</p> <p>Count 1 time as:</p> <ul style="list-style-type: none"><li>- 1 puff from an inhaler</li><li>- 1 nebulized treatment</li></ul> <p>We are aware that one nebulized treatment has more albuterol than one MDI inhalation.</p> <p>Equivalency is complicated by many factors and our goal here is to simply assess the number of treatment attempts by the parent, which usually will be measured by number of MDI inhalations.</p> <p>If the parent tried to give a treatment, but said that they weren’t sure if their child actually got any medication (e.g., child was not cooperative during treatment), we will assume that at least part of the treatment was received. Accordingly, include the attempted treatment in the count.</p> |
| 15.6.2   | <b>Number of days treated with bronchodilator</b>  | <p>Enter the number of days that the child received at least one treatment with an inhaled bronchodilator for this breathing problem.</p>   |
| 15.6.3   | <b>Nebulizer use</b>                               | <p>Enter “Yes” if the child used a home nebulizer to take an inhaled bronchodilator at any point during this breathing problem.</p>   |

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| #       | Question   | Instructions   |
|---------|--|--|
| 15.7    | <b>Inhaled corticosteroid use</b>                                | <p>Enter “No” if the child did not use a home nebulizer to take an inhaled bronchodilator at any point during this breathing problem.</p>  |
| 15.7.1  | <b>Inhaled corticosteroid use before breathing problem start</b> | <p>We want to know if the child was on regular inhaled corticosteroid treatments in the days BEFORE this breathing problem began. By “in the days before” we mean at any point in the week leading up to the breathing problem.</p> <p>Enter “Yes” if the child received regular treatments of inhaled corticosteroids in the days before this breathing problem began and go to Q15.7.1a.<br/>Enter “No” if the child did not receive regular treatments with inhaled corticosteroids in the days before this current breathing problem began and go to Q15.7.1c.</p> <p>Enter “UKN” if the parent is does not know if the child received an inhaled corticosteroid in the days before this current breathing problem and go to Q15.7.1c.</p> |
| 15.7.1a | <b>Inhaled corticosteroid use</b>                                | <p>We would like to know the type of use <u>prescribed</u> for this inhaled corticosteroid reported in Q15.7.1. Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• “Daily, year-round” if the prescribed use is for every day year round.</li> <li>• “Daily, seasonally” if the prescribed use is daily, but limited to only seasonal periods.</li> </ul>   |

| <b><u>Inhaled Corticosteroids</u></b> |                    |             |                    |              |
|---------------------------------------|--------------------|-------------|--------------------|--------------|
| Advair                                | Azmacort           | Budesonide  | Flunisolide        | Symbicort    |
| Advair Diskus                         | Asmanex Twisthaler | Ciclesonide | Fluticasone        | Triamcinolor |
| Aerobid                               | Beclomethasone     | Dulera      | Mometasone         | Vanceril     |
| Aerobid-M                             | Beclivent          | Flovent     | Pulmicort Respules | Qvar         |

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| #                  | Question   | Instructions  |
|--------------------|--|---|
| 15.7.1b            | <b>Additional burst of inhaled corticosteroids</b>     | <ul style="list-style-type: none"> <li>• “With colds” if the prescribed use is limited to the period in which the child has a cold.</li> <li>• “Other” if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• “UKN” if the parent does not know the prescribed use.</li> </ul> <p>Note that this question assesses <u>prescribed</u> use, not actual use or compliance with prescribed use.</p>   |
| 15.7.1b<br>(1,2,3) | <b>Short burst of inhaled corticosteroids received</b> | <p>We would like to know more about the receipt of this additional dose of inhaled corticosteroid. Choose ONE of the following.</p> <p>Enter “Yes” if the child received a short burst at a higher dose and then continued on a usual dose of preventive inhaled corticosteroid and specify the number of days this short burst lasted.</p> <p>Enter “Yes” if the child received a short burst at a higher dose and then continued on a higher than usual regular dose of preventive inhaled corticosteroid and specify the number of days that this short burst lasted.</p> <p>Enter “Yes” if the child received a short burst and then stopped inhaled corticosteroids (e.g., changed to another medication) and specify the number of days that this short burst lasted.</p> <p>Enter “UKN” If the parent does not know how the additional burst of inhaled corticosteroids was administered.</p> <p>Proceed to Q15.8.</p> |

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| <b>#</b>        | <b>Question</b>   | <b>Instructions</b>  |
|-----------------|---|--|
| 15.7.1c         | <b>Inhaled Corticosteroids NOT USED BEFORE breathing problem</b>                                    | <p>We would like to know if the child started inhaled corticosteroids as a part of the immediate treatment of the breathing problem.</p> <p>Enter “Yes” if the child started to receive inhaled corticosteroids as part of immediate treatment for this breathing problem and go to Q15.7.1c(1,2,3).</p> <p>Enter “No” if the child did not start inhaled corticosteroids as a part of immediate treatment and go to Q15.7.1.c4.</p> <p>Enter “UKN” if the parent does not know if the child received inhaled corticosteroids as immediate treatment for this breathing problem and go to Q15.7.1.c4.</p>  |
| 15.7.1c (1,2,3) | <b>Short burst of inhaled corticosteroids received for immediate treatment of breathing problem</b> | <p>If the child starts received inhaled corticosteroids for the immediate treatment of this current breathing problem (answered “Yes” to Q15.7 and no to Q15.7.1), we would like to know more about the administration of this medication. Choose from ONE of the following.</p> <p>Enter “Yes” if the child received a short burst of the inhaled corticosteroids and then stopped and specify the number of days this short burst lasted and go to Q15.8</p> <p>Enter “Yes” if the child received a short burst at a higher dose and then continued on a lower dose of preventive inhaled corticosteroids and specify the number of days this short burst lasted. Go to Q15.7.1.3a.</p> <p>Enter “Yes” if the child started a long term treatment with a preventive inhaled corticosteroid with the same dose throughout and go to Q15.7.1.3a.</p> <p>Enter “UKN” If the parent does not know how the burst of inhaled corticosteroids was administered.</p> |
| 15.7.1.3a       | <b>Inhaled corticosteroid use</b>   | <p>If answer was “Yes” to Q15.7.1c2 or Q15.7.1c3, we would like to know the type of use <u>prescribed</u> for this inhaled corticosteroid.</p> <p>Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• “Daily, year-round” if the prescribed use is for every day, year-round.</li> </ul>   |

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| #         | Question   | Instructions   |
|-----------|--|--|
| 15.7.1c4  | <b>Start preventive inhaled corticosteroids AFTER breathing problem</b>  | <ul style="list-style-type: none"> <li>• “Daily, seasonally” if the prescribed use is daily, but limited to only seasonal periods.</li> <li>• “With colds” if the prescribed use is limited to the period in which the child has a cold.</li> <li>• “Other” if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• “UKN” if the parent does not know the prescribed use.</li> </ul> <hr/> <p>Enter “Yes” if the child started regular treatment with preventive inhaled corticosteroids in the days AFTER this breathing problem * and go to Q15.7.1c4a.</p> <p>Enter “No” if the child did not receive preventive inhaled corticosteroids in the days AFTER this breathing problem and go to Q15.8.</p> <p>Enter “UKN” if the parent does not remember or know if inhaled corticosteroids started after the breathing problem began.</p> <p>* Please make sure the parent is aware that we are asking after the breathing problem started, if this treatment was given during the breathing problem please go back to Q15.7.1c.</p> |
| 15.7.1c4a | <b>Use of inhaled corticosteroid use AFTER breathing problem started</b> | <p>If child did not start an inhaled corticosteroid as immediate treatment for a breathing problem (no to Q15.7.1c) but did start treatment with inhaled corticosteroids after this breathing problem (“Yes” to Q15.7.1c4), we would like to know the prescribed use.</p> <p>Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• “Daily, year-round” if the prescribed use is for every day, year-round.</li> <li>• “Daily, seasonally” if the prescribed use is daily, but limited to only seasonal periods.</li> <li>• “With colds” if the prescribed use is limited to the period in which the child has a cold.</li> <li>• “Other” if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• “UKN” if the parent does not know the prescribed use.</li> </ul>   |

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| #             | Question   | Instructions   |             |                |         |            |             |        |           |         |               |                    |              |             |
|---------------|--|--|-------------|----------------|---------|------------|-------------|--------|-----------|---------|---------------|--------------------|--------------|-------------|
| 15.8          | <b>Oral or Intravenous (IV) corticosteroid use</b> | <p>Explain to the parent that the corticosteroids of interest in this question are administered differently than inhaled corticosteroids. This question asks about corticosteroids administered either orally (pills or syrup) or an intravenously (injected). Examples of oral or intravenous (systemic) corticosteroids are below.</p> <div data-bbox="732 512 1406 638" style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p><b>Oral or Intravenous Corticosteroids</b></p> <table border="0"> <tr> <td>Decadron</td> <td>Hydrocortisone</td> <td>Orapred</td> <td>Prednisone</td> </tr> <tr> <td>Depo-Medrol</td> <td>Medrol</td> <td>Pediapred</td> <td>Prelone</td> </tr> <tr> <td>Dexamethasone</td> <td>Methylprednisolone</td> <td>Prednisolone</td> <td>Solu-Medrol</td> </tr> </table> </div> <p>Enter “Yes” if the child received oral or IV corticosteroids in the days before, during or after this breathing problem and go to <i>Q34h1</i>.</p> <p>Enter “No” if the child did not receive oral or IV corticosteroids before, during or after this breathing problem and go to <i>Q15.9</i>.</p> | Decadron    | Hydrocortisone | Orapred | Prednisone | Depo-Medrol | Medrol | Pediapred | Prelone | Dexamethasone | Methylprednisolone | Prednisolone | Solu-Medrol |
| Decadron      | Hydrocortisone                                     | Orapred  | Prednisone  |                |         |            |             |        |           |         |               |                    |              |             |
| Depo-Medrol   | Medrol   | Pediapred  | Prelone     |                |         |            |             |        |           |         |               |                    |              |             |
| Dexamethasone | Methylprednisolone                                 | Prednisolone   | Solu-Medrol |                |         |            |             |        |           |         |               |                    |              |             |
| 15.8.1        | <b>Days prescribed oral corticosteroids</b>        | <p>Enter the number of days the child was prescribed oral corticosteroids. Consider all in-hospital use as prescribed treatment. Include TOTAL course (clinic + ED + hospital + post-hospital).</p> <p>Enter “Intravenous only” if the child did not receive a prescription for oral corticosteroids, but was treated with IV corticosteroids only.</p> <p>Enter “UKN” if the parent does not know how the corticosteroids were prescribed.</p>  |             |                |         |            |             |        |           |         |               |                    |              |             |
| 15.8.2        | <b>How often systemic corticosteroids taken</b>    | <p>Enter the frequency that the prescribed oral corticosteroids were <u>actually taken</u>. Consider all in-hospital use as prescribed treatment. Include TOTAL course (clinic + ED + hospital + post-hospital).</p> <p>Select from the following options:</p> <ul style="list-style-type: none"> <li>- All of the time</li> <li>- Most of the time</li> <li>- Sometimes</li> <li>- Rarely</li> <li>- Never</li> <li>- Intravenous only</li> <li>- UKN if the parent does not know</li> </ul>  |             |                |         |            |             |        |           |         |               |                    |              |             |

*Enrollment Telephone Interview Form*

| #       | Question  | Instructions   |
|---------|---|--|
|         | <b>Use of Montelukast (Singulair)</b>                                   | <p>Enter "Intravenous only" if the child did not take oral corticosteroids because he/she was treated with IV corticosteroids only.</p> <p>Enter "UKN" if the parent does not know how often the corticosteroids were taken.</p>   |
| 15.9    | <b>Use of Montelukast (Singulair)</b>                                   | <p>Enter "Yes" if the child received Montelukast (Singulair) in the days before, during or after this breathing problem and go to Q15.9.1.</p> <p>Enter "No" if the child did not used Montelukast (Singulair) in the days before, during or after this breathing problem. If so, go to Q16.</p>   |
| 15.9.1  | <b>Use of Montelukast (Singulair) BEFORE start of breathing problem</b> | <p>Enter "Yes" if the child was on Montelukast (Singulair) as a regular treatment before the current breathing problem began and go to Q15.9.1a.</p> <p>Enter "No" if the child was not on regular treatment with Montelukast (Singulair) before this current breathing problem began. If so, go to Q15.9.1c.</p> <p>Enter "UKN" if the parent does not know if the child was on regular treatment with Montelukast (Singulair) and go to Q15.9.1c.</p>  |
| 15.9.1a | <b>Prescription for Montelukast (Singulair) type of use</b>             | <p>We would like to know how montelukast (Singulair) was prescribed for use before the breathing problem began.</p> <p>Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• "Daily, year-round" if the prescribed use is for every day, year-round.</li> <li>• "Daily, seasonally" if the prescribed use is daily, but limited to only seasonal periods.</li> <li>• "With colds" if the prescribed use is limited to the period in which the child has a cold.</li> <li>• "Other" if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• "UKN" if the parent does not know the prescribed use.</li> </ul> |
| 15.9.1b | <b>Additional montelukast for episode</b>                               | <p>If the child received montelukast (Singulair) before the breathing problem began, we would like to know if he/she received an additional dose of this medication for this breathing problem episode.</p>  |

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| #                | Question  | Instructions  |
|------------------|---|---|
| 15.9.1b<br>(1&2) | <b>Dose of additional burst of montelukast (Singulair)</b>            | <p>Enter “Yes” if the child received additional montelukast to treat this episode and go to Q15.9.1b(1&amp;2).</p> <p>Enter “No” if the child did not receive additional montelukast for this episode and go to Q16.</p> <p>Enter “UKN” if the parent does not know if the child received additional montelukast for this episode and go to Q16.</p>  |
| 15.9.1c          | <b>Start montelukast as immediate treatment for breathing problem</b> | <p>If the child took montelukast (“Yes” to question 15.9) but was not on regular treatment with this medication before this breathing problem began (no to question 15.9.1), we would like to know if this medication was used as an immediate treatment for this breathing problem.</p> <p>Enter “Yes” if the child started montelukast as part of his/her immediate treatment of this breathing problem. If so, go to Q15.9.1c(1,2&amp;3).</p> <p>Enter “No” if the child did not start montelukast as part of his/her immediate treatment of this breathing problem. If so, go to Q15.9.1c4.</p> <p>Enter “UKN” if the parent does not know if the child started montelukast as part of his/her immediate treatment of this breathing problem.</p> |

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| <b>#</b>           | <b>Question</b>   | <b>Instructions</b>  |
|--------------------|---|--|
| 15.9.1c<br>(1,2&3) | <b>Short burst of montelukast (Singulair) received</b>                  | <p>If the child was not on regular treatment before the breathing problem began (no to Q15.9.1) but started montelukast as part of the immediate treatment of this particular breathing problem (answered “Yes” to Q15.9), we would like to know how montelukast was administered.</p> <p>Select from the following options:<br/>Enter “Yes” if the child received a short burst of montelukast and then stopped and specify the number of days this short burst lasted.</p> <p>Enter “Yes” if the child received a short burst at a higher dose and then continued on a lower dose of montelukast (preventive) and specify the number of days this short burst lasted and go to <i>Q15.9.1c3a</i>.</p> <p>Enter “Yes” if the child started a long term treatment with a preventive montelukast with the same dose throughout and go to <i>Q15.9.1c3a</i>.</p> <p>Enter “UKN” If the parent does not know how the burst of montelukast was administered.</p> |
| 15.9.1c3a          | <b>Type of montelukast prescription</b>                                 | <p>If the child started on long-term treatment with montelukast following its use as part of an immediate treatment for this breathing problem, specify how it was prescribed for long-term use.</p> <p>Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• “Daily, year-round” if the prescribed use is for every day year-round.</li> <li>• “Daily, seasonally” if the prescribed use is daily, but limited to only seasonal periods.</li> <li>• “With colds” if the prescribed use is limited to the period in which the child has a cold.</li> <li>• “Other” if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• “UKN” if the parent does not know the prescribed use.</li> </ul>   |
| 15.9.1c4           | <b>Start preventive montelukast (Singulair) AFTER breathing problem</b> | <p>Enter “Yes” if the child started regular treatment with preventive montelukast (Singular) in the days AFTER this breathing problem began* and go to <i>Q15.9.1c4a</i>.</p> <p>Enter “No” if the child did not start preventive montelukast in the days AFTER this breathing problem and go to <i>Q16</i>.</p>   |

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| #         | Question  | Instructions   |
|-----------|---|--|
| 15.9.1c4a | <b>Type of montelukast prescription AFTER breathing problem started</b> | <p>Enter "UKN" if the parent does not remember or know if regular treatment with montelukast started after the breathing problem began and go to Q16.</p> <p>* Please make sure the parent is aware that we are asking after the breathing problem started, if this treatment was given during the breathing problem please go to Q15.9.1c.</p> <p>If the child did not start montelukast as part of his/her immediate treatment for this breathing problem (no to Q15.9.1c) but did start treatment with montelukast after this breathing problem ("Yes" to Q15.9.1c4), we would like to know how montelukast was prescribed.</p> <p>Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"> <li>• "Daily, year-round" if the prescribed use is for every day year-round.</li> <li>• "Daily, seasonally" if the prescribed use is daily, but limited to only seasonal periods.</li> <li>• "With colds" if the prescribed use is limited to the period in which the child has a cold.</li> <li>• "Other" if other use is prescribed. Specify the way in which the medication was prescribed.</li> <li>• "UKN" if the parent does not know the prescribed use.</li> </ul> |
| 16        | <b>Total length of time (in weeks) of use of medications</b>            | <p>Enter the total length of time (in weeks) that the child took the following medications for <i>any reason</i>:</p> <ol style="list-style-type: none"> <li>a) inhaled corticosteroids</li> <li>b) systemic corticosteroids</li> <li>c) montelukast</li> <li>d) antibiotics</li> </ol> <p>If the child started a medication, but took it for less than 7 days, enter "1". Round down one week if a child took the medication for less than half a week. For example, if the child took a medication for 10 days, enter "1." Round up to the next week if a child took the medication for more than half a week. For example, if the child took a medication for 11 days (i.e. 4 days into second week), enter "2".</p> <p>***NOTE: Do not change the answer to "d.Antibiotics" after asking the next question Q17 even if clear that answers discordant. We want to ask this question alone to allow direct comparison with same question in MARC-35.</p>   |

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| #                                  | Question   | Instructions  |
|------------------------------------|--|---|
| 17                                 | <b>Oral, intravenous, or intramuscular antibiotics</b> | <p>Enter “Yes” if the child received oral, intravenous, or intramuscular antibiotics for any reason, including when he/she was in a newborn nursery. Continue with question 17a</p> <p>Enter “No” if the child did not receive oral, intravenous, or intramuscular antibiotics for any reason, including when he/she was in a newborn nursery. Continue with question 18.</p> |
| 17a                                | <b>Antibiotic illnesses</b>                            | Enter the number of illnesses for which the child received antibiotics. For each illness, complete questions 17b and 17c.   |
| 17i                                | <b>Antibiotic name</b>                                 | Enter the name of the antibiotic  |
| 17ii                               | <b>Antibiotic days</b>                                 | For each illness, enter the number of days the antibiotic was taken.  |
| 17b                                | <b>Recent antibiotic</b>                               | Enter the most recent date that the child took an antibiotic.   |
| 18                                 | <b>Eczema or atopic dermatitis</b>                     | <p>Eczema is another name for atopic dermatitis. Study personnel should describe eczema as an itchy scaly rash that comes and goes.</p> <p>Enter “Yes” if the child has a history of atopic dermatitis.</p> <p>Enter “No” if the child does not have a history of atopic dermatitis.</p>  |
| <i>Section C: Parents and Home</i> |  |   |
| 19                                 | <b>Adults currently living at home</b>                 | <p>Enter the number of adults that currently live in the same home as the child. Adults living in the home do not have to be related to the child to be included in this count. Consider anyone 18 years old or older as an adult.</p> <p>If the child splits his/her time evenly between two homes (e.g., 50/50 custody), enter the higher count between the two homes.</p>  |

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| <b>#</b> | <b>Question</b>                                     | <b>Instructions</b>  |
|----------|---|--|
| 20       | <b>Specify adults' relationship</b>                 | <p>Identify the relationship of the all adults who live in the home to the child. Check ALL THAT APPLY from the following options:</p> <ul style="list-style-type: none"><li>• Mother</li><li>• Father</li><li>• Other parent, including a step or foster parent</li><li>• Sibling, if there are any adult siblings living at home</li><li>• Grandparent</li><li>• Other, if there is any other adult living at the same house. Specify his/her relationship to the child. If there is more than one adult with an "Other" relationship, specify the relationships of each adult</li></ul>                     |
| 21       | <b>Number of children younger than 18 years old</b> | <p>Enter the number of children that currently live in the same home as the child, INCLUDING the child. Children living in the home do not have to be related to the child to be included in this count. Consider anyone less than 18 years a child.</p> <p>If the child enrolled splits his/her time evenly between two homes (e.g., 50/50 custody), enter the higher count between the two homes.</p> <p>If any non-enrolled child lives in the home part-time (e.g., parent has shared custody of a child from a previous relationship), include this child in count.</p>                                   |
| 22       | <b>Cat at home</b>                                  | <p>This question asks about the home environment from the time the child was born until the time of this interview.</p> <p>Enter "Yes" if there was a cat in the child's home at any point from the time he/she was born until now. Also enter "Yes" if the parent reports that the child lived in more than one home (e.g., child lives part-time with one parent and part-time with the other [joint custody]) and there was a cat in one or more of the homes where the child lived.</p> <p>Enter "No" if there was not a cat in the child's home at any point from the time he/she was born until now.</p> |

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| <b>#</b> | <b>Question</b>                                | <b>Instructions</b>   |
|----------|--|---|
| 23       | <b>Dog at home</b>                             | <p>This question ask about the home environment from the time the child was born until right before they turned one year old (age 0-11.99 months).</p> <p>Enter “Yes” if there was a dog in the child’s home at any point during the first year of the child’s life. Also enter “Yes” if the parent reports that the child lived in more than one home (e.g., child lives part-time with one parent and part-time with the other [joint custody]) and there was a dog in one or more of the homes where the child lived.</p> <p>Enter “No” if there was not a dog in the child’s home at any point during the first year of the child’s life.</p>   |
| 24       | <b>Regular child contact with farm animals</b> | <p>This question asks about contact with farm animals from the time the child was born until the time of the interview.</p> <p>Enter “Yes” if the child had regular (at least once a week, on average) contact with farm animals from birth until now. The type of farm animal is not important; the child may have had contact with only a single type of animal (e.g., lived on a cattle farm) or different types of animals.</p> <p>Enter “No” if the child did not have regular (at least once a week, on average) contact with any type of farm animal from birth until now.</p>   |
| 25       | <b>Building where child lives</b>              | <p>Enter the type of building where the child currently lives.</p> <p>Enter “Detached house/single family/duplex/row house” if the child’s primary residence is described as a single-family house, or a detached house, or as a “duplex” (more than one family living in a home), or as a “row house” (houses, side-by-side, attached to each other). Include any home that is divided into units, even if there are more than two units in that building (e.g., a three story house with three separate units),</p> <p>Enter “Apartment/Flat” if the child’s primary residence is described as an apartment or flat (includes multi-level apartments with one family).</p> <p>Enter “Trailer” if the child’s primary residence is described as a trailer.</p> |

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| #  | Question  | Instructions   |
|----|---|--|
|    |   | <p>Enter "Other" if the child's primary residence is not described as any of the above. Specify the type of residence (e.g., houseboat).</p> <p>If the child enrolled splits his/her time evenly between two homes (e.g., 50/50 custody), enter "Other" and provide details.</p> <p>If a parent indicates that their building is a shelter, motel, or other temporary residence, confirm that they meet the inclusion criteria (permanent residence). If they do not, the child is ineligible. Proceed to section G.</p>   |
| 26 | <b>Household income</b>                               | <p>Enter the yearly total household income for the household in which the child lives. Select from the following ranges:</p> <ul style="list-style-type: none"> <li>- Less than \$20,000</li> <li>- \$20,000 to \$39,999</li> <li>- \$40,000 to \$59,999</li> <li>- \$60,000 to \$79,999</li> <li>- \$80,000 to \$99,999</li> <li>- \$100,000 or more</li> </ul> <p>Enter "Prefer not to answer" if the parent is not willing to answer this question.</p> <p>Enter "UKN" if the parent does not know the yearly household income or if the person responding to the survey is the legal guardian, but does not live with the child.</p> |
| 27 | <b>Completion of High School or GED.</b>              | <p>If conducting the interview with the guardian, ask for his/her education, and then ask the subsequent questions about the child's mother/father. If you are conducting the interview with the mother/father, only ask questions 27 and 28.</p> <p>Answer "Yes" if the person completing the interview has completed high school or the equivalent, and "No" if they have not.</p>   |
| 28 | <b>Mother/Father completion of High School or GED</b> | <p>Answer "Yes" if the mother/father has completed high school or the equivalent, and "No" if they have not. If the person interviewed does not know the answer for the particular person in question, answer "UKN"</p>  |
| 29 | <b>Mother/Father completion of High School or GED</b> | <p>Answer "Yes" if the mother/father has completed high school or the equivalent, and "No" if they have not. If the person interviewed does not know the</p>   |

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| #  | Question               | Instructions  |
|----|------------------------|---|
| 30 | <b>Hispanic Origin</b> | <p>answer for the particular person in question, answer "UKN"</p> <hr/> <p>If conducting the interview with the guardian, ask whether or not he/she is of Hispanic origin, and then ask the subsequent questions about the child's mother/father. If you are conducting the interview with the mother/father, only ask questions 32 and 34.</p> <p>Enter "Yes" if the person completing the interview is of Hispanic, Latino, or Spanish origin.</p> <p>Hispanic refers to peoples having origins in Mexico, Puerto Rico, Cuba, Central America, South America, or any other Spanish-American culture or origin. Persons of Hispanic origin may be of any race.</p> <p>Enter "No" the person completing the interview is NOT of Hispanic or Latino origin.</p>  |
| 31 | <b>Race</b>            | <hr/> <p>If conducting the interview with the guardian, ask for his/her race, and then ask the subsequent questions about the child's mother/father. If you are conducting the interview with the mother/father, only ask questions 33 and 35.</p> <p>Check all options that apply for the person conducting the interview's stated race.</p> <p>If their race is "Other" please specify the race. Please do not list an ethnicity or nationality under this category.</p> <p>Check "Refused" if the person conducting the interview refused to answer the question. Using the information available to you, enter their race, in your opinion, in the box provided. Use the medical record and all other clues available.</p> <p>Note: People of Hispanic/Latino origin may be of any race and should answer the question on race by selecting one or more race categories shown on the form (White, Black or African American, American Indian and Alaska Native, Asian, Native Hawaiian and Other Pacific Islander, or Other Race). Hispanics should indicate their ethnic origin in the Hispanic question, not in the race question, because in NIH and other federal agencies consider ethnic origin a separate concept from race.</p> |

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| #  | Question                      | Instructions   |
|----|-------------------------------|--|
|    |                               | <p>If a subject reports that he/she is of Latino/Hispanic origin and their race is "other: Hispanic" or "other: Latino" please ask follow-up questions to determine the category of race (e.g., white Hispanic).</p> <p>Please refer to the following definitions:</p> <p>White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.</p> <p>Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian", "Caribbean", "West Indian", "African", or "Ethiopian" can be used in addition to "Black or African-American."</p> <p>Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)</p> <p>Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p> <p>American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.</p> |
| 32 | <b>Hispanic Origin mother</b> | <p>Enter "Yes" if the mother is of Hispanic, Latino, or Spanish origin.</p> <p>Hispanic refers to peoples having origins in Mexico, Puerto Rico, Cuba, Central America, South America, or any other Spanish-American culture or origin. Persons of Hispanic origin may be of any race.</p> <p>Enter "No" the mother is NOT of Hispanic or Latino origin.</p>   |
| 33 | <b>Race mother</b>            | <p>Check all options that apply for the mother's stated race.</p>  |

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| # | Question | Instructions   |
|---|----------|--|
|   |          | <p>If their race is "Other" please specify the race. Please do not list an ethnicity or nationality under this category.</p> <p>Check "Refused" if the mother refused to answer the question. Using the information available to you, enter their race, in your opinion, in the box provided. Use the medical record and all other clues available.</p> <p>Note: People of Hispanic/Latino origin may be of any race and should answer the question on race by selecting one or more race categories shown on the form (White, Black or African American, American Indian and Alaska Native, Asian, Native Hawaiian and Other Pacific Islander, or Other Race). Hispanics should indicate their ethnic origin in the Hispanic question, not in the race question, because in NIH and other federal agencies consider ethnic origin a separate concept from race.</p> <p>If a subject reports that he/she is of Latino/Hispanic origin and their race is "other: Hispanic" or "other: Latino" please ask follow-up questions to determine the category of race (e.g., white Hispanic).</p> <p>Please refer to the following definitions:</p> <p>White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.</p> <p>Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian", "Caribbean", "West Indian", "African", or "Ethiopian" can be used in addition to "Black or African-American."</p> <p>Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)</p> <p>Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p> |

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| #  | Question                      | Instructions   |
|----|-------------------------------|--|
| 34 | <b>Hispanic Origin father</b> | <p>American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.</p> <hr/> <p>Enter "Yes" if the father is of Hispanic, Latino, or Spanish origin.</p> <p>Hispanic refers to peoples having origins in Mexico, Puerto Rico, Cuba, Central America, South America, or any other Spanish-American culture or origin. Persons of Hispanic origin may be of any race.</p> <p>Enter "No" the mother is NOT of Hispanic or Latino origin.</p>  |
| 35 | <b>Race father</b>            | <p>Check all options that apply for the father's stated race.</p> <p>If their race is "Other" please specify the race. Please do not list an ethnicity or nationality under this category.</p> <p>Check "Refused" if the father refused to answer the question. Using the information available to you, enter their race, in your opinion, in the box provided. Use the medical record and all other clues available.</p> <p>Note: People of Hispanic/Latino origin may be of any race and should answer the question on race by selecting one or more race categories shown on the form (White, Black or African American, American Indian and Alaska Native, Asian, Native Hawaiian and Other Pacific Islander, or Other Race). Hispanics should indicate their ethnic origin in the Hispanic question, not in the race question, because in NIH and other federal agencies consider ethnic origin a separate concept from race.</p> <p>If a subject reports that he/she is of Latino/Hispanic origin and their race is "other: Hispanic" or "other: Latino" please ask follow-up questions to determine the category of race (e.g., white Hispanic).</p> <p>Please refer to the following definitions:</p> <p>White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.</p> <p>Black or African American: A person having origins in any of the black racial groups of Africa. Terms</p> |

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| #  | Question                    | Instructions  |
|----|-----------------------------|---|
| 36 | <b>Long Distance Travel</b> | <p>such as "Haitian", "Caribbean", "West Indian", "African", or "Ethiopian" can be used in addition to "Black or African-American."</p> <p>Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)</p> <p>Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p> <p>American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.</p>   |
| 37 | <b>Daycare attendance</b>   | <p>This question asks means of transportation. It asks the parent how they would travel if they had to travel a long distance with the child. The options are:</p> <ul style="list-style-type: none"> <li>-Drive your car</li> <li>-Borrow a car</li> <li>-Use Public Transportation</li> <li>-Have a friend or relative drive</li> <li>-Other (specify)</li> </ul> <p>By daycare we mean a center or family-based program for infants and young children. This includes any type of supervision of and care for children provided during the day by a person or organization that involves at least one other unrelated (i.e. not from immediate family) child; the care may be residential or home-based.</p> <p>Enter "Yes" if the child has ever gone to a daycare outside his/her own home for more than 2 weeks. Also enter "Yes" if the parent operates their own family-based day care and their child participates in this daycare.</p> <p>If "Yes" and child is &lt;6 months, go to Q37a1.<br/>If "Yes" and child is 6 months or older, go to Q37b1.</p> <p>Enter "No" if the child never went to a daycare outside the home for more than 2 weeks.</p> |

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| #    | Question   | Instructions  |
|------|--|---|
| 37a1 | <b>Age (in months) of first daycare attendance</b> | Enter the age, in months, in which the child first went to a daycare outside his own home.  |
| 37a2 | <b>Currently in daycare</b>                        | Enter "Yes" if the child currently attends daycare.<br><br>Enter "No" if the child does not currently attend daycare.   |
| 37b1 | <b>Age (in months) of first daycare attendance</b> | Enter the age, in months, in which the child first went to a daycare outside his own home. If the parent or legal guardian reports that the child attended daycare at 6.5 months round up to 7 months. If he/she says the child attends at 6.4 months or younger round as 6 months.             |
| 37b2 | <b>6 month old daycare attendance</b>              | Enter "Yes" if the child was attending daycare when the child was 6 months old. If "Yes", ask the parent to think back to the daycare the child attended when they were 6 months old.<br><br>Enter "No" if the child was not attending daycare when he or she was 6 months old and go to Q37b6. |
| 37b3 | <b>Average time in daycare</b>                     | Enter the <i>average</i> hours per week the child was in daycare from the following list:<br>- 0-4 hours<br>- 5-8 hours<br>- 9-16 hours<br>- 17-24 hours<br>- 25-32 hours<br>- 33-40 hours<br>- 41 or more hours  |
| 37b4 | <b>Presence of unrelated children</b>              | Enter the number of unrelated children that were present at the child's daycare. Unrelated children are defined as children not in the child's immediate family.<br><br>This number should be the average number of children present in the child's daycare on a daily basis.                   |
| 37b5 | <b>Type of daycare attended</b>                    | Enter "Home" if the daycare was located at the residence of the daycare provider, including if the child attends a daycare in the parent's home.  |

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| #    | Question                        | Instructions   |
|------|---------------------------------|--|
| 37b6 | <b>Currently in daycare</b>     | <p>Enter "Nonresidential" if the daycare was not located in a residence but in another location.</p> <p>Enter "Mixed" if the daycare the child attended was located in both residential and nonresidential sites.</p> <p>Enter "Yes" if the child currently attends daycare.</p> <p>Enter "No" if the child does not currently attend daycare.</p>   |
| 38   | <b>Smoking near child</b>       | <p>Check "Yes" if any of the following individuals <b>ever</b> smoke or smoked on a regular basis while near the child:</p> <ul style="list-style-type: none"> <li>- Someone who lives with the child</li> <li>- Someone who sees the child on a regular basis</li> <li>- Someone who takes care of the child in the child's residence</li> <li>- Someone who takes care of the child outside the child's residence</li> </ul> <p>Also enter "Yes" if any of the above persons ever smokes in a car or another enclosed space with the child. If it is reported that someone smokes "on the porch," "outside the front door," or something similar, count this as smoking near the child. If "Yes", go to Q38a.</p> <p>Enter "No" if no one who has regular contact with the child ever smokes or smoked while near the child. Consider smoking "outside" or "in the backyard" to be "No." If no, go to Q39.</p> |
| 38a  | <b>Smoking in the same room</b> | <p>If someone smokes or has smoked near the child, we would like to know if he/she has smoked in the same room as the child even if the child was not in the room at the same time (i.e., smoked indoors while the child was not there).</p> <p>Enter "Yes" if someone has smoked in the same room as the child.</p> <p>Enter "No" if the individual never smoked in the same room as the child.</p> <p>Enter "UKN" if the parent does not know if the child has been at the same room as the person who smokes/smoked.</p>  |

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| <b>#</b> | <b>Question</b>   | <b>Instructions</b>   |
|----------|---|---|
| 38b      | <b>Days per week exposed to tobacco over entire life</b>      | Enter the average number of days per week that that the child has been exposed to tobacco smoke over his/her entire life.   |
| 38c      | <b>Anyone currently living, caring or seeing child smoke</b>  | Enter "Yes" if there is anyone who CURRENTLY lives with, takes care of, or visits the child regularly who ever smokes near the child and go to Q38c1.<br><br>Enter "No" if no one who CURRENTLY lives with, takes care of, or visits the child regularly smokes near the child and go to Q39.   |
| 38c1     | <b>Smoking at the same room as child during the past week</b> | Enter "Yes" if there is someone who currently lives with, takes care of, or visits the child who has smoked in the same room as the child DURING THE PAST WEEK and go to Q38c2.<br><br>Enter "No" if this person has not smoked in the same room as the child during the past week<br>Enter "UKN" if the parent does not know if the smoker has smoked at the same room as the child in the past week                           |
| 38c2     | <b>Total days exposed to tobacco smoke</b>                    | Enter the number of days in which the child was exposed to tobacco smoke DURING THE PAST WEEK. If there is a smoker currently living with, caring for or seeing the child ("Yes" to Q38c), but the child was not exposed to tobacco smoke during the past week (no to Q38c1) enter "0".<br><br>Enter "UKN" if the parent does not know the number of days in which the child was exposed to tobacco smoke during the past week. |
| 39       | <b>Biological mother's year of birth</b>                      | Enter the biological mother's year of birth.<br><br>Enter "UKN" if the parent does not know the biological mother's year of birth (e.g., the child is adopted).   |
| 40       | <b>Biological mother conditions</b>                           | Check ALL of the conditions that the biological mother reports that she currently has or has had in the past. If the biological mother believes that a condition has "gone away" (e.g., she definitely had asthma as a child, but thinks she outgrew it during adolescence), please record it as present. The condition does not have to be doctor-diagnosed, but one that the biological mother thinks she has.                |

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| #   | Question                                   | Instructions  |
|-----|--|---|
|     |  | <p>Check “Asthma” if the biological mother has ever had asthma and complete Q40a &amp; Q40c.</p> <p>Check “Hayfever (allergic rhinitis)” if the biological mother has ever had hayfever and complete Q40b &amp; Q40c.</p> <p>Check “Eczema (atopic dermatitis)” if the biological mother has ever had eczema. Describe this condition to the parent as an itchy and scaly rash that comes and goes. Complete Q40d.</p> <p>Check “Food allergy” if the biological mother has ever been allergic to any food. Complete Q40e.</p> <p>Check “Medication allergy” if the biological mother has ever been allergic to any medication. Complete Q40f.</p> <p>Check “Other allergy” if the biological mother has ever had any other allergy not previously covered. Complete Q40g.</p> <p>Check “UKN” if the parent does not know if the mother has had any allergies (e.g., the child is adopted and the adopted parent does not know the medical history of the biological mother).</p> |
| 40a | <b>Mother Asthma</b>                       | <p>Enter “All year” if the mother has asthma during the entire year, regardless of the season of the year.</p> <p>Also enter “All year” if mother responds “exercised induced asthma”</p> <p>Enter “Seasonal” if the mother has asthma during a particular season of the year, but not year-round.</p> <p>Enter “UKN” if the parent does not know if the mother has asthma year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological mother).</p>   |
| 40b | <b>Mother Hayfever (allergic rhinitis)</b> | <p>Enter “All year” if the mother has hayfever (allergic rhinitis) throughout the year.</p> <p>Enter “Seasonal” if the mother experiences hayfever during a particular season of the year, but not year-round.</p>  |

*Enrollment Telephone Interview Form*

| #    | Question   | Instructions  |
|------|--|---|
| 40c1 | <b>Allergens causing Asthma or Hayfever (allergic rhinitis) in biological mother</b> | <p>Enter "UKN" if the parent does not know if the mother has hayfever year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological mother).</p> <hr/> <p>If the biological mother has asthma or hayfever (allergic rhinitis) she may have been tested for reactions to specific allergens or told by a doctor that she has allergies.</p> <p>Please enter Yes, No or UKN if the biological mother has been told by a doctor for whatever reason (clinical, blood testing, skin prick testing) that she <u>may</u> be allergic to any of the following allergens:</p> <ul style="list-style-type: none"> <li>- Weeds</li> <li>- Tree</li> <li>- Grass</li> <li>- Cat</li> <li>- Dog</li> <li>- Cockroach</li> <li>- Dust mite</li> <li>- Mold</li> </ul> <p>Enter "Yes" if the mother has been told by a doctor that she may be allergic to the specific allergen.</p> <p>Enter "No" if the mother has not been told by a doctor that she may be allergic to the specific allergen.</p> <p>Enter "UKN" if it is not known if the mother has ever been told by a doctor that she may be allergic to a specific food.</p> |
| 40d1 | <b>Eczema (atopic dermatitis) in Biological Mother</b>                               | <p>Enter "All year" if the biological mother has eczema (atopic dermatitis) throughout the year.</p> <p>Enter "Seasonal" if the biological mother experiences eczema (atopic dermatitis) during a particular season of the year and go to <i>Q40d1a</i>.</p> <p>Enter "UKN" if the parent does not know if the mother has eczema (atopic dermatitis) year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological mother).</p>   |

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| <b>#</b>     | <b>Question</b>   | <b>Instructions</b>  |
|--------------|---|--|
| 40d1a        | <b>Seasonal Eczema (atopic dermatitis) in biological mother</b> | <p>Enter “Yes” if the biological mother has eczema (atopic dermatitis) that worsens during the seasons of late fall or winter (November through March).</p> <p>Enter “No” if the biological mother has seasonal eczema (atopic dermatitis) that does not worsen during the seasons of late fall or winter (November through March).</p> <p>Enter “UKN” if the parent does not know about worsening eczema (atopic dermatitis) in the late fall or winter (e.g., the child is adopted and the adopted parent does not know the medical history of the biological mother).</p>   |
| 40e1         | <b>Food Allergy of Biological Mother</b>                        | <p>If the biological mother has food allergies she may have been tested for reactions to specific allergens or told by a doctor that she has allergies.</p> <p>Please enter Yes, No or UKN if the biological mother has been told by a doctor for whatever reason (clinical, blood testing, skin prick testing) that she <u>may</u> be allergic to any of the following allergens:</p> <ul style="list-style-type: none"> <li>- Peanuts</li> <li>- Tree nuts</li> <li>- Cow’s milk</li> <li>- Egg</li> <li>- Shellfish</li> </ul> <p>Enter “Yes” if the mother has been told by a doctor that she may be allergic to the specific allergen.</p> <p>Enter “No” if the mother has not been told by a doctor that she may be allergic to the specific allergen.</p> <p>Enter “UKN” if it is not known if the mother has ever been told by a doctor that she may be allergic to a specific food.</p> |
| 40f<br>40f1a | <b>Medication Allergy of Biological Mother</b>                  | <p>If the biological mother of the child has been told by a doctor that she has a specific allergy to a medication, enter specific name of the medication or medications to which the biological mother is allergic.</p>   |

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| <b>#</b>     | <b>Question</b>                             | <b>Instructions</b>   |
|--------------|---|---|
| 40g<br>40g1a | <b>Other allergies of Biological Mother</b> | If the biological mother of the child has been told by a doctor that she has another type of specific allergy, enter the specific item(s) to which the biological mother is allergic.   |
| 41           | <b>Biological father's date of birth</b>    | Enter the biological father's year of birth.<br><br>Enter "UKN" if the parent does not know the biological father's year of birth (e.g., the child is adopted).   |
| 42           | <b>Biological father conditions</b>         | <p>Check ALL of the conditions that the biological father reports that he currently has or has had in the past. If the biological father believes that a condition has "gone away" (e.g., he definitely had asthma as a child, but thinks he outgrew it during adolescence), please record it as present. The condition does not have to be doctor-diagnosed, but one that the biological father thinks he has.</p> <p>Check "Asthma" if the biological father has ever had asthma. Complete <i>Q42a</i> &amp; <i>Q42c</i>.</p> <p>Check "Hayfever (allergic rhinitis)" if the biological father has ever had hayfever. Complete <i>Q42b</i> &amp; <i>Q42c</i>.</p> <p>Check "Eczema (atopic dermatitis)" if the biological father has ever had eczema. Describe this condition to the parent as an itchy and scaly rash that comes and goes. Complete <i>Q42d</i>.</p> <p>Check "Food allergy" if the biological father has ever been allergic to any food. Complete <i>Q42e</i>.</p> <p>Check "Medication allergy" if the biological father has ever been allergic to any medication. Complete <i>Q42f</i>.</p> <p>Check "Other allergy" if the biological father has ever had any other allergy not previously covered. Complete <i>Q42g</i>.</p> <p>Check "UKN" if the parent does not know if the father has had any allergies (e.g., the child is adopted and the adopted parent does not know the medical history of the biological father).</p> |

*Enrollment Telephone Interview Form*

| <b>#</b> | <b>Question</b>  | <b>Instructions</b>  |
|----------|--|--|
| 42a      | <b>Father Asthma</b>   | <p>Enter "All year" if the father has asthma during the entire year, regardless of the season of the year.</p> <p>Also enter "All year" if father responds "exercised induced asthma"</p> <p>Enter "Seasonal" if the father has asthma during a particular season of the year, but not year-round.</p> <p>Enter "UKN" if the parent does not know if the father has asthma year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological father).</p>  |
| 42b      | <b>Father Hayfever (allergic rhinitis)</b>   | <p>Enter "All year" if the father has hayfever (allergic rhinitis) throughout the year.</p> <p>Enter "Seasonal" if the father experiences hayfever during a particular season of the year, but not year-round.</p> <p>Enter "UKN" if the parent does not know if the father has hayfever year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological father).</p>  |
| 42c1     | <b>Allergens causing Asthma or Hayfever (allergic rhinitis) in biological father</b> | <p>If the biological father has asthma or hayfever (allergic rhinitis) he may have been tested for reactions to specific allergens or told by a doctor that he has allergies.</p> <p>Please enter Yes, No or UKN if the biological father has been told by a doctor for whatever reason (clinical, blood testing, skin prick testing) that he <u>may</u> be allergic to any of the following allergens:</p> <ul style="list-style-type: none"><li>- Weeds</li><li>- Tree</li><li>- Grass</li><li>- Cat</li><li>- Dog</li><li>- Cockroach</li><li>- Dust mite</li><li>- Mold</li></ul> <p>Enter "Yes" if the father has been told by a doctor that he may be allergic to the specific allergen.</p> |

*Enrollment Telephone Interview Form*

| #     | Question  | Instructions  |
|-------|---|---|
| 42d1  | <b>Eczema (atopic dermatitis) in Biological Father</b>          | <p>Enter “No” if the father has not been told by a doctor that he may be allergic to the specific allergen.</p> <p>Enter “UKN” if it is not known if the father has ever been told by a doctor that he may be allergic to a specific allergen.</p>  |
| 42d1a | <b>Seasonal Eczema (atopic dermatitis) in biological father</b> | <p>Enter “All year” if the biological father has eczema (atopic dermatitis) throughout the year.</p> <p>Enter “Seasonal” if the biological father experiences eczema (atopic dermatitis) during a particular season of the year. Go to <i>Q42d1a</i>.</p> <p>Enter “UKN” if the parent does not know if the father has eczema (atopic dermatitis) year-round or during a particular season (e.g., the child is adopted and the adopted parent does not know the medical history of the biological father).</p> <p>Enter “Yes” if the biological father has eczema (atopic dermatitis) that worsens during the seasons of late fall or winter (November through March).</p> <p>Enter “No” if the biological father has seasonal eczema (atopic dermatitis) that does not worsen during the seasons of late fall or winter (November through March).</p> <p>Enter “UKN” if the parent does not know about worsening eczema (atopic dermatitis) in the late fall or winter (e.g., the child is adopted and the adopted parent does not know the medical history of the biological father).</p> |
| 42e1  | <b>Food Allergy of Biological Father</b>                        | <p>If the biological father has food allergies he may have been tested for reactions to specific allergens or told by a doctor that he has allergies.</p> <p>Please enter Yes, No or UKN if the biological father has been told by a doctor for whatever reason (clinical, blood testing, skin prick testing) that he <u>may</u> be allergic to any of the following allergens:</p> <ul style="list-style-type: none"> <li>- Peanuts</li> <li>- Tree nuts</li> <li>- Cow’s milk</li> <li>- Egg</li> <li>- Shellfish</li> </ul>  |

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| #   | Question  | Instructions   |
|---|---|--|
|   |   | <p>Enter "Yes" if the father has been told by a doctor that he may be allergic to the specific allergen.</p> <p>Enter "No" if the father has not been told by a doctor that he may be allergic to the specific allergen.</p> <p>Enter "UKN" if it is not known if the father has ever been told by a doctor that he may be allergic to a specific allergen.</p>                          |
| 42f<br>42f1   | <b>Medication Allergy of Biological Father</b>      | If the biological father of the child has been told by a doctor that he has a specific allergy to a medication, enter specific name of the medication or medications to which the biological father is allergic.   |
| 42g<br>42g1   | <b>Other allergies of Biological Father</b>         | If the biological father of the child has been told by a doctor that he has another type of specific allergy, enter the specific item(s) to which the biological father is allergic.   |
| <i>Section D: Pregnancy &amp; Nutrition Information</i> |   |  |
| 43  | <b>Antibiotics during labor/delivery</b>            | <p>Enter "Yes" if the mother took antibiotics anytime during labor or delivery of the child (e.g., for Strep B).</p> <p>Enter "No" if the mother did not take antibiotics anytime during labor or delivery of the child.</p> <p>Enter "Unknown" if there is no knowledge if the mother took any antibiotics during labor or delivery of the child.</p>                                   |
| 44  | <b>Antibiotics during pregnancy</b>                 | <p>Enter "Yes" if the mother took antibiotics anytime while pregnant with the child.</p> <p>Enter "No" if the mother did not take antibiotics anytime while pregnant with the child.</p> <p>Enter "Unknown" if the respondent does not know if the mother took any antibiotics while pregnant with the child.</p>  |
| 44a   | <b>Weeks antibiotics were used during pregnancy</b> | <p>If the mother took antibiotics while pregnant with the child, please indicate the total number of weeks in which the mother took antibiotics during the pregnancy.</p> <p>Enter "Less than 1 week" if the duration of antibiotic use was less than 1 week during pregnancy.</p> <p>Enter "1-2 weeks" if the duration of antibiotic use was between 1 to 2 weeks during pregnancy.</p> |

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| <b>#</b> | <b>Question</b>                                     | <b>Instructions</b>  |
|----------|---|--|
|          |   | <p>Enter "3-4 weeks" if the duration of antibiotic use was between 3 to 4 weeks during pregnancy.</p> <p>Enter "5-6 weeks" if the duration of antibiotic use was between 5 to 6 weeks during pregnancy.</p> <p>Enter "More than 6 weeks" if the duration of antibiotic use was more than 6 weeks during pregnancy.</p> <p>Enter "Unknown" if the respondent does not know how many weeks the mother took any antibiotics while pregnant.</p>   |
| 45       | <b>Probiotics during pregnancy</b>                  | <p>Enter "Yes" if the mother took probiotics at least once per week while pregnant with the child.</p> <p>Enter "No" if the mother did not take probiotics at least once per week while pregnant with the child.</p> <p>Enter "Unknown" if the respondent does not know if the mother took probiotics at least once a week while pregnant with the child.</p>  |
| 45a      | <b>Months probiotics were used during pregnancy</b> | <p>If the mother took probiotics at least once per week while pregnant with the child, please indicate the total number of weeks in which the mother took probiotics during the pregnancy.</p> <p>Enter "1 month or less" if the duration of probiotic use was 1 month or less during pregnancy.</p> <p>Enter "2-3 months" if the duration of probiotic use was between 2 to 3 months during pregnancy.</p> <p>Enter "4-5 months" if the duration of probiotic use was between 4 to 5 months during pregnancy.</p> <p>Enter "6 month or more" if the duration of antibiotic use was 6 months or longer during pregnancy.</p> <p>Enter "Unknown" if the respondent does not know how many weeks the mother took any antibiotics while pregnant.</p> |
| 46       | <b>H2 blockers/PPIs during pregnancy</b>            | <p>Enter "Yes" if the mother took H2 blockers or proton pump inhibitors (PPIs) anytime during the pregnancy.</p> <p>Include medications like Pepcid Tagamet, and Zantac, Prilosec, Nexium, and Prevacid.</p>   |

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| #   | Question                                      | Instructions  |
|-----|---|---|
| 46a | <b>Weeks PPI's were used during pregnancy</b> | <p>Do not include antacids like Maalox or TUMS.</p> <p>Enter "No" if the mother did not take H2 blockers or PPIs anytime during the pregnancy.</p> <p>Enter "Unknown" if the respondent does not know if the mother took any H2 blockers or PPIs while pregnant.</p> <p>If the mother took H2 blockers or PPIs while pregnant with the child, please indicate the total number of months the mother took H2 blockers or PPIs during the pregnancy.</p> <p>Enter "1 month or less" if the duration of H2 or PPI use was less than 1 month or less during pregnancy.</p> <p>Enter "2-3 months" if the duration of H2 or PPI use was between 2 to 3 months during pregnancy.</p> <p>Enter "4-5 months" if the duration of H2 or PPI use was between 4 to 5 months during pregnancy.</p> <p>Enter "6 months or more" if the duration of antibiotic use was 6 months or more during pregnancy.</p> <p>Enter "Unknown" if the respondent does not know how many weeks the mother took any antibiotics while pregnant.</p> |
| 47  | <b>Smoking during pregnancy</b>               | <p>Enter "Yes" if the mother smoked cigarettes anytime while pregnant with the child.</p> <p>Enter "No" if the mother did not smoke cigarettes anytime while pregnant with the child.</p> <p>Enter "Unknown" if the respondent does not know if the mother smoked cigarettes anytime while pregnant with the child.</p>   |
| 47a | <b>Pregnancy smoking trimester</b>            | <p>If the mother of the child smoked cigarettes while pregnant, specify the trimester(s) in which she smoked. If the mother smoked in more than one trimester, check ALL trimesters in which she smoked.</p> <p>Check "1<sup>st</sup> trimester" if the mother smoked during the first three months (weeks 0 to 12) of pregnancy.</p>   |

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| #   | Question                                   | Instructions   |
|-----|--|--|
| 48  | <b>Contact with farm animals</b>           | <p>Check “2<sup>nd</sup> trimester” if the mother smoked during the fourth, fifth and sixth months (weeks 13 to 26) of pregnancy.</p> <p>Check “3<sup>rd</sup> trimester” if the mother smoked during the seventh, eighth and ninth months (weeks 27 to 42) of pregnancy.</p> <p>Enter “Unknown” if the respondent does not know which trimester the mother smoked cigarettes during the pregnancy.</p>  |
| 48a | <b>Trimester contact with farm animals</b> | <p>This question asks about the biological mother’s contact with farm animals during pregnancy.</p> <p>Enter “Yes” if the biological mother had regular (at least once a week, on average) contact with farm animals during pregnancy. The type of farm animal is not important; the mother may have had contact with only a single type of animal (e.g., lived on a cattle farm) or different types of animals.</p> <p>Enter “No” if the mother did not have regular (at least once a week, on average) contact with any type of farm animal during pregnancy.</p> <p>Enter “Unknown” if the respondent does not know if the mother had contact with farm animals during pregnancy.</p> |
| 49  | <b>Name of child birth hospital</b>        | <p>Select which trimester(s) of pregnancy the mother had regular contact with farm animals – CHECK ALL THAT APPLY</p> <p>Enter “Unknown” if the respondent does not know which trimester(s) the mother had contact with farm animals.</p>  |
| 49a | <b>Information of child birth hospital</b> | <p>Enter “Yes” if the child was born at the hospital performing this interview.</p> <p>Enter “No” if the child was born at a hospital other than the one performing this interview. If “No”, continue to question 49a</p>  |
| 50  | <b>Multiple birth</b>                      | <p>Enter the information of the hospital where child was born, including name of hospital, city, and state.</p> <p>Enter “Yes” if the child was part of a multiple birth.</p> <p>Enter “No” if the child was not part of a single birth.</p>   |

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| <b>#</b> | <b>Question</b>                   | <b>Instructions</b>   |
|----------|-----------------------------------|---|
|          |                                   | Enter "Unknown" if the respondent does not know if the child was part of a multiple birth.  |
| 50a      | <b>Quantity of multiple birth</b> | <p>If the child was born as part of a multiple birth, indicate the type of multiple birth.</p> <p>Enter "Twins" if the child was part of a delivery of twins.</p> <p>Enter "Triplets" if the child was part of a delivery of triplets.</p> <p>Enter "Quadruplets" if the child was part of a delivery of quadruplets.</p> <p>Enter "Quintuplets or more" if the child was part of a delivery of quintuplets or more.</p> <p>Enter "Unknown" if the respondent does not know the type of multiple birth.</p> |
| 50b      | <b>Type of multiple birth</b>     | <p>Enter "Identical" if the children born at delivery were identical (monozygotic).</p> <p>Enter "Fraternal" if the children born at delivery were fraternal (dizygotic).</p> <p>Enter "Unknown" if the respondent does not know if the children born at delivery were identical or fraternal.</p>  |
| 51       | <b>Delivery route</b>             | <p>Enter "Vaginal birth" if the child was delivered vaginally.</p> <p>Enter "planned C-section" if the child was delivered through a planned C-section.</p> <p>Enter "emergency (unplanned) C-section" if the child was delivered through an unplanned C-section.</p> <p>Enter "Unknown" if the respondent does not know the delivery route of the child.</p>   |
| 52       | <b>Mother's height</b>            | <p>Enter mother's weight in feet and inches.</p> <p>Enter "Refused to Report" if respondent refused to report the mother's height.</p> <p>Enter "Unknown" if respondent does not know the mother's height.</p>  |

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| <b>#</b>                    | <b>Question</b>                              | <b>Instructions</b>   |
|-----------------------------|--|---|
| 53                          | <b>Mother's weight before pregnancy</b>      | Enter mother's weight before becoming pregnant in pounds.<br><br>Enter "Refused to Report" if respondent refused to report the mother's weight.<br><br>Enter "Unknown" if respondent does not know the mother's weight.   |
| 54                          | <b>Mother's weight gain during pregnancy</b> | Enter weight gained when mother was pregnant in pounds.<br><br>Enter "Refused to Report" if respondent refused to report the mother's weight gain.<br><br>Enter "Unknown" if respondent does not know the mother's weight gain.   |
| 55                          | <b>Mother's current weight</b>               | Enter mother's current weight in pounds. If currently pregnant, please give weight before becoming pregnant.<br><br>Enter "Refused to Report" if respondent refused to report the mother's current weight.<br><br>Enter "Unknown" if respondent does not know the mother's current weight.  |
| 56                          | <b>Father's height</b>                       | Enter father's weight in feet and inches.<br><br>Enter "Refused to Report" if respondent refused to report the father's height.<br><br>Enter "Unknown" if respondent does not know the father's height.   |
| 57                          | <b>Father's current weight</b>               | Enter father's current weight in pounds.<br><br>Enter "Refused to Report" if respondent refused to report the father's current weight.<br><br>Enter "Unknown" if respondent does not know the father's current weight.  |
| <i>Vitamins/Supplements</i> |  |   |
| 58                          | <b>Multivitamins/ prenatal vitamins</b>      | Enter "Yes" if the mother took any prenatal vitamins or multivitamin supplements at least 3 times a week at any point while pregnant.<br><br>Enter "No" if the mother did not take any prenatal vitamins or multivitamin supplements at least 3 times a week at any point while pregnant. Also enter "No" if the mother only took a prenatal or multivitamin supplement less than 3 times a week, enter "No". |

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| #   | Question   | Instructions  |
|-----|--|---|
| 58a | <b>Trimester of Multivitamins/ prenatal vitamins use</b> | <p>Enter "Unknown" if the respondent does not know if the mother took any prenatal vitamins or multivitamins or does not know how often she took them.</p> <p>If the mother of the child took multivitamins or prenatal vitamins at least 3 times a week, specify the trimester(s) in which she took these supplements. If the mother took these supplements in more than one trimester, check EVERY trimester in which she took them.</p> <p>Check "1<sup>st</sup> trimester" if the mother took prenatal vitamins or multivitamins at least 3 times a week during at least one of the first three months (weeks 0 to 12) of pregnancy.</p> <p>Check "2<sup>nd</sup> trimester" if the mother took prenatal vitamins or multivitamins at least 3 times a week during at least one of the second three months (months 4 to 6; weeks 13 to 26) of pregnancy.</p> <p>Check "3<sup>rd</sup> trimester" if the mother took prenatal vitamins or multivitamins at least 3 times a week during at least one of the third three months (months 7 to 10; weeks 27 to 42) of pregnancy.</p> <p>Enter "Unknown" if the respondent does not know during which trimesters the mother took multivitamins or prenatal vitamins.</p> |
| 58b | <b>Multivitamins/ prenatal vitamin Brand(s)</b>          | <p>Enter "Yes" if the mother of the child remembers the brand of prenatal vitamins or multivitamins. Enter the name of the brand.</p> <p>Enter "No" if the mother does not remember the name of the brand of multivitamins or prenatal vitamins she took during the pregnancy.</p>  |
| 59  | <b>Vitamin D use during pregnancy</b>                    | <p>For this question, the respondent should focus only on vitamin D supplements taken separately from the prenatal or multivitamin supplements.</p> <p>Enter "Yes" if the mother took vitamin D at least once per week while pregnant. Also answer "Yes" if the mother took a non-multivitamin supplement that contained other vitamins in addition to vitamin D (e.g., a calcium and vitamin D combination supplement).</p> <p>Enter "No" if the mother did not take vitamin D at least once per week while pregnant.</p>  |

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| #   | Question                                  | Instructions  |
|-----|---|---|
| 59a | <b>Trimester of Vitamin D use</b>         | <p>Enter "Unknown" if the respondent does not know if the mother took vitamin D at least once per week during pregnancy.</p>  |
|     |   | <p>If the mother of the child took vitamin D (separately from other vitamin supplements), specify the trimester(s) in which she took vitamin D at least once per week. If the mother took vitamin D in more than one trimester, check each trimester in which she took vitamin D.</p> |
|     |   | <p>Check "1<sup>st</sup> trimester" if the mother took vitamin D at least once per week during one of the first three months (weeks 0 to 12) of pregnancy.</p>  |
|     |   | <p>Check "2<sup>nd</sup> trimester" if the mother took vitamin D at least once per week during at least one of the second three months (months 4 to 6; weeks 13 to 26) of pregnancy.</p>  |
|     |   | <p>Check "3<sup>rd</sup> trimester" if the mother took vitamin D at least once per week during at least one of the third three months (months 7 to 10; weeks 27 to 42) of pregnancy.</p>  |
|     |   | <p>Check "Unknown" if the respondent does not know during which trimesters the mother took vitamin D.</p>   |
| 59b | <b>Vitamin D average dose (IUs)</b>       | <p>Enter "Yes" if the respondent remembers the average dose of vitamin D that she took during pregnancy. Enter the dose in International Units (IUs).</p>   |
|     |   | <p>If the dose provided is micrograms (mcg), convert mcg to IUs. There are 40 IUs per 1 mcg (e.g., 5 mcg = 200 IUs.)</p>  |
|     |   | <p>Enter "No" if the respondent does not remember the average dose of vitamin D that she took during pregnancy.</p>   |
| 60  | <b>Cod liver oil use during pregnancy</b> | <p>Enter "Yes" if the mother took cod liver oil at least once per week while pregnant.</p>  |
|     |   | <p>Enter "No" if the mother did not take cod liver oil at least once per week while pregnant.</p>   |
|     |   | <p>Enter "Unknown" if the respondent does not know if the mother took cod liver oil at least once per week while pregnant.</p>  |

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| #   | Question   | Instructions   |
|-----|--|--|
| 60a | <b>Trimester of cod liver oil use</b>                      | <p>If the mother of the child took cod liver oil, specify the trimester(s) in which she took cod liver oil. If the mother took cod liver oil in more than one trimester, check EVERY trimester in which she took the cod liver oil.</p> <p>Check “1<sup>st</sup> trimester” if the mother took cod liver oil at least once per week during one of the first three months (weeks 0 to 12) of pregnancy.</p> <p>Check “2<sup>nd</sup> trimester” if the mother took cod liver oil at least once per week during at least one of the second three months (months 4 to 6; weeks 13 to 26) of pregnancy.</p> <p>Check “3<sup>rd</sup> trimester” if the mother took cod liver oil at least once per week during at least one of the third three months (months 7 to 10; weeks 27 to 42) of pregnancy.</p> <p>Check “Unknown” if the respondent does not know during which trimesters the mother took cod liver oil.</p> |
| 61  | <b>Fish oil (omega-3 fatty acids) use during pregnancy</b> | <p>Enter “Yes” if the mother took fish oil (omega-3 fatty acids) supplements at least once per week while pregnant. Also answer “Yes” if the mother took a non-multivitamin supplement that contained other vitamins in addition to fish oil (e.g., an omega-3 fatty acid and Coq10 combination supplement). This question assesses fish oil supplement use only and should not include intake of omega-3 fatty acids in food.</p> <p>Enter “No” if the mother did not take fish oil (omega-3 fatty acids) supplements at least once per week while pregnant.</p> <p>Enter “Unknown” if the respondent does not know if the mother took fish oil (omega-3 fatty acids) supplements at least once per week during pregnancy.</p>  |
| 61a | <b>Trimester of Fish oil (omega-3 fatty acids) use</b>     | <p>If the biological mother of the child took a fish oil (omega-3 fatty acids) supplement, specify the trimester(s) in which she took fish oil (omega-3 fatty acids). If the mother took fish oil (omega-3 fatty acids) in more than one trimester, check EVERY trimester in which she took the fish oil (omega-3 fatty acids).</p> <p>Check “1<sup>st</sup> trimester” if the mother took a fish oil (omega-3 fatty acids) supplement at least once per</p>   |

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| #  | Question                                       | Instructions  |
|----|--|---|
| 62 | <b>Other supplements used during pregnancy</b> | <p>week during the first three months (weeks 0 to 12) of pregnancy.</p> <p>Check “2<sup>nd</sup> trimester” if the mother took a fish oil (omega-3 fatty acids) supplement at least one of the second three months (months 4 to 6; weeks 13 to 26) of pregnancy.</p> <p>Check “3<sup>rd</sup> trimester” if the mother took a fish oil (omega-3 fatty acids) at least once per week during at least one of the third three months (months 7 to 10; weeks 27 to 42) of pregnancy.</p> <p>Check “Unknown” if the respondent does not know during which trimesters the biological mother took fish oil (omega-3 fatty acids).</p> <p>Check “None” if the biological mother did not take any other supplement besides vitamin D, cod liver oil, and fish oil (omega-3 fatty acids).</p> <p>If the mother took a non-multivitamin supplement that contained vitamins <u>in addition to</u> vitamin D, cod liver oil, and fish oil (omega-3 fatty acids), check the additional component of the supplement in this question. For example, if the mother took a calcium and vitamin D combination supplement, report the vitamin D component in the Q59 and check calcium in this question (Q62).</p> <p>If the mother took a combination supplement that included more than one of the items listed, check the individual components of the supplement. For example, if the supplement contained iron with vitamin C, you would check both iron and vitamin C.</p> <p>Check “Beta Carotene” if the mother took beta carotene at least once per week while pregnant.</p> <p>Check “Calcium” if the mother took calcium at least once per week while pregnant.</p> <p>Check “Iron” if the mother took Iron at least once per week while pregnant.</p> <p>Check “Vitamin A” if the mother took vitamin A at least once per week while pregnant.</p> <p>Check “Vitamin C” if the mother took vitamin C at least once per week while pregnant.</p> |

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| # | Question | Instructions  |
|---|----------|---|
|   |          | <p>Check "Folate" if the mother took folate at least once per week while pregnant.</p> <p>Check "Vitamin B" if the mother took vitamin B at least once per week while pregnant.</p> <p>Check "Vitamin E" if the mother took vitamin E at least once per week while pregnant.</p> <p>Check "Zinc" if the mother took zinc at least once per week while pregnant.</p> <p>Check "Fluoride drops (i.e. Tri-Vi-Flor or Poly-Vi-Flor)" if the mother took Fluoride drops at least once per week while pregnant.</p> <p>Check "Other" and specify the supplement the mother took at least once per week while pregnant. Include all types of supplement, including herbal supplements.</p> <p>Check "None" if the biological took no other types of supplements.</p> <p>Check "Unknown" if responded does not know if mother took any of the supplements listed above</p> <p>Check ALL that apply.</p> |

**Diet During Third Trimester**

The following questions are about the last three months of pregnancy only – the third trimester. Average the total intake during the 7<sup>th</sup>, 8<sup>th</sup> and 9<sup>th</sup> months of pregnancy.

|    |                               |   |
|----|-------------------------------|---|
| 63 | <b>Milk servings per week</b> | <p>Select the option that best describes the servings of cow's milk consumed, on average, during the third trimester. A serving is considered an 8 oz glass. Consider consumption of any kind of milk (whole, 2%, 1%, or skim) the same.</p> <p>Check "Never/less than 1 per month" if the mother never drank milk or had less than 1 glass per month during the last trimester.</p> <p>Check "1-3 glasses per month" if the mother drank 1 to 3 glasses of milk per month during the last trimester.</p> <p>Check "1 glass per week" if the mother drank 1 glass per week during the last trimester.</p> |
|----|-------------------------------|---|

*Enrollment Telephone Interview Form*

| #  | Question                       | Instructions   |
|----|--------------------------------|--|
| 64 | <b>Fruit servings per week</b> | <p>Check “2-4 glasses per week” if the mother drank 2 to 4 glasses per week during the last trimester.</p> <p>Check “5-6 glasses per week” if the mother drank 5 to 6 glasses of milk per week during the last trimester.</p> <p>Check “1 glass per day” if the mother drank 1 glass of milk per day during the last trimester.</p> <p>Check “2-3 glasses per day” if the mother drank 2 to 3 glasses of milk per day during the last trimester.</p> <p>Check “4 or more glasses per day” if the mother drank 4 or more glasses of milk per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many glasses of milk the mother drank in her last trimester of pregnancy.</p> <p>Not counting fruit juices, select the option that best describes the servings of fruit consumed, on average, during the third trimester. A serving is considered a whole fruit, like an apple or an orange.</p> <p>Check “Never/less than 1 per month” if the mother never ate fruit or had less than 1 serving of fruit per month during the last trimester.</p> <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of fruit per month during the last trimester.</p> <p>Check “1 serving of fruit per week” if the mother ate 1 serving of fruit per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of fruit per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of fruit per week during the last trimester.</p> <p>Check “1 serving of fruit per day” if the mother ate 1 serving of fruit per day during the last trimester.</p> <p>Check “2-3 servings per day” if the mother ate 2 to 3 servings of fruit per day during the last trimester.</p> <p>Check “4-5 servings per day” if the mother ate 4 to 5 servings of fruit per day during the last trimester.</p> |

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| #  | Question                            | Instructions  |
|----|-------------------------------------|---|
| 65 | <b>Vegetables servings per week</b> | <p>Check “6 or more servings per day” if the mother ate 6 or more servings of fruit per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many servings of fruit the mother ate during the last trimester of pregnancy.</p> <p>Not counting iceberg lettuce or potatoes, select the option that best describes the servings of vegetables consumed, on average, during the third trimester. A serving of vegetables is ½ cup of raw or cooked vegetables or 1 cup of spinach.</p> <p>Select from the following options:</p> <p>Check “Never/less than 1 per month” if the mother never ate vegetable or had less than 1 serving of vegetables per month during the last trimester.</p> <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of vegetables per month during the last trimester.</p> <p>Check “1 serving of vegetables per week” if the mother ate 1 serving of vegetables per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of vegetables per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of vegetables per week during the last trimester.</p> <p>Check “1 serving of vegetables per day” if the mother ate 1 serving of vegetables per day during the last trimester.</p> <p>Check “2-3 servings per day” if the mother ate 2 to 3 servings of vegetables per day during the last trimester.</p> <p>Check “4-5 servings per day” if the mother ate 4 to 5 servings of vegetables per day during the last trimester.</p> <p>Check “6 or more servings per day” if the mother ate 6 or more servings of vegetables per day during the last trimester.</p> |

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| #  | Question   | Instructions  |
|----|--|---|
| 66 | <b>Egg Beaters or egg whites servings per week</b> | <p>Check "Unknown" if the respondent does not know how many servings of vegetables the mother ate during the last trimester.</p>  |
|    |  | <p>Select the option that best describes the servings of Egg Beaters (or other egg white product) or egg whites consumed, on average, during the third trimester. A serving is considered 1 egg white or ¼ of a cup of egg white product.</p> |
|    |  | <p>Check "Never/less than 1 per month" if the mother never ate Egg Beaters/egg whites or had less than 1 serving of Egg Beaters/egg whites per month during the last trimester.</p>   |
|    |  | <p>Check "1-3 servings per month" if the mother ate 1 to 3 servings of Egg Beaters/egg whites per month during the last trimester.</p>  |
|    |  | <p>Check "1 serving per week" if the mother ate 1 serving of Egg Beaters/egg whites per week during the last trimester.</p>   |
|    |  | <p>Check "2-4 servings per week" if the mother ate 2 to 4 servings of Egg Beaters/ egg whites per week during the last trimester.</p>   |
|    |  | <p>Check "5-6 servings per week" if the mother ate 5 to 6 servings of Egg Beaters/egg whites per week during the last trimester.</p>  |
|    |  | <p>Check "1 serving per day" if the mother ate 1 serving of Egg Beaters/egg whites per day during the last trimester.</p>   |
|    |  | <p>Check "2 or more servings per day" if the mother ate 2 or more servings of Egg Beaters/egg whites per day during the last trimester.</p>   |
|    |  | <p>Check "Unknown" if the respondent does not know how many servings of Egg Beaters/egg whites the mother ate during the last trimester.</p>  |
| 67 | <b>Egg servings per week</b>                       | <p>Select the option that best describes the servings of whole eggs (including the yolk) consumed, on average, during the third trimester. A serving is considered 1 egg.</p>   |

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| #  | Question                                  | Instructions   |
|----|---|--|
| 68 | <b>Canned tuna fish servings per week</b> | <p>Check “Never/less than 1 per month” if the mother never ate eggs or had less than 1 serving of eggs per month during the last trimester.</p> <p>Check “1-3 eggs per month” if the mother ate 1 to 3 servings of eggs per month during the last trimester.</p> <p>Check “1 egg per week” if the mother ate 1 serving of eggs per week during the last trimester.</p> <p>Check “2-4 eggs per week” if the mother ate 2 to 4 servings of eggs per week during the last trimester.</p> <p>Check “5-6 eggs per week” if the mother ate 5 to 6 servings of eggs per week during the last trimester.</p> <p>Check “1 egg per day” if the mother ate 1 serving of eggs per day during the last trimester.</p> <p>Check “2 or more eggs per day” if the mother ate 2 or more servings of eggs per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many servings of whole eggs the mother ate in the last trimester of pregnancy.</p> |
|    |   | <p>Select the option that best describes the servings of canned tuna fish consumed, on average, during the third trimester. A serving is considered 3-4 oz. Consider the consumption of oil- or water-canned tuna fish the same.</p> <p>Check “Never/less than 1 per month” if the mother never ate canned tuna fish or had less than 1 serving of canned tuna fish per month during the last trimester.</p> <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of canned tuna fish per month during the last trimester.</p> <p>Check “1 serving per week” if the mother ate 1 serving of canned tuna fish per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of canned tuna fish per week during the last trimester.</p>   |

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| #  | Question  | Instructions  |
|----|---|---|
| 69 | <b>Breaded fish cakes, pieces, or fish sticks servings per week</b> | <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of canned tuna fish per week during the last trimester.</p> <p>Check “1 serving per day” if the mother ate 1 serving of canned tuna fish per day during the last trimester.</p> <p>Check “2 or more servings per day” if the mother ate 2 or more servings of canned tuna fish per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many servings of canned tuna fish the mother ate during the last trimester.</p> <p>Select the option that best describes the servings of breaded fish cakes, pieces, or fish sticks consumed, on average, during the third trimester. Breaded fish cakes, pieces or fish sticks that are store-bought vary on the amount to considered one serving. Base the response on the serving size of the product most frequently consumed.</p> <p>Check “Never/less than 1 per month” if the mother never ate breaded fish cakes, pieces or fish sticks or had less than 1 serving of breaded fish cakes, pieces or fish sticks per month during the last trimester.</p> <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of breaded fish cakes, pieces or fish sticks per month during the last trimester.</p> <p>Check “1 serving per week” if the mother ate 1 serving of breaded fish cakes, pieces or fish sticks per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of breaded fish cakes, pieces or fish sticks per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of breaded fish cakes, pieces or fish sticks per week during the last trimester.</p> |

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| #  | Question                                | Instructions   |
|----|---|--|
| 70 | <b>Dark meat fish servings per week</b> | <p>Check "1 or more servings per day" if the mother ate 1 or more servings of breaded fish cakes, pieces or fish sticks per day during the last trimester.</p> <p>Check "Unknown" if the respondent does not know how many servings of breaded fish cakes, pieces or fish sticks the mother ate during the last trimester.</p> <p>Select the option that best describes the servings of dark meat fish consumed, on average, during the third trimester. Examples of dark meat fish are mackerel, salmon, sardines, bluefish and swordfish. A serving is considered 3-5 oz of cooked fish.</p> <p>Check "Never/less than 1 per month" if the mother never ate dark meat fish or had less than 1 serving of dark meat fish per month during the last trimester.</p> <p>Check "1-3 servings per month" if the mother ate 1 to 3 servings of dark meat fish per month during the last trimester.</p> <p>Check "1 serving per week" if the mother ate 1 serving of dark meat fish per week during the last trimester.</p> <p>Check "2-4 servings per week" if the mother ate 2 to 4 servings of dark meat fish per week during the last trimester.</p> <p>Check "5-6 servings per week" if the mother ate 5 to 6 servings of dark meat fish per week during the last trimester.</p> <p>Check "1 or more servings per day" if the mother ate 1 or more servings of dark meat fish per day during the last trimester.</p> <p>Check "Unknown" if the respondent does not know how many servings of dark meat fish the mother ate during the last trimester.</p> |
| 71 | <b>Other fish servings per week</b>     | <p>Select the option that best describes the servings of other fish consumed, on average, during the third trimester. Examples of other fish are cod, haddock or halibut. A serving is considered 3-5 oz.</p> <p>Check "Never/less than 1 per month" if the mother never ate other fish or had less than 1 serving of other fish per month during the last trimester.</p>  |

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| #  | Question  | Instructions   |
|----|---|--|
| 72 | <b>Shrimp, lobster, scallops, clams servings per week</b> | <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of other fish per month during the last trimester.</p> <p>Check “1 serving per week” if the mother ate 1 serving of other fish per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of other fish per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of other fish per week during the last trimester.</p> <p>Check “1 or more servings per day” if the mother ate 1 or more servings of other fish per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many servings of other fish the mother ate during the last trimester.</p> <p>Select the option that best describes the servings of shrimp, lobster, scallops, clams as a main dish consumed, on average, during the third trimester. Serving size varies by the type of shellfish consumed. We are interested in the frequency that the mother consumed this as a <u>main dish</u>.</p> <p>Check “Never/less than 1 per month” if the mother never ate shrimp, lobster, scallops or clams or had less than 1 serving of shrimp, lobster, scallops or clams per month during the last trimester.</p> <p>Check “1-3 servings per month” if the mother ate 1 to 3 servings of shrimp, lobster, scallops or clams per month during the last trimester.</p> <p>Check “1 serving per week” if the mother ate 1 serving of shrimp, lobster, scallops or clams per week during the last trimester.</p> <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of shrimp, lobster, scallops or clams per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of shrimp, lobster, scallops or clams per week during the last trimester.</p> |

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| #  | Question                               | Instructions   |
|----|--|--|
| 73 | <b>Peanut butter servings per week</b> | <p>Check "1 or more serving per day" if the mother ate 1 or more serving of shrimp, lobster, scallops or clams per day during the last trimester.</p> <p>Check "Unknown" if the respondent does not know how many servings of shrimp, lobster, scallops or clams the mother ate during the last trimester.</p> <p>Select the option that best describes the servings of peanut butter consumed, on average, during the third trimester. Consider different brands or versions (e.g., regular, natural) of peanut butter the same. Consider peanut butter spreads as peanut butter. A serving is considered 1 tablespoon.</p> <p>Check "Never/less than 1 per month" if the mother never ate peanut butter or had less than 1 tablespoon of per month during the last trimester.</p> <p>Check "1-3 tablespoons per month" if the mother ate 1 to 3 tablespoons of peanut butter per month during the last trimester.</p> <p>Check "1 tablespoon per week" if the mother ate 1 tablespoon of peanut butter per week during the last trimester.</p> <p>Check "2-4 tablespoons per week" if the mother ate 2 to 4 tablespoons of peanut butter per week during the last trimester.</p> <p>Check "5-6 tablespoons per week" if the mother ate 5 to 6 tablespoons of peanut butter per week during the last trimester.</p> <p>Check "1 tablespoon per day" if the mother ate 1 tablespoon of peanut butter per day during the last trimester.</p> <p>Check "2-3 tablespoons per day" if the mother ate 2 to 3 tablespoons of peanut butter per day during the last trimester.</p> <p>Check "4 or more tablespoons per day" if the mother ate 4 or more tablespoons of peanut butter per day during the last trimester.</p> |

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| #  | Question                            | Instructions  |
|----|-------------------------------------|---|
| 74 | <b>Peanuts servings per week</b>    | <p>Check "Unknown" if the respondent does not know how many servings of peanut butter the mother ate during the last trimester.</p>   |
|    |                                     | <p>Select the option that best describes the servings of peanuts consumed, on average, during the third trimester. A serving is considered one small packet or 1 oz.</p>                  |
|    |                                     | <p>Check "Never/less than 1 per month" if the mother never ate peanuts or had less than 1 serving of peanuts per month during the last trimester.</p>                                     |
|    |                                     | <p>Check "1-3 servings per month" if the mother ate 1 to 3 servings of peanuts per month during the last trimester.</p>   |
|    |                                     | <p>Check "1 serving of peanuts per week" if the mother ate 1 serving of peanuts per week during the last trimester.</p>   |
|    |                                     | <p>Check "2-4 servings per week" if the mother ate 2 to 4 servings of peanuts per week during the last trimester.</p>   |
|    |                                     | <p>Check "5-6 servings per week" if the mother ate 5 to 6 servings of peanuts per week during the last trimester.</p>   |
|    |                                     | <p>Check "1 or more servings per day" if the mother ate 1 or more servings of peanuts per day during the last trimester.</p>  |
|    |                                     | <p>Check "Unknown" if the respondent does not know how many servings of peanuts the mother ate during the last trimester.</p>   |
| 75 | <b>Other nuts servings per week</b> | <p>Select the option that best describes the servings of other nuts (non-peanuts) consumed, on average, during the third trimester. A serving is considered one small packet or 1 oz.</p> |
|    |                                     | <p>Check "Never/less than 1 per month" if the mother never ate other nuts or had less than 1 serving of other nuts per month during the last trimester.</p>                               |
|    |                                     | <p>Check "1-3 servings per month" if the mother ate 1 to 3 servings of other nuts per month during the last trimester.</p>  |
|    |                                     | <p>Check "1 serving per week" if the mother ate 1 serving of other nuts per week during the last trimester.</p>   |

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| #  | Question                         | Instructions  |
|----|----------------------------------|---|
| 76 | <b>Alcohol servings per week</b> | <p>Check “2-4 servings per week” if the mother ate 2 to 4 servings of other nuts per week during the last trimester.</p> <p>Check “5-6 servings per week” if the mother ate 5 to 6 servings of other nuts per week during the last trimester.</p> <p>Check “1 or more servings per day” if the mother ate 1 or more servings of other nuts per day during the last trimester.</p> <p>Check “Unknown” if the respondent does not know how many servings of other nuts the mother ate during the last trimester.</p>  |
|    |                                  | <p>Select the option that best describes the servings of alcohol consumed, on average, during the third trimester. What constitutes one serving depends on the kind of alcohol consumed. Consider 1 beer, 4 oz of wine, one cocktail, or one shot of hard liquor as a single serving.</p> <p>Check “Never/less than 1 per month” if the mother never drank alcohol or had less than 1 serving of alcohol per month during the last trimester.</p> <p>Check “1-3 per month” if the mother drank 1 to 3 servings of alcohol per month during the last trimester.</p> <p>Check “1 per week” if the mother drank 1 serving of alcohol per week during the last trimester.</p> <p>Check “2-4 per week” if the mother drank 2 to 4 servings of alcohol per week during the last trimester.</p> <p>Check “5-6 per week” if the mother drank 5 to 6 servings of alcohol per week during the last trimester.</p> <p>Check “1 per day” if the mother drank 1 or more servings of alcohol per day during the last trimester.</p> <p>Check “2-3 per day” if the mother drank 1 or more servings of alcohol per day during the last trimester.</p> <p>Check “4 or more per day” if the mother drank 1 or more servings of alcohol per day during the last trimester.</p> |

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| # | Question | Instructions   |
|---|----------|--|
|   |          | Check "Unknown" if the respondent does not know how many servings of alcohol the mother drank during the last trimester. |

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*Section E: From Birth to Age 5.99 months*

The following questions cover the time since the child's birth until the child turned 6 months old. **This section should only be administered if the child is more than 6 months old.** The parent should only answer for the time period between birth and when the child turned 6 months old.

|    |   |  |
|----|---|--|
| 77 | <b>Multivitamins<br/>1<sup>st</sup> 6 months</b>      | <p>Check each month during the first 6 months of age in which the child received a multivitamin with a frequency of at least 3 times per week. Check all that apply.</p> <ul style="list-style-type: none"> <li>- Check "age &lt;1 month old" if child took any multivitamin during the first month of life.</li> <li>- Check "age 1 month" if the child took any multivitamin during the second month of life (5 to 8 weeks old).</li> <li>- Check "age 2 months" if the child took any multivitamin during the third month of life (9 to 12 weeks old).</li> <li>- Check "age 3 months" if the child took any multivitamin during the fourth month of life (13 to 16 weeks old).</li> <li>- Check "age 4 months" if the child took any multivitamin during the fifth month of life (17 to 20 weeks old).</li> <li>- Check "age 5 months" if the child took any multivitamin during the sixth month of life (21 to 24 weeks old).</li> <li>- Check "Never" if the child did not take multivitamin during the first 6 months of age.</li> <li>- Check "UKN" if the parent does not know if the child took any multivitamin during the first six months of life.</li> </ul> |
| 78 | <b>Vitamin D in<br/>the first 6<br/>months of age</b> | <p>Check each month during the first 6 months of age in which the child received a Vitamin D supplement (separate from any other vitamin/supplement that he/she already received) at least 3 times per week. Check all that apply.</p> <ul style="list-style-type: none"> <li>- Check "&lt;1 month old" if child took any vitamin D supplement during the first month of life.</li> <li>- Check "age 1 month" if the child took any vitamin D supplement during the second month of life (5 to 8 weeks old).</li> </ul>  |

*Enrollment Telephone Interview Form*

| #  | Question                               | Instructions  |
|----|--|---|
| 79 | <b>Child probiotics first 6 months</b> | <ul style="list-style-type: none"> <li>- Check “age 2 months” if the child took any vitamin D supplement during the third month of life (9 to 12 weeks old).</li> <li>- Check “age 3 months” if the child took any vitamin D supplement during the fourth month of life (13 to 16 weeks old).</li> <li>- Check “age 4 months” if the child took any vitamin D supplement during the fifth month of life (17 to 20 weeks old).</li> <li>- Check “age 5 months” if the child took any vitamin D supplement during the sixth month of life (21 to 24 weeks old).</li> <li>- Check “Never” if the child did not take a vitamin D supplement during the first 6 months of age.</li> <li>- Check “UKN” if the parent does not know if the child took any vitamin D supplement during the first six months of life.</li> </ul> <p>Enter ages at which child was given probiotics at least once per week during the first 6 months of life</p> <ul style="list-style-type: none"> <li>- Check “&lt;1 month old” if child took any probiotics during the first month of life.</li> <li>- Check “age 1 month” if the child took any probiotics during the second month of life (5 to 8 weeks old).</li> <li>- Check “age 2 months” if the child took any probiotics during the third month of life (9 to 12 weeks old).</li> <li>- Check “age 3 months” if the child took any probiotics during the fourth month of life (13 to 16 weeks old).</li> <li>- Check “age 4 months” if the child took any probiotics during the fifth month of life (17 to 20 weeks old).</li> <li>- Check “age 5 months” if the child took any probiotics supplement during the sixth month of life (21 to 24 weeks old).</li> <li>- Check “Never” if the child did not take probiotics during the first 6 months of age.</li> </ul> <p>Check “UKN” if the parent does not know if the child took any probiotics<br/>Check ALL that apply</p> |
| 80 | <b>Mostly Drank 0-2.99 months old</b>  | <p>Enter the type of liquid that the child mostly drank during the first three months of life. This period is from 0 weeks up until the time that the child turned 3 months old.</p> <p>Enter “Formula” if the child mostly drank formula and go to Q80a.</p>   |

*Enrollment Telephone Interview Form*

| #   | Question                                     | Instructions  |
|-----|--|---|
| 80a | <b>Brand of formula</b>                      | <p>Enter “Breastmilk” if the child mostly drank breastmilk.</p> <p>Enter “Cow’s milk” if the child mostly drank cow’s milk.</p> <p>Enter “Other milk” if the child mostly drank other types of milk such as soy milk or goat’s milk.</p> <p>Enter “UKN” if the parent does not know what type of milk the child drank from birth up until the child turned 3 months of age.</p>   |
| 81  | <b>Additional drink 0-2.99 months of age</b> | <p>From birth up until the child turned 3 months of age, indicate what other items the child also drank. Check all that apply. <b>DO NOT RECHECK THE DRINK ALREADY IDENTIFIED PREVIOUSLY</b> as being the primary type of drink consumed.</p> <p>Enter “Formula” if the child also drank formula and go to Q81a</p> <p>Enter “Breastmilk” if the child also drank breastmilk.</p> |

*Enrollment Telephone Interview Form*

| #   | Question                              | Instructions  |
|-----|---------------------------------------|---|
| 81a | <b>Brand of formula</b>               | <p>Enter "Cow's milk" if the child also drank cow's milk.</p> <p>Enter "Other milk" if the child also drank other types of milk such as goat's milk.</p> <p>Enter "Water" if the child was also given water.</p> <p>Enter "Juices" if the child also drank juices</p> <p>Enter "No other type of drink" if the child was given only the type of drink mentioned in Q81.</p> <p>Enter "Other" if the child drank a type of drink other than the drink mentioned in Q81 that is not listed here, and specify what kind of drink.</p> <p>Enter "UKN" if the parent does not know if the child drank additional liquids from birth up until the child turned 3 months of age.</p>   |
| 82  | <b>Mostly Drank 3-5.99 months old</b> | <p>If the child also drank formula, indicate the brand of formula that the child drank from birth to almost 3 months.</p> <p>Enter "Enfamil or Similac" if this is the brand the child mostly drank during this period. Please enter this option if the reported brand is a known equivalent to these.</p> <p>Enter "Gerber Good Start" if this is the type of formula the child mostly drank during this period. Please enter this option if the reported brand is a known equivalent.</p> <p>Enter "Soy-based formula" if this is the type of formula the child mostly drank during this period. There are several soy-based formula brands such as Isomil, Prosobee, Nursoy.</p> <p>Enter "Other" if the child mostly drank another brand of formula for during this period. Specify the name of the brand.</p> <p>Enter "UKN" if the parent does not know the type of formula that the child mostly drank during this period.</p> |
|     |                                       | <p>Enter the type of liquid that the child mostly drank from age 3 months to almost 6 months.</p>   |

*Enrollment Telephone Interview Form*

| #   | Question                                     | Instructions  |
|-----|--|---|
| 82a | <b>Brand of formula</b>                      | <p>Enter "Formula" if the child mostly drank formula and complete Q82a.</p> <p>Enter "Breastmilk" if the child mostly drank breastmilk.</p> <p>Enter "Cow's milk" if the child mostly drank cow's milk.</p> <p>Enter "Other milk" if the child mostly drank other types of milk such as soy milk or goat's milk.</p> <p>Enter "UKN" if the parent does not know what type of milk the child drank from age 3 months until the child turned 6 months of age.</p> |
| 83  | <b>Additional drink 3-5.99 months of age</b> | <p>From 3 months until the child turned 6 months, indicate what other items the child also drank. Check all that apply. DO NOT RECHECK THE DRINK ALREADY IDENTIFIED PREVIOUSLY as being the primary type of drink consumed.</p> <p>Enter "Formula" if the child also drank formula and complete Q83a.</p>   |

*Enrollment Telephone Interview Form*

| #   | Question                | Instructions  |
|-----|-------------------------|---|
|     |                         | <p>Enter "Breastmilk" if the child also drank breastmilk.</p> <p>Enter "Cow's milk" if the child also drank cow's milk.</p> <p>Enter "Other milk" if the child also drank other types of milk such as goat's milk.</p> <p>Enter "Water" if the child was also given water.</p> <p>Enter "Juices" if the child also drank juices</p> <p>Enter "No other type of drink" if the child was given only the type of drink mentioned in Q83.</p> <p>Enter "Other" if the child drank a type of drink other than the drink mentioned in Q83 that is not listed here, and specify what kind of drink.</p> <p>Enter "UKN" if the parent does not know if the child drank additional liquids from birth up until the child turned 3 months of age.</p>   |
| 83a | <b>Brand of formula</b> | <p>If the child also drank formula, indicate the brand of formula that the child drank from 3 months to almost 6 months.</p> <p>Enter "Enfamil or Similac" if this is the brand the child mostly drank during this period. Please enter this option if the reported brand is a known equivalent to these.</p> <p>Enter "Soy-based formula" if this is the type of formula the child mostly drank during this period. There are several soy-based formula brands such as Isomil, Prosobee, Nursoy.</p> <p>Enter "Gerber Good Start" if this is the type of formula the child mostly drank during this period. Please enter this option if the reported brand is a known equivalent</p> <p>Enter "Other" if the child mostly drank another brand of formula for during this period. Specify the name of the brand.</p> <p>Enter "UKN" if the parent does not know the type of formula that the child mostly drank during this period.</p> |

*Enrollment Telephone Interview Form*

| #  | Question                | Instructions  |
|--|-------------------------|---|
| 84   | <b>Solid Foods</b>      | <p>Enter ages at which child was given solid foods at least once per week during the first 6 months of life</p> <ul style="list-style-type: none"> <li>- Check "&lt;1 month old" if child ate any solid foods during the first month of life.</li> <li>- Check "age 1 month" if the child ate any solid foods during the second month of life (5 to 8 weeks old).</li> <li>- Check "age 2 months" if the child ate any solid foods during the third month of life (9 to 12 weeks old).</li> <li>- Check "age 3 months" if the child ate any solid foods during the fourth month of life (13 to 16 weeks old).</li> <li>- Check "age 4 months" if the child ate any solid foods during the fifth month of life (17 to 20 weeks old).</li> <li>- Check "age 5 months" if the child ate any solid foods supplement during the sixth month of life (21 to 24 weeks old).</li> <li>- Check "Never" if the child did not eat solid foods during the first 6 months of age.</li> </ul> |
| <p>Check "UKN" if the parent does not know if the child ate any solid foods.</p> |                         |   |
| 84a  | <b>First Solid Food</b> | <p>Select the solid food that was first introduced to the child.</p> <p>Select "Cereal" if this is the first solid food that was introduced to the child.</p> <p>Select "Fruit" if this is the first solid food that was introduced to the child.</p> <p>Select "Vegetable" if this is the first solid food that was introduced to the child.</p> <p>Select "Yogurt" if this is the first solid food that was introduced to the child.</p> <p>Select "Meat" if this is the first solid food that was introduced to the child.</p> <p>Select "Fish" if this is the first solid food that was introduced to the child.</p> <p>Select "Other" if the first solid food that was introduced to the child is not listed above. Please specify which solid food was first introduced.</p>  |

*Enrollment Telephone Interview Form*

| <b>#</b> | <b>Question</b> | <b>Instructions</b>  |
|----------|-----------------|--|
| 84b      | <b>Yogurt</b>   | <p>Enter the number of servings of yogurt that requires refrigeration the child usually eats. Do not include types of baby yogurt that do not require refrigeration.</p> <p>Check “Never/less than 1 per month” if the child never ate yogurt or had less than 1 serving of yogurt per month.</p> <p>Check “1-3 per month” if the child ate 1 to 3 servings of yogurt per month.</p> <p>Check “1 per week” if the child ate 1 serving of yogurt per week during.</p> <p>Check “2-4 per week” if the child ate 2 to 4 servings of yogurt per week.</p> <p>Check “5-6 per week” if the child ate 5 to 6 servings of yogurt per week.</p> <p>Check “1 per day” if the child ate 1 or more servings of yogurt per day.</p> <p>Check “Unknown” if the respondent does not know how many servings of yogurt the child ate.</p> |

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*Section F: Past Month Health*

The next set of questions (85-91) addresses breathing problems that happened over the past month.

The goal is to understand how the child was doing from day-to-day with respect to breathing problems and respiratory health. We are interested in any breathing problems, even ones that did not require a visit to the doctor's office, clinic or emergency room but are still important for us to understand

The questions are from the Test for Respiratory and Asthma Control in Kids (TRACK) [<http://www.asthmatracktest.com>]

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|    |   |   |
|----|---|---|
| 85 | <b>Breathing problems frequency over past month</b> | <p>Indicate how often over the past month the child was bothered with breathing problems such as wheezing, coughing, or shortness of breath.</p> <p>Enter “Not at all” if the child has not had any breathing problems or was not bothered at all by breathing problems over the past month.</p> <p>Enter “1-3 times” if the child was bothered by a breathing problem 1 to 3 times during the past 4 weeks. If the child was bothered by 4 breathing</p> |
|----|---|---|

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*Enrollment Telephone Interview Form*

| #  | Question  | Instructions  |
|----|---|---|
| 86 | <b>Breathing problems waking up frequency over past month</b> | <p>problems during the past month please select the “once every week” option.</p> <p>Enter “Once every week” if the child was bothered by a breathing problem 1 time per week, or 4 times per month.</p> <p>Enter “2 or 3 times a week” if the child was bothered by breathing problems 2 or 3 times per week during the past month.</p> <p>Select “4 or more times a week” if the child was bothered by breathing problems more than 4 times per week during the past month.</p> <p>If the child was bothered by breathing problems, ask Q86-91.</p> |
| 87 | <b>Breathing problems burden over past month</b>              | <p>Indicate the degree that breathing problems such as wheezing, cough, or shortness of breath interfered with the child’s ability to engage in his/her usual activities (such as playing or attending daycare).</p>  |

*Enrollment Telephone Interview Form*

| #  | Question  | Instructions  |
|----|---|---|
| 88 | <b>Inhaled bronchodilator use average over past month</b> | <p>Enter “Not at all” if breathing problems have not affected the child’s ability to participate in his/her usual activities over the past month.</p> <p>Enter “Slightly” if breathing problems have somewhat affected the child’s ability to participate in his/her usual activities over the past month.</p> <p>Enter “Moderately” if the child has had some problems participating in his/her usual activities over the past month.</p> <p>Enter “Quite a lot” if breathing problems have significantly affected the child’s ability to participate in his/her usual activities over the past month.</p> <p>Enter “Extremely” if during has been unable to participate in his/her usual activities over the past month due to breathing problems.</p> <p>Indicate the days per week, on average, that the child used an inhaled bronchodilator for breathing problems over the past month.</p> <p>Enter “Not at all” if no inhaled bronchodilators were used over the past month.</p> <p>Enter “1-3 times” if an inhaled bronchodilator was used, 1 to 3 times over the past month.</p> <p>Enter “Once every week” if an inhaled bronchodilator was used, on average, once every week over the past month.</p> <p>Enter “Twice every week” if an inhaled bronchodilator was used, on average, around two times every week over the past month.</p> <p>Enter “Three times every week” if an inhaled bronchodilator was used, on average, around three time each week over the past month.</p> <p>Enter “4 to 6 times a week” if an inhaled bronchodilator was used, on average, 4 to 6 times each week over the past month.</p> <p>Enter “Daily” if an inhaled bronchodilator was used every day over the past month.</p> |

*Enrollment Telephone Interview Form*

| #  | Question   | Instructions   |
|----|--|--|
| 89 | <b>Parent waking up for child's breathing problems over past month</b> | <p>Enter "Several times per day" if an inhaled bronchodilator was used several times a day over the past month.</p> <p>Indicate the number of days per week, on average, that the parent woke up or lost sleep due to the child's breathing problems over the past month.</p> <p>Enter "None" if the parent says that he/she has not been woken up by the child's breathing problems over the past month.</p> <p>Enter "<math>\leq</math> 2 days/week" if the parent says that he/she has been woken up by the child's breathing problems 2 days per week or less over the past month.</p> <p>Enter "&gt; 2 days/week but not daily" if the parent says that he/she has been woken up by the child's breathing problems more than 2 days per week over the past month.</p> <p>Enter "Daily" if the parent says that he/she has been woken up by the child's breathing problems every night over the past month.</p> <p>Enter "Not applicable" if the person completing the interview does not live with the child or has not lived with the child over the past month.</p> |
| 90 | <b>Change of plans due to illness over past month</b>                  | <p>Indicate how frequently the parent had to change his/her daytime or evening plans due to the child's breathing problems over the past month.</p> <p>Enter "None" if the parent says that he/she did not change plans due to the child's breathing problems over the past month.</p> <p>Enter "<math>\leq</math> 2 days/week" if the parent says that he/she had to change plans due to the child's breathing problems 2 days per week or less over the past month.</p> <p>Enter "&gt; 2 days/week but not daily" if the parent says that he/she had to change plans due to the child's breathing problems more than 2 days per week over the past month.</p>  |

*Enrollment Telephone Interview Form*

| #                                   | Question   | Instructions   |
|-------------------------------------|--|--|
| 91                                  | <b>Missing work on average due to breathing problems over the past month</b> | <p>Enter "Daily" if the parent says that he/she had to change plans due to the child's breathing problems every night over the past month.</p> <p>Enter "Not applicable" if the person completing the interview is not the primary caretaker or has not lived with the child over the past month.</p> <p>Indicate the number of days in the past month that the parent has missed any work as a result of the child's illness. If the person has missed half days on different days, count each half-day as a day and enter the result. For example, if the parent missed a half day on Tuesday and a half day on Thursday, this would count as 2 days of missed work.</p> <p>Enter "None" if the parent says that he/she did not miss any work due to the child's breathing problems over the past month.</p> <p>Enter "≤ 2 days/week" if the parent says that he/she missed work due to the child's breathing problems 2 days per week or less over the past month.</p> <p>Enter "&gt; 2 days/week but not daily" if the parent says that he/she missed work due to the child's breathing problems more than 2 days per week over the past month.</p> <p>Enter "Daily" if the parent says that he/she missed work due to the child's breathing problems every day over the past month.</p> <p>When parent does not work outside the home, assess if homemaker/home office duties were compromised/limited enough to qualify as "missed work." If the parent does not work, enter "Not applicable".</p> |
| <i>Section G: FOR SITE USE ONLY</i> |  |  |
| 92                                  | <b>Decline participation</b>   | <p>Enter "Yes" if the patient declined further participation before the end of the call.<br/>If "Yes", please explain further.</p> <p>Enter "No" if the patient did not decline further participation before the end of the call</p>   |

*Enrollment Telephone Interview Form*

| <b>#</b> | <b>Question</b>              | <b>Instructions</b>   |
|----------|------------------------------|---|
| 93       | <b>Ineligible</b>            | Enter "Yes" if a participant was interviewed but later found ineligible (e.g., non-working phone number)<br><br>Enter "No" if participant was interviewed and not found ineligible. |
|          | <b>Interview End Time</b>    | Enter time when interview end in HH:MM format   |
|          | <b>Interview interrupted</b> | Enter whether interview was interrupted or completed in one sitting   |
|          | <b>Data confirmation</b>     | Enter initials of interviewer stating all field with missing values were intentionally left blank because the information is unavailable.   |

## Enrollment Visit Scheduling Form

This form should be filled for all subjects who are eligible and who agree to attend an in-person visit. Please use this Scheduling Form to track attempts to schedule an in-person visit, or to track attempts to complete all parts of the in-person visit (e.g., a parent that needs to return to the hospital/clinic with a dirty diaper). At minimum, please enter the information regarding the date and time of the in-person visit and whether or not the visit was completed (“Scheduling the Visit” and “Visit Tracking”).

| #   | Question                                   | <i>Instructions</i>  |
|---|--|--|
|   | <b>Screening ID</b>                        | The Screening ID is a number automatically assigned by REDCap. Please note that this is NOT the Study ID.  |
|   | <b>Next clinical appointment scheduled</b> | Enter “Yes” if child has a clinical appointment scheduled in the near future (e.g., in the next month). If Yes, enter date and time of the clinical appointment below.<br><br>Enter “No” if child has no clinical appointment scheduled in the near future (e.g., in the next month).  |
|   | <b>Date and time of appointment</b>        | Enter date of scheduled clinical appointment in MM/DD/YYYY format.<br><br>Enter time of scheduled clinical appointment in military time (HH:MM).   |
| <i>Telephone Correspondence Log</i>   |  |  |
| The site/clinic staff must log both successful and unsuccessful telephone call attempts with the parent/legal guardian. |  |  |
|   | <b>Study staff initials</b>                | Enter initials of staff completing the form and call.<br><br>If the hospital/clinic staff member does not have a middle name, use X for the middle initial.<br><br>Example:<br>Jane A. Jones: J A J<br>Sam Smith: S X S  |
|   | <b>Date/Time call</b>                      | Enter the date of the call in MM/DD/YYYY format. Enter the time of the call in military time format (HH:MM).   |
|   | <b>Relationship to child</b>               | Select ‘Mother’ if call recipient is the child’s mother.<br><br>Select ‘Father’ if call recipient is the child’s father.<br><br>Select ‘Legal guardian’ if call recipient is the child’s legal guardian.<br><br>Select ‘Other (specify)’ if the call recipient does not fit into any of the categories listed above (e.g., alternate contact). |

|                                  |  |
|----------------------------------|--|
| <b>Please specify 'Other'</b>    | If 'Other (specify)' was selected for 'Relationship to child', describe the relationship to the child in the text box. |
| <b>Brief description of call</b> | Use the free text to describe content of the telephone call (screening, collection of stool after enrollment, etc.).   |

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*E-mail Correspondence Log*

The user logs all e-mail correspondence attempts with parent/legal guardian.

|                                       |   |
|---------------------------------------|---|
| <b>Hospital/Clinic staff initials</b> | <p>Enter initials of staff completing the form and e-mail.</p> <p>If the hospital/clinic staff member does not have a middle name, use X for the middle initial.</p> <p>Example:<br/> Jane A. Jones: J A J<br/> Sam Smith: S X S</p>  |
| <b>Date/Time e-mail</b>               | <p>Enter the date of the e-mail in MM-DD-YYYY format.<br/> Enter the time of the e-mail in military time format (HH:MM).</p>  |
| <b>Relationship to child</b>          | <p>Select 'Mother' if e-mail recipient is the child's mother.</p> <p>Select 'Father' if e-mail recipient is the child's father.</p> <p>Select 'Legal guardian' if e-mail recipient is the child's legal guardian.</p> <p>Select 'Other (specify)' if the e-mail recipient does not fit into any of the categories listed above (e.g., alternate contact).</p> |
| <b>Please specify 'Other'</b>         | If 'Other (specify)' was selected for 'Relationship to child', describe the relationship to the child in the text box.  |
| <b>Brief description of e-mail</b>    | Use the free text to describe content of the e-mail.  |

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### *Scheduling the Visit*

This section is completed by hospital/clinic staff after scheduling the visit and prior to the visit occurring. Please complete this section even if the participant was screened and enrolled in person on the same visit.

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|   |   |
|---|---|
| <b>Hospital/clinic staff initials</b>                                     | Enter the initials of the hospital/clinic staff member completing the form.<br><br>If the hospital/clinic staff member does not have a middle name, use X for the middle initial.<br><br>Example:<br>Jane A. Jones: J A J<br>Sam Smith: S X S   |
| <b>Schedule Visit Outcome</b>   | Select 'Yes' if you were able to successfully schedule the visit.<br><br>Select 'No, parent/legal guardian not reachable' if the parent/legal guardian was not reachable after multiple call and e-mail attempts were made. <i>This may occur if a screening call or in-person visit was interrupted.</i><br><br>Select 'No, parent/legal guardian does not want to participate in the study' if parent/legal guardian is no longer interested in participating in the research study. No further action is required for this form.<br><br>Select 'No, other (specify)' if there is another reason (not specified above) for why the exam was not successfully scheduled. |
| <b>Please enter the date of the scheduled visit</b>                       | If 'Yes' selected for 'Were you able to successfully schedule the visit for [child's name]?' enter the date of the scheduled visit in MM-DD-YYYY format.  |
| <b>Please specify 'other' reason visit was not scheduled successfully</b> | If 'No, other (specify)' was selected for 'Were you able to successfully schedule the visit for [child's name]?' and use free text box to describe reason.  |

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### *Visit Tracking*

This section is completed by hospital/clinic staff. Please complete this section even if the participant was screened and enrolled in person on the same visit.

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|   |   |
|---|---|
| <b>Did child and parent/legal guardian attend</b> | Select 'Yes, and visit is complete' if visit has successfully occurred. No further action is needed on this form. |
|---|---|

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|   |   |
|---|---|
| <b>scheduled visit?</b>   | <p>Select 'Yes, but participant must return in order to complete visit (specify)' if the visit occurred but some assessments were missing, which necessitate an additional visit to complete. If the participant forgot to bring a diaper or the sample brought in was deemed unsuitable, please schedule a diaper pick up. <b>Use the comments box at the bottom of the form to track subsequent attempts to get the stool sample.</b></p> <p>Select 'Yes, but participant needs to send stool sample in order to complete visit' if the visit occurred but the participant forgot to bring a diaper or the sample brought in was deemed unsuitable, please give the parent a stool collection kit for the parent to collect at home.</p> <p>Select 'No' if the visit was not attended by child and parent/legal guardian.</p> |
| <b>Please specify why child must return to the hospital/clinic to complete the visit</b>  | <p>If 'Yes, but participant must return to clinic in order to complete visit (specify)' was selected for 'Did child and parent/legal guardian attend scheduled visit?' use the text box to describe the reason in detail.</p>   |
| <p><i>If 'Yes, but participant needs to return to clinic in order to complete visit (specify)' OR 'No' to 'Did child and parent/legal guardian attend scheduled visit?' complete the questions below:</i></p> |   |
| <b>Another visit scheduled</b>  | <p>Enter 'Yes' if another visit was scheduled. Enter number of rescheduled visits in the question below.</p> <p>Enter 'No' if no other visit was scheduled. Continue to question "please indicate the reason visit was not successfully re-scheduled"</p>   |
| <b>Times rescheduled</b>  | <p>Enter the number of times the additional visits were rescheduled. You will start with just 1 reschedule and you can come back to this question if more rescheduling occurs, and change the number of reschedules so that additional fields pop up below. Once you change the number of reschedules, click somewhere on the form and the fields to enter information about the additional visit appear.</p>   |
| <p><i>Fill out the following information for each of the additional visits rescheduled</i></p>  |   |
| <b>Reason for reschedule</b>  | <p>Enter "incomplete visit" if the reschedule is due to the previous visit being incomplete.</p> <p>Enter "missed visit" if the participant was a "no show" to the previous scheduled visit.</p>  |

|  |   |
|--|---|
|  | Enter "Other" for any other reason.   |
| <b>Specify reason for additional visit</b>   | If "Other" to question about reason for reschedule, please specify the reason in this text box.   |
| <b>Please specify date of the additional visit</b>                                       | Enter the date of the additional scheduled visit in MM-DD-YYYY format.  |
| <b>Successfully attended the enrollment visit</b>  | <p>After the date of this visit has occurred, please indicate if the child and parent/guardian attended the visit:</p> <p>Select 'Yes, and visit is complete' if the child and parent/legal guardian successfully attended and completed the additional visit</p> <p>Select 'Yes, but participant needs to return in order to complete visit' if the child and parent/legal guardian attended the visit but did not complete the entire additional visit.</p> <p>Select 'No' if the child and parent/legal guardian did not successfully attend the additional visit.</p> |
| <b>Reason for not attending</b>  | <p>If 'No' or "Yes, but participant needs to return in order to complete visit" to 'After the date of this visit has occurred, please indicate if the child and parent/legal guardian attended the visit:'</p> <p>Please comment on the reason parent did not attend the visit and any other relevant information:</p>  |
| <b>Reason for return</b>   | <p>If "Yes, but participant needs to return in order to complete visit" to 'After the date of this visit has occurred, please indicate if the child and parent/legal guardian attended the visit:'</p> <p>Please specify reason why parent needs to return.</p>   |
| <b>Please indicate the reason the enrollment visit was not successfully re-scheduled</b> | <p>If 'No' was selected for 'Were you able to re-schedule the visit?':</p> <p>Select 'Parent/legal guardian not reachable' if parent/legal guardian was not reachable by phone or e-mail after multiple attempts.</p> <p>Select 'Parent/legal guardian changed mind and would no longer like to participate in this visit' if parent/legal guardian did not want to participate in the study.</p> <p>Select 'Other (specify)' if there is another reason (not specified above) that the enrollment visit was not successfully re-scheduled.</p>                           |

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|--|--|
| <b>Please specify 'other' reason the visit was not re-schedule</b> | If 'Other (specify) was selected for 'Please indicate the reason the enrollment visit was not successfully re-scheduled,' use the text box to describe the reason. |
| <b>Comments</b>  | Enter any relevant information in this text box. For example: track subsequent attempts to get the stool sample.   |

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## Tracking Form

Complete this form for all participants who sign a consent form.

| <b>#</b> | <b>Question</b>                  | <b>Instructions</b>   |
|----------|----------------------------------|---|
|          | <b>Study ID</b>                  | <p>Enter the child's 6-digit Study ID.</p> <p>If the child is enrolled in the study, manually enter the next available Study ID number. This is a unique study identification number used to identify participants throughout the study. The Study ID number is made up of a 3-digit site-specific number followed by a 3-digit study participant number, starting in the 700s, and continuing in sequential order based on enrollment date/time. For example, the 10th participant for site 098 will be 098710.</p> <p>If you are uncertain of the 3-digit site-specific number, email <a href="mailto:afsullivan@partners.org">afsullivan@partners.org</a>.</p> <p>To determine the next available Study ID, one can consult the Study ID numbers in REDCap, a list kept on-site, or use the next sheet of labels.</p> <p>Remember to also enter the Study ID number in the Screening Form. All participants who have a signed consent should be assigned a Study ID.</p> |
|          | <b>Child's First name</b>        | Enter child's last name   |
|          | <b>Child's Last name</b>         | Enter child's last name   |
|          | <b>Confirm Study ID</b>          | Re-enter the child's 6 digit Study ID.  |
| 1.       | <b>Enrollment Date</b>           | Enter date of enrollment (date that parent signed consent form) in MM/DD/YYYY format  |
| 2.       | <b>Child's Date of Birth</b>     | Enter child's DOB in MM/DD/YYYY format  |
| 3.       | <b>Signed Authorization form</b> | <p>Enter 'Yes' if parent has signed a medical records release authorization form.</p> <p>Enter 'No' if parent did not sign a medical records release authorization form. A medical records release is required for participation.</p>   |

|     |                                      |  |
|-----|--------------------------------------|--|
| 3.a | <b>Number of authorization forms</b> | Enter number of authorization forms signed by parent and attach a scanned PDF copy of the medical release authorization form   |
| 4.  | <b>Participant Status</b>            | <p>This participant status variable will be used throughout the study to identify the status of each child enrolled.</p> <p>Enter 'consented only' if a consent form was signed, but the enrollment requirements were not fulfilled. Participants who signed consent and were later found to be ineligible are also included in this category.</p> <p>Enter 'active' if a consent form was signed and all enrollment requirements were fulfilled.</p> <p>Enter 'withdraw by participant during enrollment visit' if a consent form was signed, but the participant decided to withdraw from the study before the end of the enrollment visit.</p> <p>Enter 'withdraw by participant after enrollment visit' if a consent form was signed, but the participant decided to withdraw from the study after the enrollment visit.</p> <p>Enter 'withdraw by PI' if a consent form was signed, but the PI decided to withdraw the participant from the study.</p> <p>Enter 'child died' if child died at any point after signing the consent form.</p> <p>Enter 'other' if the participant's status is anything other than the options listed above. Please specify in the text box what the participant's status is</p> |
|     | <b>If Consented Only</b>             | <p>Please specify the enrollment requirements the participant did not fulfill. Check all that apply.</p> <p>Enter 'no signed copy of medical records release' if participant did not sign a medical records release form</p> <p>Enter 'no nasal swab specimen collected at enrollment' if participant refused the nasal swab collection at enrollment</p> <p>Enter 'no email address provided during subsequent contact attempt' if participant did not provide an e-mail address, even after multiple attempts</p>  |

|  |  |
|--|--|
|  | <p>Enter 'no alternate contact information provided during subsequent contact attempts' if participant did not provide an alternate contact, even after multiple attempts</p> <p>Enter 'enrolled but found later to be ineligible' if participant signed consent but was later found ineligible</p> <p>Enter 'other' for any other reason besides the ones listed above. Please specify in the text box.</p>   |
| <b>If Enrolled but ineligible</b>                        | <p>Please explain here. Please clarify which Screening Form answer(s) are incorrect and provide the correct values originally requested here.</p> <p>Please also complete a protocol deviation form (major protocol deviation).</p>  |
| <b>If Withdraw by participant after enrollment visit</b> | <p>Select the level of contact the participant is willing to maintain despite partial or complete withdrawal. When trying to understand what level of contact participant is willing to maintain despite withdrawal it is important not to suggest more than is necessary. Instead of immediately presenting all "levels" of contact, suggest the most complete level of contact possible and only offer an alternative if the participant refuses. Please follow hierarchy below, only presenting the next step down if the participant refuses the higher level of contact offered:</p> <ol style="list-style-type: none"> <li><b>1. Reduced Participation – no in person visits</b><br/>Includes sample collection, 6-month assessments, medical record review and final call.</li> <li><b>2. Reduced Participation – no in person visits and no sample collection</b><br/>Includes 6-month assessments, medical record review and final call.</li> <li><b>3. Reduced Participation – no in person visits, no samples, short form for telephone follow-up</b><br/>Includes the short form version of the 6-month assessments, medical record review and the final call.</li> <li><b>4. Medical record review only with final call</b><br/>Includes medical chart review only with a final call at 3 years/ 6 years.</li> <li><b>5. Medical record review only without final call</b></li> </ol> |

|    |                                     |  |
|----|-------------------------------------|--|
|    |                                     | Includes medical chart review only and no phone assessments.   |
|    |                                     | <b>6. Complete withdrawal</b><br>No further contact will be made.  |
|    | <b>Date of withdrawal</b>           | Enter date of withdrawal in MM/DD/YYYY form  |
| 5  | <b>Opt out of sample collection</b> | Enter 'Yes' if parent permanently opts out of any sample collection<br><br>Enter 'No' if parent did not permanently opt out of sample collection portion of the study<br><br>Please enter "No" until parent changes his/her mind. Please do not give this as an option for them to opt out of sample collection.   |
| 5a | <b>Type of sample opt out</b>       | Select sample the parent opts out of:<br><br>Enter 'nasal swab specimen' if parent opts out of nasal swabs, except for the nasal swab collected at enrollment (this is required for enrollment)<br><br>Enter 'saliva swab specimen' if parent opts out of saliva swabs<br><br>Enter 'stool specimen' if parent opts out of stool specimens<br><br>Enter 'blood specimen' if parent opts out of blood specimens<br><br>Check ALL that apply |
|    | <b>Nasal Swab opt out</b>           | Enter date participant opted out of nasal swab specimens in MM/DD/YYYY format  |
|    | <b>Saliva Swab opt out</b>          | Enter date participant opted out of saliva swab specimens in MM/DD/YYYY format   |
|    | <b>Stool specimen opt out</b>       | Enter date participant opted out of stool specimens in MM/DD/YYYY format   |
|    | <b>Blood specimen opt out</b>       | Enter date participant opted out of blood specimens in MM/DD/YYYY format   |
| 6  | <b>Changes in Custody</b>           | Enter 'Yes' if there have been known changes in custody  |

|    |   |   |
|----|---|---|
|    |   | Enter 'No' if there have been no known changes in custody   |
|    |   | Please select "No" until staff becomes aware of changes in custody of child.  |
| 6a | <b>Date change in custody documented</b>    | Enter date the custody change was first documented in MM/DD/YYYY format   |
| 6b | <b>Date change in custody last verified</b> | Enter date the custody change was last verified in MM/DD/YYYY format<br><br>Update this date every time the custody change is verified  |
| 6c | <b>Comments change in custody</b>           | Enter comments regarding custody change of child here   |
| 7  | <b>Other comments</b>                       | Enter any relevant information regarding the status of this participant here  |
|    | <b>Data Confirmation</b>                    | If required fields are left blank when saving the record, a display will appear with every question left unanswered. If these fields can be completed later, change the status to Unverified to indicate that you will return to complete the form at a later time. When all available information has been entered, change the status to complete and enter your initials on the final question to confirming that the information missing cannot be obtained. |

# Contact Form

After the parent signs the consent form, complete the Contact Form. Please read the scripts at the start of each section of the Contact Form to explain why we are collecting this information.

After the Contact Form is complete, the RA should try the “best telephone number” once to confirm that it is in service (i.e., make sure the phone rings). If the phone number is not in service, the RA should re-approach the subject to resolve the problem. If the line is inconsistent or inactive, the RA will remind the subject that he/she needs an active line to participate in the study. If the issue remains unresolved, the subject should not continue in the study. In such a case, the subject should be withdrawn from the study.

## *Contact Form*

| <b>#</b> | <b>Question</b>                        | <b>Instructions</b>   |
|----------|--|---|
|          | <b>Study ID</b>                        | Automatically populated by REDCap   |
|          | <b>Confirm Study ID</b>                | Re-enter the Study ID previously assigned to the child.<br><br>This Study ID must match the Study ID assigned on the Tracking Form.   |
|          | <b>Confirm child’s DOB</b>             | Re-enter the child’s date of birth.   |
| 1        | <b>Child’s Name</b>                    | Enter the first name, middle initial, last name, and any suffix (like Jr.) in the spaces provided. Make sure to enter the right letter case, as subsequent checks of the child’s name will be based on how it is entered into REDCap here.                        |
| 2        | <b>Child’s Nickname</b>                | Enter “Yes” if the child has a nickname and enter it in the space provided.<br><br>Enter “No” if the child does not have a nickname.  |
| 3        | <b>Gender</b>                          | Enter “Male” if the child is male.<br><br>Enter “Female” if the child is female.  |
| 4        | <b>Contact’s Name</b>                  | Write the first name, middle initial, last name, and any suffix (like Jr.) of the person who consented to participate in the study. Confirm the spelling of the name.   |
| 5        | <b>Contact’s Relationship to child</b> | Identify the contact’s relationship to the child. Select from “Mother,” “Father,” or “Legal Guardian.”<br><br>If the contact’s relationship to the child is the mother or father, please specify if the individual is the biological mother or biological father. |

Contact Form

| #  | Question  | Instructions   |
|----|---|--|
|    |   | If the contact is the legal guardian, please select whether he/she is the grandparent, sibling, or other. If other, please specify.  |
| 6  | <b>Home Address</b>                                   | <p>Enter the number, street, apartment number, city, state and zip code of the address of the contact for the child.</p> <p>If the parent is unable to provide an address, the child is NOT ELIGIBLE for the study and the interview should not continue. Go to the Tracking Form and report that the child was subsequently found to be ineligible. Also complete a protocol deviation form in REDCap.</p>  |
| 7  | <b>Confirmation if Address is the same as Child's</b> | <p>Enter "Yes" if the child lives at the same address as the contact.</p> <p>Enter "No" if the child lives at a different address. There could be situations, for example, in which the parents might live separately. If this is the case, please clarify these situations in the text box provided.</p>  |
| 8  | <b>Home address change</b>                            | <p>FOR FOLLOW-UP (POST-ENROLLMENT) USE ONLY. Please leave this question blank until child passes enrollment. Once the participant passes enrollment, mark this question as "No" until "Yes" is necessary.</p> <p>Enter "Yes" if the participant's home address changed since the last time they spoke with our study team.</p> <p>Enter "No" if the participant's home address has not changed since the last time they spoke with our study team.</p> |
|    | <b>If address changed</b>                             | <p>Enter the current home address information in the fields above (Q6) and move former home address information to the fields below. Adjust question 7 accordingly.</p>  |
| 8i | <b>Address changes</b>                                | <p>Enter number of times the address changed. Update this number any time the participant's address changes</p> <p>For each address change, enter the date the child moved from the address and enter the</p>  |

*Contact Form*

| #   | Question                        | Instructions  |
|-----|---------------------------------|---|
|     |                                 | former home address information, including street, apt #, city, state, and zip code below   |
| 9   | <b>Best telephone number</b>    | Enter the best phone number to use to reach the parent, including area code.  |
| 9a  | <b>Telephone number type</b>    | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed. |
| 9b  | <b>Leaving messages</b>         | Enter "Yes" if the contact is able and willing to receive messages at this number.  |
|     |                                 | Enter "No" if the contact is not able or willing to receive messages at this number.  |
| 9c  | <b>Sending text messages</b>    | Enter "Yes" if the contact is able and willing to receive text messages at this number.   |
|     |                                 | Enter "No" if the contact is not able or willing to receive text messages at this number.   |
| 10  | <b>Second best phone number</b> | Enter "Yes" if the subject has a second phone number they are willing to share.   |
|     |                                 | Enter "No" if the subject does not have a second phone number that they are willing to share.   |
| 10a | <b>Second telephone number</b>  | Enter the second phone number to use to reach the parent, including area code.  |
| 10b | <b>Telephone number type</b>    | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed. |
| 10c | <b>Leaving messages</b>         | Enter "Yes" if the contact is able and willing to receive messages at this number.  |
|     |                                 | Enter "No" if the contact is not able or willing to receive messages at this number.  |
| 10d | <b>Sending text messages</b>    | Enter "Yes" if the contact is able and willing to receive text messages at this number.   |
|     |                                 | Enter "No" if the contact is not able or willing to receive text messages at this number.   |
| 11  | <b>Third best number</b>        | Enter "Yes" if the subject has a third phone number they are willing to share.  |
|     |                                 | Enter "No" if the subject does not have a third phone number that they are willing to share.  |

Contact Form

| #   | Question                      | Instructions  |
|-----|-------------------------------|---|
| 11a | <b>Third telephone number</b> | Enter the third phone number to use to reach the subject, including area code.  |
| 11b | <b>Telephone number type</b>  | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.   |
| 11c | <b>Leaving messages</b>       | Enter "Yes" if the contact is able and willing to receive messages at this number.<br><br>Enter "No" if the contact is not able or willing to receive messages at this number.  |
| 11d | <b>Sending text messages</b>  | Enter "Yes" if the contact is able and willing to receive text messages at this number.<br><br>Enter "No" if the contact is not able or willing to receive text messages at this number.  |
| 12  | <b>Best Times to Call</b>     | Enter the parent's preferred days (weekdays vs. weekends) and times (mornings, afternoons, evenings, any of these times) for receiving follow-up telephone calls. Check all that apply. At minimum, check at least one option.  |
| 13  | <b>Calling instructions</b>   | Enter any specific instructions when calling (e.g., parent may request that we only call cell phone as a last resort because the parent pays by the minute.)  |
| 14  | <b>Spoken Language</b>        | If the parent is English speaking, you may skip this question and enter "English"<br><br>If the parent prefers to speak Spanish or speaks Spanish only, enter "Spanish" as the option for follow-up calls.<br><br>If the parent has no preference, check the option "Either English or Spanish".                |
| 15  | <b>Written Language</b>       | If the parent is English speaking, you may skip this question and enter "English"<br><br>If the parent prefers to read Spanish or reads Spanish only, enter "Spanish" as the option for follow-up written communications.<br><br>If the parent has no preference, check the option "Either English or Spanish". |

## Contact Form

| #          | Question                                | Instructions   |
|------------|---|--|
| 16-<br>16a | <b>Email address 1</b>                  | <p>Enter “Yes” if the parent has an email address they are willing to provide. If the parent has more than one email address, ask for the email address used most often. Enter the email address.</p> <p>Enter “No” if the parent does not have an email address or does not wish to share an email address.</p> <p>Communicate to the parent that we need an email address on file in order for them to participate in the study (i.e., it’s required). If they do not provide an email address after multiple attempts post-enrollment, they are NOT ELIGIBLE to participate in the study. Go to the Tracking Form and report that the child was subsequently found to be ineligible. Also complete a protocol deviation form in REDCap.</p> |
| 16b        | <b>Email address 2</b>                  | <p>Enter “Yes” if the parent has a second email address available that they are willing to provide. Enter the email address.</p> <p>Enter “No” if the parent does not have a second email address or does not wish to share a second email address.</p>  |
| 17-<br>19  | <b>Alternate contact 1 name</b>         | <p>Enter the alternate contact’s first and last name. Confirm the spelling of the name.</p> <p>Communicate to the parent that we need one alternate contact for them to participate in the study (i.e., it’s required). If they do not provide an alternate contact after multiple attempts post-enrollment, they are NOT ELIGIBLE to participate in the study. Go to the Tracking Form and report that the child was subsequently found to be ineligible. Also complete a protocol deviation form in REDCap.</p>  |
| 20         | <b>Alternate contact 1 relationship</b> | <p>Identify the contact’s relationship to the child. If the contact’s relationship to the child is the mother or father please specify if the individual is the biological mother or biological father.</p> <p>Enter “Other” if the relationship is not adequately captured by one of the response options. Specify the type of relationship.</p>  |

*Contact Form*

| #   | Question   | Instructions   |
|-----|--|--|
| 21  | <b>Alternate contact 1 Home address</b>                | Enter the number, street, apartment number, city, state and zip code of the address of the alternate contact 1 for the child.  |
| 22  | <b>Best number to reach alternate contact 1</b>        | Enter the best phone number to use to reach alternate contact 1. If the contact has the same phone number as the parent, please re-enter the phone number.<br><br>Communicate to the parent that we need the phone number of one alternate contact for them to participate in the study (i.e., it's required). If they do not provide an alternate contact after multiple attempts post-enrollment, they are NOT ELIGIBLE to participate in the study. Go to the Tracking Form and report that the child was subsequently found to be ineligible. Also complete a protocol deviation form in REDCap. |
| 22a | <b>Alternate contact 1 type of telephone number</b>    | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.  |
| 23  | <b>Second best number to reach contact 1</b>           | Enter the "Yes" if the subject has a second best phone number to use to reach alternate contact 1.<br><br>Enter "No" if the subject does not have a second best phone number for the alternate contact 1.  |
| 23a | <b>Second best number to reach contact 1</b>           | Enter the second phone number to use to reach the alternate contact 1, including area code. If the alternate contact has the same phone number as the parent, please re-enter the phone number.  |
| 23b | <b>Second best number type for alternate contact 1</b> | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.  |
| 24  | <b>Third best number to reach contact 1</b>            | Enter the "Yes" if the subject has a third best phone number to use to reach alternate contact 1.<br><br>Enter "No" if the subject does not have a third best phone number for the alternate contact 1.  |

## Contact Form

| #             | Question  | Instructions   |
|---------------|---|--|
| 24a           | <b>Third best number to reach contact 1</b>                 | Enter the third best phone number to use to reach alternate contact 1. If the alternate contact has the same phone number as the parent, please re-enter the phone number.   |
| 24b           | <b>Third best number type for alternate contact 1</b>       | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.  |
| 25<br>&<br>26 | <b>Alternate contact 1<br/>&amp;<br/>Email 1 &amp; 2</b>    | <p>Enter "Yes" if the alternate contact has an email address that the parent is willing to provide. If the alternate contact has more than one email address, ask for the email address used most often. Enter the email address.</p> <p>Enter "No" if the alternate contact does not have an email address or the parent does not wish to share it.</p> |
| 27            | <b>Comments/special instruction</b>                         | Enter any comments or special instructions that the subject may have about communicating with the alternate contact.   |
| 28            | <b>Alternate contact 2</b>                                  | <p>Enter "Yes" if there is a second alternate contact that the parent is willing to provide.</p> <p>Enter "No" if there is no second alternate contact that the parent is willing to provide.</p>  |
| 29<br>&<br>30 | <b>Alternate contact 2<br/>&amp;<br/>name and last name</b> | Enter the alternate contact's first and last name. Confirm the spelling of the name.   |
| 31            | <b>Alternate contact 2<br/>relationship</b>                 | <p>Identify the contact's relationship to the child. If the contact's relationship to the child is the mother or father please specify if the individual is the biological mother or biological father.</p> <p>Enter "Other" if the relationship is not adequately captured by one of the response options. Specify the type of relationship.</p>        |
| 32            | <b>Alternate contact 2<br/>Home address</b>                 | Enter the number, street, apartment number, city, state and zip code of the address of the alternate contact 2 for the child.  |
| 33            | <b>Best number to reach<br/>alternate contact 2</b>         | Enter the best phone number to use to reach alternate contact 2. If the contact has the same phone number as the parent, please re-enter the phone number.   |

Contact Form

| #       | Question   | Instructions  |
|---------|--|---|
| 33a     | <b>Alternate contact 2 type of telephone number</b>    | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.   |
| 34      | <b>Second best number to reach contact 2</b>           | Enter the "Yes" if the subject has a second best phone number to use to reach alternate contact 2.<br><br>Enter "No" if the subject does not have a second best phone number for the alternate contact 2.   |
| 34a     | <b>Second best number to reach contact 2</b>           | Enter the second phone number to use to reach the alternate contact 2, including area code. If the alternate contact has the same phone number as the parent, please re-enter the phone number.   |
| 34b     | <b>Second best number type for alternate contact 2</b> | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.   |
| 35      | <b>Third best number to reach contact 2</b>            | Enter the "Yes" if the subject has a third best phone number to use to reach alternate contact 2.<br><br>Enter "No" if the subject does not have a third best phone number for the alternate contact 2.   |
| 35a     | <b>Third best number to reach contact 2</b>            | Enter the third best phone number to use to reach alternate contact 2. If the alternate contact has the same phone number as the parent, please re-enter the phone number.  |
| 35b     | <b>Third best number type for alternate contact 2</b>  | Specify what type of phone number this is; choose from "Home," "Work," "Cell" or "Other." If "Other," please specify the type of phone number listed.   |
| 36 & 37 | <b>Alternate contact 2 Email 1 &amp; 2</b>             | Enter "Yes" if the alternate contact has an email address that the parent is willing to provide. If the alternate contact has more than one email address, ask for the email address used most often. Enter the email address.<br><br>Enter "No" If the alternate contact does not have an email address or the parent does not wish to share it. |

Contact Form

| #             | Question                            | Instructions  |
|---------------|-------------------------------------|---|
| 38            | <b>Comments/special instruction</b> | Enter any comments or special instructions that the subject may have about communicating with the alternate contact. You may also use this space to note information that still needs to be collected during a 1-week call. The purpose of this call is only to collect contact information.  |
| 39            | <b>Social Security Number</b>       | <p>Because this study involves monetary payment we need to collect the social security number (SSN) of the consenting parent in order to meet our institutional and Federal guidelines that regulate payment to research subjects. SSN can be a sensitive topic so it is important to approach this question with a clear explanation of the purpose of collection of this information and confidentiality protection.</p> <p>SSN is required to make study payments, but it is not required if the parent wants to participate without pay.</p> <p>Enter "Yes" if the parent is willing to provide their SSN. Enter the SSN with dashes.</p> <p>Enter "No" if the parent does not want to provide their SSN. If the parent is willing to participate without pay, proceed. If the parent is unwilling to participate without pay, stop the interview and proceed to Tracking Form. Indicate that the person was found later to be ineligible. Also, please complete a protocol deviation form.</p> <p>If the parent does not have a SSN, please write "FOREIGN" in the space provided for the social security number. We will be able to issue a check to the participant even if they do not have a social security number. Please make sure you only use this option for those who do not have a SSN, NOT for those who don't want to provide one.</p> |
| 40<br>&<br>41 | <b>PCP's name and last name</b>     | <p>Enter the first and last name of the PCP. Providing PCP information is a requirement of the study.</p> <p>By primary care, we mean coordinated, comprehensive, longitudinal care (including prevention). The PCP is usually one person but may be a clinic.</p>  |

Contact Form

| #  | Question                              | Instructions   |
|----|---------------------------------------|--|
|    |                                       | If the parent is unwilling to provide PCP information, the child is ineligible for the study. Proceed to the Tracking Form and indicate that the person was found later to be ineligible. Also, please complete a protocol deviation form.   |
| 42 | <b>PCP's Address</b>                  | Enter the number, street, city, state and ZIP code of the primary care provider's office address. If the parent cannot provide the address, it is the study staff's responsibility to obtain this information. This information is essential to the annual collection of medical records.  |
| 43 | <b>PCP's telephone and fax number</b> | <p>Enter the PCP's telephone number.</p> <p>If the parent does not know or does not currently have this information, they can still participate in the study. Remind the subject that he/she can provide this number at a call initiated post-enrollment. If they still cannot provide the phone number after multiple attempts, it is the study staff's responsibility to obtain this information.</p> <p>Enter the PCP's fax number, if available.</p> <p>If the parent does not know or does not currently have this information, they can still participate in the study. Remind the subject that he/she can provide this number at a call initiated post-enrollment. If they still cannot provide the phone number after multiple attempts, it is the study staff's responsibility to obtain this information.</p> <p>If the PCP does not have a fax, leave this field blank.</p> |
| 44 | <b>PCP's Email address</b>            | <p>Enter the email address of the primary care provider.</p> <p>Remind the subject that he/she can provide this number at a call initiated post-enrollment. If they still cannot provide the phone number after multiple attempts, it is the study staff's responsibility to obtain this information.</p> <p>If the PCP does not have an email address, leave this field blank.</p>  |

Contact Form

| #   | Question                 | Instructions   |
|-----|--------------------------|--|
|     | <b>PCP Contact Notes</b> | Enter any additional information that may facilitate our ability to contact the PCP.   |
| 45  | <b>PCP changes</b>       | <p><u>For follow-up use only (primarily for EMNet use).</u> Please leave this question blank until child passes enrollment. Once the participant passes enrollment, mark this question as “No” until “Yes” is necessary.</p> <p>Enter “Yes” child’s PCP has changed from the one listed above</p> <p>Enter “No” if child’s PCP is still the PCP listed above</p>   |
| 45a | <b>If new PCP</b>        | <p>Enter number of times the PCP changed. Change this value to the number of former PCPs seen by child every time the PCP changes.</p> <p>Move the former PCP info to the fields below and enter the current PCP info in the field above (PCP above should always be the current one). Enter the date the child stopped seeing prior PCP and then transfer all of the old PCP information to the fields below.</p>   |
|     | <b>Tracked Changes</b>   | <p>This field is for interviewer use only. Please make a note of each time an update is made to this form that requires overwriting information. Enter the date and the information that was replaced.</p> <p>For example, if there are any fields overwritten based on information obtained at a 1-week call (follow-up call), enter that information here. The entry would appear as something like:<br/>“3/01/2017 JS: Primary email updated at 1 week call”</p> <p>It is not necessary to enter the new information (i.e. the actual email address) in the tracked changes box. However, if you are <u>replacing</u> information (i.e., a new phone number, email address, etc.) please copy the old information into the tracked changes box along with the date, your initials, and the reason for the change.</p> |
|     | <b>Data Confirmation</b> | <p>If required fields are left blank when saving the record, a display will appear with every question left unanswered. If these fields can be completed later, change the status to Unverified to indicate</p>  |

Contact Form

| # | Question | Instructions   |
|---|----------|--|
|   |          | that you will return to complete the form at a later time. When all available information has been entered, change the status to complete and enter your initials on the final question to confirming that the information missing cannot be obtained. |

## Enrollment Visit Form

This form should be filled for all participants who attend their enrollment visit.

|  |                                   |   |
|--|-----------------------------------|---|
|  | <b>Confirm Child's First Name</b> | See <a href="#">Contact Form Child's Name</a> .                   |
|  | <b>Confirm Child's Last Name</b>  | See <a href="#">Contact Form Child's Name</a> .                   |
|  | <b>Confirm Study ID</b>           | Re-enter the child's 6-digit Study ID.                            |
|  | <b>Enrollment date</b>            | Re-enter date parent enrolled in the study (signed consent form). |

Ask parent questions about change's to child's health since the last time you spoke on the phone.

|    |                                     |  |
|----|-------------------------------------|--|
| 1  | <b>Stomach symptoms past 24 hrs</b> | <p>Check "2 or more watery or much loose stools" if child has had 2 or more watery or much loose stools in the past 24 hours</p> <p>Check "any episode of vomiting, not including spit-ups" if child has vomited at least once in the past 24 hours</p> <p>Check "any fever (or felt hot or had chills)" if child has had a fever, felt hot, or had chills in the past 24 hours</p> <p>Check "None" if child has had none of the above symptoms in the past 24 hours</p> <p>Check ALL that apply</p> |
| 2  | <b>Cough</b>                        | <p>Enter "Yes" if child has a cough. Continue with question 2a.</p> <p>Enter "No" if child doesn't have a cough.</p>   |
| 2a | <b>Cough severity</b>               | <p>Indicate the severity of this cough.</p> <p>Enter "Mild" if cough caused mostly gagging.</p> <p>Enter "Moderate" if cough was significant, but did not wake the child at night</p> <p>Enter "Severe" if cough caused the child to vomit or woke the child at night.</p>   |

|    |                            |  |
|----|----------------------------|--|
| 3  | <b>Runny Nose</b>          | <p>Enter “Yes” if the child has a runny nose and go to Q3a.</p> <p>Enter “No” if the child does not have a runny nose.</p>   |
| 3a | <b>Runny nose severity</b> | <p>Indicate the severity of this runny nose.</p> <p>Enter “Mild” if the runny nose had to be suctioned 0-4 times per day or wiped every 2 hours or less.</p> <p>Enter “Severe” if runny nose had to be suctioned 5 or more times per day or wiped 1 or more times per hour.</p>  |
| 4  | <b>Fever</b>               | <p>Enter “Yes, temp <math>\geq 100^{\circ}\text{F}</math>” if the child has a fever of <math>100^{\circ}\text{F}</math> or higher.</p> <p>Enter “No” if the child has temperature(s) lower than <math>100^{\circ}\text{F}</math>.</p>  |
| 5  | <b>Hoarse Voice</b>        | <p>Enter “Yes” if the parent indicates that the child has a muffled, scratchy voice.</p> <p>Enter “No” if the child does not have a muffled, scratchy voice. Also enter “No” if the parent reports that the child doesn’t make enough sounds to make this determination (i.e., the child is too young to have reached the developmental milestone of make sounds that could be described as “hoarse”).</p> |
| 6  | <b>Breathing Faster</b>    | <p>Enter “Yes” if the parent indicates that the child is breathing faster than normal.</p> <p>Enter “No” if the child is breathing with the usual frequency.</p>   |
| 7  | <b>Wheezing</b>            | <p>After reading the question, explain to the parent what wheezing means by stating that it is a high-pitched whistling sound that the child might make when breathing out.</p> <p>Enter “Yes” if the parent indicates that he/she hears a wheezing sound.</p> <p>Enter “No” if the parent denies hearing a wheezing sound.</p>  |
| 8  | <b>Medical problems</b>    | <p>Enter “Yes” if child has been diagnosed with any medical problems since the last time you spoke with them</p> <p>If “Yes”, specify the problem</p>  |

|              |                                   |  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
|--------------|-----------------------------------|--|-------------|--------|--------------|------------|------------------|------------|-----------|---------------|--------|--------------|----------------|--------------|---------|-------------|------------|----------|-------|------------|--------------|-----------|--|
|              |                                   | <p>Enter “No” if child has not be diagnosed with any medical problems since the last time you spoke with them</p> <p>Enter “UKN” if the parent does not know if the child has been diagnosed with any medical problems since the last time you spoke with them</p>   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9            | <b>Antibiotic use</b>             | <p>Enter “Yes” if during the past month the child took any oral, intravenous, or intramuscular antibiotics. See the chart below for some common antibiotics. If “Yes” continue to question 9a and 9b</p> <table border="1"> <tr> <td>Amoxicillin</td> <td>Biaxin</td> <td>Erythromycin</td> </tr> <tr> <td>Ampicillin</td> <td>Cipro Cephalexin</td> <td>Gentamicin</td> </tr> <tr> <td>Augmentin</td> <td>Ciprofloxacin</td> <td>Keflex</td> </tr> <tr> <td>Azithromycin</td> <td>Clarithromycin</td> <td>Levofloxacin</td> </tr> <tr> <td>Bactrim</td> <td>Doxycycline</td> <td>Penicillin</td> </tr> <tr> <td>Rifampin</td> <td>Sepra</td> <td>Vancomycin</td> </tr> <tr> <td>Streptomycin</td> <td>Zithromax</td> <td></td> </tr> </table> <p>Enter “No” if the child did not receive any antibiotics during this period.</p> <p>Enter “UKN” if the parent does not know if the child received any antibiotics during this period.</p> | Amoxicillin | Biaxin | Erythromycin | Ampicillin | Cipro Cephalexin | Gentamicin | Augmentin | Ciprofloxacin | Keflex | Azithromycin | Clarithromycin | Levofloxacin | Bactrim | Doxycycline | Penicillin | Rifampin | Sepra | Vancomycin | Streptomycin | Zithromax |  |
| Amoxicillin  | Biaxin                            | Erythromycin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Ampicillin   | Cipro Cephalexin                  | Gentamicin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Augmentin    | Ciprofloxacin                     | Keflex   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Azithromycin | Clarithromycin                    | Levofloxacin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Bactrim      | Doxycycline                       | Penicillin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Rifampin     | Sepra                             | Vancomycin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Streptomycin | Zithromax                         |  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9a           | <b>Name of antibiotics</b>        | <p>Select the type of antibiotic from options listed.</p> <p>Enter “others” if the antibiotic is taken is not listed and specify the antibiotic name</p> <p>Enter “UNK” if the parent does not know name of the antibiotic received during this period.</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9b           | <b>Date of antibiotic</b>         | <p>Enter date that child most recently took an antibiotic in MM/DD/YYYY format.</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 10           | <b>Probiotics</b>                 | <p>Enter “Yes” if child took probiotics in the past month. If “Yes” continue with question 10a</p> <p>Enter “No” if child did not take probiotics in the past month</p> <p>Enter “UKN” if parent does not know if child took probiotics in the past month</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 10a          | <b>Date of probiotics</b>         | <p>Enter date that child most recently took probiotics in MM/DD/YYYY format.</p>   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 11           | <b>Over the counter medicines</b> | <p>Check all the over the counter medicines that the child received during the past week.</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |

|      |                                    |   |
|------|------------------------------------|---|
|      |                                    | <p>If the child was given any specific vitamin(s) or dietary supplement(s) during this period, specify the type of vitamin(s) or supplement(s).</p> <p>If the medicine is not listed, check "Other OTC medicine" and specify the type of medicine.</p> <p>Check "None" if the child did not receive any over the counter medicines.</p>   |
| 12   | <b>Diaper with stool</b>           | <p>Enter "Yes" if parent brought in a diaper with the child's stool in it. If "Yes" continue to question 12b1.</p> <p>Enter "No" if parent did not bring in a diaper with the child's stool in it. If "No" continue to question 12a1.</p>   |
| 12a1 | <b>Stool needed</b>                | <p>Select parent's preference for providing a stool sample.</p> <p>Select "come back to clinic" if the parent would like to bring in a diaper to the clinic and specify the date/time when parent can come to the office.</p> <p>Select "study staff to visit house" if parent would like study staff to pick up the diaper from the parent's house and specify the date and time of pick up. Verify that the home address on file is correct and if it isn't, ask for correct address.</p> <p>Select "stool collection kit" if parent would like to take home a stool collection kit and then mail it to EMNet with a specimen inside.</p> <p>Select "Other" if parent would like to give us a sample using a method other than the ones listed and specify.</p> |
| 12b1 | <b>Number of diapers</b>           | <p>Enter number of diapers that were brought to the visit. For each diaper, please enter answers to questions 12b2-12b5. If more than 4 diapers were brought in, please enter the information about the additional diaper(s) in the comments box at the bottom of the form.</p>   |
| 12b2 | <b>Date and time of collection</b> | <p>Enter date and time that diaper was collected at home in MM/DD/YYYY and HH:MM format.</p>  |
| 12b3 | <b>Diaper frozen</b>               | <p>Enter "Yes" if diaper was frozen at home after collection and enter date and time it was placed into freezer in MM/DD/YYYY and HH:MM format.</p> <p>Enter "No" if diaper was not frozen at home after collection and specify reason(s) diaper was not frozen.</p>  |

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|      |   |   |
|------|---|---|
| 12b4 | <b>Diaper rash<br/>creams,<br/>pastes, or<br/>ointments</b> | Enter “Yes” if diaper rash creams, pastes, or ointments were used on the child before the diaper was removed and specify what was used.<br><br>Enter “No” if diaper rash creams, pastes, or ointments were <u>not</u> used on the child before the diaper was removed.  |
| 12b5 | <b>Urine present</b>  | Enter “No” if no urine was present in the diaper (stool only).<br><br>Enter “Yes, urine present but diaper not saturated” if urine was present in the diaper but not a significant amount. Use your best judgment in determining saturated vs. not saturated.<br><br>Enter “Yes, diaper saturated” if a significant amount of urine was present. Again, use your best judgment in determining saturated vs. not saturated.<br><br>Enter “Unknown” if you are unable to tell if any urine was present in the diaper. |

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# Specimen Checklist

## *Specimen Checklist*

| Question  | Instructions  |
|---|---|
| <b>Confirm Child's First Name</b>                     | See <a href="#">Contact Form Child's Name</a> .   |
| <b>Confirm Child's Last Name</b>                      | See <a href="#">Contact Form Child's Name</a> .   |
| <b>Confirm Study ID</b>                               | Re-enter the child's 6 digit Study ID.  |
| <b>Confirm Enrollment Date</b>                        | Re-enter date of enrollment   |
| <i>Nasal Swab Specimen</i>                            |   |
| <b>1. Was an index nasal swab collected</b>           | <p>Enter "Yes" if an index nasal swab was collected.</p> <p>Enter "No" if an index nasal swab was not collected. REDCap will give the prompt: "Warning: An index swab is required." Arrange for another visit to get the nasal swab. If parent refuses another visit, child cannot continue participation in the study. Please note this by updating the participant status on the Tracking Form.</p> |
| <b>1a&amp;b. Nasal Swab Collection Date and time</b>  | <p>Enter the date in MM/DD/YYYY format that the nasal swab was collected.</p> <p>Enter the time in HH:MM that the nasal swab was collected.</p>   |
| <i>Saliva Swab Specimen</i>                           |   |
| <b>2. Was an index saliva swab collected</b>          | <p>Enter "Yes" if an index saliva swab was collected.</p> <p>Enter "No" if an index saliva swab was not collected.</p>  |
| <b>2a&amp;b. Saliva Swab Collection Date and time</b> | <p>Enter the date in MM/DD/YYYY format that the saliva swab was collected.</p> <p>Enter the time in HH:MM that the saliva swab was collected.</p>   |
| <i>Stool Specimen</i>                                 |   |
| <b>3. Stool sample obtained</b>                       | <p>Enter "No" if a stool specimen sample was not obtained. Continue to question 3a &amp; 3b</p> <p>Enter "Yes" if a stool sample was obtained. Continue to question 3c</p>  |
| <b>3a. No specimen obtained</b>                       | <p>Select reason why stool specimen was not obtained:</p> <p>Select "parent forgot to bring diaper to visit" if parent did not bring a diaper to the visit</p>  |

## Specimen Checklist

| Question  | Instructions  |
|---|---|
|   | <p>Select “parent brought diaper but sample was not optimal” if parent brought in a diaper but you were unable to obtain optimal samples from it</p> <p>Select “other” for any other reason besides the ones listed above. NOTE: Also, select “other if the participant was screened and enrolled in person (on the same day) and was unable to provide a dirty diaper. Once the stool sample is obtained, please change the answer to question 3 (stool sample obtained) to “Yes”</p>  |
| <b>3b. Alternative method stool</b>                           | <p>Select parent’s preference to give us a stool sample:</p> <p>Select “none, parent withdrew consent” if parent no longer wants to participate in the study anymore. Please update the Tracking Form with the participant’s status.</p> <p>Select “parent to come back with a diaper” if parent is willing to come back to the clinic/office with a dirty diaper. Specify the date/time when the parent will come back with diaper. Encourage the parent to come back with the diaper as soon as possible.</p> <p>Select “give stool collection kit and mail back” if parent would prefer to take home a stool collection kit and mail the tube back to EMNet with a stool sample collected.</p> <p>Select “study staff to pick up diaper” if study still will pick up diaper from a location arranged with parent. Select the location from the options listed and specify if “Other” location is selected. Also, specify date and time when the staff can pick up the diaper.</p> <p>Select “Other” if parent prefers an option for giving us the diaper other than the ones listed above. Specify the alternative method in the text box.</p> |
| <b>3c. If stool sample is obtained</b>                        | <p>Enter number of sample tubes that were collected and frozen. Fill each tube with ¼ teaspoon for up to 4 tubes.</p> <p>For each tube collected, indicate whether or not the tube contained at least ¼ of a teaspoon of stool and answer question 3d</p>   |
| <b>3c1. One stool tube and less than ¼ teaspoon collected</b> | <p>If only one stool sample tube was collected and it contains less than ¼ teaspoon of stool, select the alternative method to obtain stool specimen:</p> <p>Select “none, parent withdrew consent” if parent no longer wants to participate in the study anymore. Please update the Tracking Form with the participant’s status</p>  |

## Specimen Checklist

| Question  | Instructions   |
|---|--|
|   | <p>Select “parent to come back with a diaper” if parent is willing to come back to the clinic/office with a dirty diaper. Specify the date/time when the parent will come back with diaper<br/>Encourage the parent to come back with the diaper as soon as possible.</p> <p>Select “give stool collection kit and mail back” if parent would prefer to take home a stool collection kit and mail the tube back to EMNet with a stool sample collected</p> <p>Select “study staff to pick up diaper” if study still will pick up diaper from a location arranged with parent. Select the location from the options listed and specify if “Other” location is selected. Also, specify date and time when the staff can pick up the diaper</p> <p>Select “Other” if parent prefers an option for giving us the diaper other than the ones listed above. Specify the alternative method in the text box</p> |
| <b>3d. Diapers used</b>                               | <p>For each tube collected, specify number of diapers that were used to obtain the ¼ teaspoon sample of stool<br/>If no tubes were frozen because diaper(s) brought to the visit were deemed ineligible, please record that no sample was obtained in question 3.</p> <p>For each diaper that was used, use the answers in the Stool Specimen Form completed by parent to complete questions 3d1-3d3. If parent forgot to fill out the Stool Specimen Form, please ask the parent to estimate the answers to these questions.</p>  |
| <b>3d1. Date and time diaper removed</b>              | Enter the date and time that the diaper was removed from child.  |
| <b>3d2. Diaper frozen</b>                             | <p>Enter “No” if diaper was not frozen at home after collection. Please describe the reason the diaper was not frozen at home after collection.</p> <p>Enter “Yes” if diaper was frozen at home after collection. For each diaper that was frozen, enter the date and time (MM/DD/YYYY and HH:MM) the diaper was placed in the freezer.</p>  |
| <b>3d3. Diaper rash, creams, pastes, or ointments</b> | <p>Enter “No” if parent reports that there were no creams, pastes, or ointments present on the child before the diaper was removed</p> <p>Enter “Yes” if parent reports that there were creams, pastes, or ointments present on the child before the diaper was removed</p>  |
| <b>3d4. Urine present</b>                             | For each diaper removed, enter “No” if no urine was present in the diaper (stool only).  |

## Specimen Checklist

| Question                                | Instructions   |
|---|--|
|   | <p>Enter “Yes, urine present but diaper not saturated” if urine was present in the diaper but not a significant amount. Use your best judgment in determining saturated vs. not saturated.</p> <p>Enter “Yes, diaper saturated” if a significant amount of urine was present. Again, use your best judgment in determining saturated vs. not saturated.</p> <p>Enter “Unknown” if you are unable to tell if any urine was present in the diaper.</p> |
| <b>Stool frozen -20°C</b>               | <p>For each stool specimen, enter “Yes” if the stool was ever frozen at -20°C before transfer to -80°C.</p> <p>Enter “No” if the stool was never stored at -20°C and went directly to -80°C.</p>   |
| <b>Stool frozen -20°C date and time</b> | For each stool specimen frozen at -20°C enter the date and time (MM/DD/YYYY and HH:MM) it was delivered to the lab to be frozen at -20°C.  |
| <b>Stool frozen -80°C date and time</b> | Enter the date and time (MM/DD/YYYY and HH:MM) the specimen was delivered to the lab to be frozen at -80°C.  |
| <b>Enrollment Status</b>                | <p>If No to Q1 or 3 (on Tracking Form), Stop Enrollment: Enrollment is incomplete because you have <u>not</u> fulfilled the following requirements:</p> <p>No nasal swab specimen collected.</p> <p>No signed copy of medical records release (see Tracking Form)</p>  |
| <b>4. Comments</b>                      | Enter any additional comments about the specimen collection that would be of interest to data analysis.  |
| <b><u>AGE 1-YEAR/2-YEAR VISIT</u></b>   |  |
| <b>Attended 1-year/2-year visit</b>     | Enter “Yes” if the participant attended the age 1-year/2-year visit. Continue to questions 5-7   |
| <b>5. Nasal Swab Specimen</b>           | See questions under enrollment visit specimens   |
| <b>6. Saliva Swab Specimen</b>          | See questions under enrollment visit specimens   |
| <b>7. Stool Specimen</b>                | See questions under enrollment visit specimens   |
| <i>CBC with differential</i>            |  |
| <b>8. CBC with differential ordered</b> | Enter “Yes” if a <u>CBC with differential</u> has been ordered. Continue to date and time of collection.   |

## Specimen Checklist

| Question  | Instructions  |
|---|---|
|   | <p>Enter "No" if a <u>CBC with differential</u> has not yet been ordered. Please specify why the CBC/diff was not collected and comment on plans for future blood draw attempts</p> <p>NOTE: CBC with differential results from a collection that is taken between age 9 months and 11.99 months is acceptable. You should select "Yes" if this is the case and record the results.</p>   |
| <b>8a. CBC Date and Time</b>                      | Write the date (in MM/DD/YYYY format) and time (in HH:MM format) that the blood specimen for the CBC was collected.   |
| <b>8b. Hematology</b>                             | Document the hematology values. ALL hematology tests listed are required.   |
| <i>Blood Specimen</i>                             |   |
| <b>9. Red Top Blood Sample Collected</b>          | <p>Enter "Yes" if a blood sample of any volume was collected in a red top tube.</p> <p>Enter "No" if a blood sample of any volume was collected in a red top tube. Please specify why a red top blood specimen was not collected and comment on plans for future blood draw attempts</p>  |
| <b>9a. Red Top Blood Collection Date and Time</b> | <p>Enter the date in MM/DD/YYYY format that the red top blood sample was collected.</p> <p>Enter the time in HH:MM that the blood draw was done.</p> <p>If more than one blood draw is performed, enter the date and time of the first blood draw.</p>  |
| <b>Volume of Red Top Blood Draw</b>               | <p>Enter the approximate total volume in milliliters collected in this red top blood draw.</p> <p>For this whole blood volume estimate, do not include the blood collected for CBC (purple top).</p>  |
| <b>Total Volume of Blood Sample</b>               | <p>REDCap will automatically calculate the volume of blood collected (in milliliters). If you have only filled out the previous question then this volume will be the same as the answer to your previous question. If an additional blood specimen is collected then REDCap will automatically add this to the first blood specimen collected.</p> <p>If this total red top blood volume is &lt;4.5 mL, continue to the questions below.</p> |
| <b>Additional Red Top Blood Draw(s)</b>           | Enter "Yes" if an additional red top blood draw was performed and enter the number of additional red top blood draws that   |

## *Specimen Checklist*

| <b>Question</b>                                 | <b>Instructions</b>   |
|---|---|
|   | <p>were done. Consider a red top blood draw as being performed if the phlebotomist acquired a measurable volume of blood.</p> <p>Enter "No" if an additional red top blood draw was not performed, either was not attempted or attempted but no blood was acquired. Please specify reason additional red top blood draw was not attempted or scheduled for a future date.</p> |
| <b>Date and Time of Additional Blood Sample</b> | Enter the date and time (MM/DD/YYYY and HH:MM) at which each additional blood sample was collected.   |
| <b>Volume of Additional Blood Draw</b>          | <p>Enter the approximate total volume in milliliters collected in this red top blood draw.</p> <p>For this whole blood volume estimate, do not include the blood collected for CBC (purple top).</p>  |
| <b>Serum Tubes</b>                              | Enter the total number of serum tubes available from a red top tube draw for this participant.  |
| <b>Pellet Tubes</b>                             | Enter the total number of pellet tubes available from a red top tube draw for this participant.   |
| <b>Additional blood</b>                         | <p>Enter "Yes" if any other blood samples are available from this participant (e.g. from the CBC with diff or any other discarded sample) from ANY type of tube and write the number of tubes collected.</p> <p>Enter "No" if there are no other blood samples available from this participant.</p>   |
| <b>Additional tubes</b>                         | <p>For each additional tube collected enter the type of tube based on its appearance. Specify "Other" if the tube does not fall into one of the listed categories.</p> <p>Enter the approximate volume of each tube in mL.</p> <p>Enter the type of blood-related sample contained in each tube. If other, be as specific as possible in describing the type of sample.</p>   |
| <b>Total Blood Available</b>                    | <p>For each type of tube (serum, pellet, whole blood, plasma or other) add together all available tubes of that type.</p> <p>This total is the number of that type of tube we will expect to receive in the sample shipment.</p>  |

## Visit Scheduling Form

This form should be filled for all subjects who are enrolled in the study and are due for an in-person visit (Age 1, Age 2, 3-year exam, and 6-year exam)

|   |   |
|---|---|
| <b>Study ID</b>   | Re-enter participant's study ID.  |
| <b>Next clinical appointment scheduled</b>  | <p>Enter "Yes" if child has a clinical appointment scheduled in the near future (e.g., in the next month). If Yes, enter date and time below</p> <p>Enter "No" if child has not clinical appointment scheduled in the near future (e.g., in the next month).</p>  |
| <b>Date and time of appointment</b>   | <p>Enter date of scheduled clinical appointment in MM/DD/YYYY format</p> <p>Enter time of scheduled clinical appointment in military time (HH:MM)</p>   |
| <p><i>Child's age calculator</i></p> <p>Use this section to assist you in calculating the age of the child in months at the date of the visit.</p>                        |   |
| <b>Child's DOB</b>  | Enter child's date of birth in MM/DD/YYYY format  |
| <b>Date of scheduled visit</b>  | Enter date of scheduled visit in MM/DD/YYYY format  |
| <b>Child's age in months</b>  | <p>REDCap will automatically calculate this age. Please make sure child's age is within the ranges specified for each visit:</p> <p>Age 1 visit: 9 months-21.99 months old</p> <p>Age 2 visit: 24 months – 35.99 months old</p> <p>Age 3-year exam: 3.0 years – 4.9 years</p> <p>Age 6-year exam: 6.0 years – 7.9 years</p> |
| <p><i>Telephone Correspondence Log</i></p> <p>The site/clinic staff must log both successful and unsuccessful telephone call attempts with the parent/legal guardian.</p> |   |
| <b>Study staff initials</b>   | Enter initials of staff completing the form and call  |
| <b>Date/Time call</b>   | <p>Enter the date of the call in MM-DD-YYYY format.</p> <p>Enter the time of the call in military time format (HH:MM).</p>  |

|                                  |  |
|----------------------------------|--|
| <b>Name of call recipient</b>    | Enter name of the person receiving the call  |
| <b>Relationship to child</b>     | Select 'Mother' if call recipient is the child's mother.<br><br>Select 'Father' if call recipient is the child's father.<br><br>Select 'Legal guardian' if call recipient is the child's legal guardian.<br><br>Select 'Other (specify)' if the call recipient does not fit into any of the categories listed above (e.g., alternate contact). |
| <b>Please specify 'Other'</b>    | If 'Other (specify)' was selected for 'Relationship to child', describe the relationship to the child in the text box.   |
| <b>Brief description of call</b> | Use the free text to describe content of the telephone call.   |

*E-mail Correspondence Log*

The user logs all e-mail correspondence attempts with parent/legal guardian.

|                                       |  |
|---------------------------------------|--|
| <b>Hospital/Clinic staff initials</b> | Enter initials of staff completing the form and e-mail   |
| <b>Date/Time e-mail</b>               | Enter the date of the e-mail in MM-DD-YYYY format.<br>Enter the time of the e-mail in military time format (HH:MM).  |
| <b>Name of e-mail recipient</b>       | Enter name of the person receiving the e-mail  |
| <b>Relationship to child</b>          | Select 'Mother' if e-mail recipient is the child's mother.<br><br>Select 'Father' if e-mail recipient is the child's father.<br><br>Select 'Legal guardian' if e-mail recipient is the child's legal guardian.<br><br>Select 'Other (specify)' if the e-mail recipient does not fit into any of the categories listed above (e.g., alternate contact). |
| <b>Please specify 'Other'</b>         | If 'Other (specify)' was selected for 'Relationship to child', describe the relationship to the child in the text box.   |

|                                    |  |
|------------------------------------|--|
| <b>Brief description of e-mail</b> | Use the free text to describe content of the telephone e-mail. |
|------------------------------------|--|

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*Scheduling the Visit*

This section is completed by hospital/clinic staff after scheduling the visit and prior to the visit occurring.

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|                                       |  |
|---------------------------------------|--|
| <b>Hospital/clinic staff initials</b> | <p>Enter the initials of the hospital/clinic staff member completing the form.</p> <p>If the hospital/clinic staff member does not have a middle name, use X for the middle initial.</p> <p>Example:<br/>Jane A. Jones: J A J<br/>Sam Smith: S X S</p> |
|---------------------------------------|--|

|                                  |   |
|----------------------------------|---|
| <b>Successful visit schedule</b> | <p>Select 'Yes' if you were able to successfully schedule the visit.</p> <p>Select 'No, parent/legal guardian not reachable' if the parent/legal guardian was not reachable after multiple call and e-mail attempts were made.</p> <p>Document all communication efforts in the 'Telephone Correspondence Log' and 'E-mail Correspondence Log'.</p> <p>Select 'No, parent/legal guardian does not want to participate in the study' if parent/legal guardian is no longer interested in participating in the research study. No further action is required for this form.</p> <p>Select 'No, other (specify)' if there is another reason (not specified above) for why the exam was not successfully scheduled.</p> |
|----------------------------------|---|

|   |  |
|---|--|
| <b>Please enter the date of the scheduled visit</b> | If 'Yes' selected for 'Were you able to successfully schedule the visit for [child's name]?' enter the date of the scheduled visit in MM-DD-YYYY format. |
|---|--|

|   |  |
|---|--|
| <b>Please specify 'other' reason visit was not scheduled successfully</b> | If 'No, other (specify)' was selected for 'Were you able to successfully schedule the visit for [child's name]?' and use free text box to describe reason. |
|---|--|

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|   |   |
|---|---|
| <b>Medication Allergies</b>   | <p>Select 'Yes (specify)' if parent/legal guardian reports any known medication allergies for their child. Use the free text box to describe the medication allergies in detail.</p> <p>Select 'No' if parent/legal guardian reports no known medication allergies for their child.</p>   |
| <b>Latex allergies</b>  | <p>Select 'Yes (specify)' if parent/legal guardian reports any known latex allergies for their child.</p> <p>Use text box to describe the latex allergies in detail. If there is no additional information shared by the parent, enter 'No additional information provided.'</p> <p>Select 'No' if parent/legal guardian reports no known latex allergies for their child.</p>  |
| <b>Food allergies</b>   | <p>Select 'Yes (specify)' if parent/legal guardian reports any known food allergies for their child. Use text box to describe the food allergies in detail.</p> <p>Select 'No' if parent/legal guardian reports no known food allergies for their child.</p>  |
| <b>Special requests/concerns</b>  | <p>Select 'Yes (specify)' if parent/legal guardian has any special requests or concerns regarding the exam to share with you. Use the free text box to describe these requests or concerns in detail.</p> <p>Select 'No' if parent/legal guardian does not have any special requests or concerns regarding the exam to share with you.</p>  |
| <p><i>Visit Tracking</i><br/>This section is completed by hospital/clinic staff</p> |   |
| <b>Did child and parent/legal guardian attend scheduled visit?</b>                  | <p>Select 'Yes, and visit is complete' if visit has successfully occurred. No further action is needed on this form.</p> <p>Select 'Yes, but participant must return in order to complete visit (e.g., minimum blood volume not obtained at original visit) (specify)' if the visit occurred but some assessments were missing, which necessitate an additional visit to complete.</p> <p>Select 'Yes, but participant needs to send/come back with stool sample in order to complete visit' if the visit occurred but the participant forgot to bring a diaper or the sample brought in was deemed unsuitable, please give the parent a stool collection kit for the parent to collect at home. If the participant</p> |

|  |   |
|--|---|
|  | <p>forgot to bring a diaper or the sample brought in was deemed unsuitable, please schedule a diaper pick up. <b>Use the comments box at the bottom of the form to track subsequent attempts to get the stool sample.</b></p> <p>Select 'No' if visit was not attended by child and parent/legal guardian.</p>  |
| <p><b>Please specify why child must return to the hospital/clinic to complete the visit</b></p>  | <p>If 'Yes, but participant must return in order to complete visit (specify)' was selected for 'Did child and parent/legal guardian attend scheduled visit?' use the text box to describe the reason in detail.</p>   |
| <p><i>If 'Yes, and visit is complete', 'Yes, but participant needs to return in order to complete visit (e.g., minimum blood volume not obtained at original visit) (specify)', or 'Yes, but participant needs to send/come back with stool sample in order to complete visit'</i></p> |   |
| <p><b>Did participant travel &gt;25 miles to attend visit?</b></p>   | <p>Select 'Yes' if participant traveled &gt;25 miles to attend the visit</p> <p>Select 'No' if participant traveled &lt;25 miles to attend the visit</p>  |
| <p><i>If 'Yes, but participant needs to return to clinic in order to complete visit (specify)' OR 'No' to 'Did child and parent/legal guardian attend scheduled visit?' complete the questions below:</i></p>  |   |
| <p><b>Another visit scheduled</b></p>  | <p>Enter 'Yes' if another visit was scheduled. Enter number of reschedules in question below.</p> <p>Enter 'no' if no other visit was scheduled. Continue to question "please indicate the reason visit was not successfully re-scheduled"</p>  |
| <p><b>Times rescheduled</b></p>  | <p>Enter the number of times the additional visits were rescheduled. You will start with just 1 reschedule and you can come back to this question if more rescheduling occurs, and change the number of reschedules so that additional fields pop up below. Once you change the number of reschedules, click somewhere on the form and the fields to enter information about the additional visit appear.</p> |
| <p><i>Fill out the following information for each of the additional visits rescheduled</i></p>   |   |
| <p><b>Reason for reschedule</b></p>  | <p>Enter "incomplete visit" if the reschedule is due to the previous visit being incomplete</p> <p>Enter "missed visit" if the participant was a "no show" to the previous scheduled visit</p> <p>Enter "Other" for any other reason</p>  |

|  |  |
|--|--|
| <b>Specify reason for additional visit</b>   | If “Other” to question about reason for reschedule, please specify the reason in this text box   |
| <b>Please specify date of the additional visit</b>                                 | Enter the date of the additional scheduled visit in MM-DD-YYYY format.   |
| <b>Successfully attended the enrollment visit</b>                                  | <p>After the date of this visit has occurred, please indicate if the child and parent/guardian attended the visit:</p> <p>Select ‘Yes, and visit is complete’ if the child and parent/legal guardian successfully attended and completed the additional visit</p> <p>Select ‘Yes, but participant needs to return in order to complete visit’ if the child and parent/legal guardian attended the visit but did not complete the entire additional visit</p> <p>Select ‘No’ if the child and parent/legal guardian did not successfully attend the additional visit.</p>   |
| <b>Is this the first time the participant attended an age 1-year/2-year visit?</b> | <p>If ‘Yes, and visit is complete’ or ‘Yes, but participant needs to return in order to complete visit (specify)’:</p> <p>Select ‘Yes, this is the first time the participant attended an age 1-year/age 2-year visit’ if participant hasn’t attended any previously scheduled age 1y/age 2y visits</p> <p>Select ‘No, collected partial age 1-year/2-year visit data during a previous visit’ if participant attended a previously scheduled visit and came back to complete the visit/collect missing data during this additional visit</p> <p><i>Note to interviewer: Answer “No” if you have already collected age 1-year/2-year visit data from this participant.</i></p> |
| <b>Did participant travel &gt;25 miles to attend visit?</b>                        | <p>If ‘Yes, and visit is complete’ or ‘Yes, but participant needs to return in order to complete visit (specify)’:</p> <p>Select ‘Yes’ if participant traveled &gt;25 miles to attend the visit</p> <p>Select ‘No’ if participant traveled &lt;25 miles to attend the visit</p>  |
| <b>Was this visit combined with an existing</b>                                    | If ‘Yes, and visit is complete’ or ‘Yes, but participant needs to return in order to complete visit (specify)’ to question above and ‘No, collected partial age 1-year/2-year visit data during a previous visit’:   |

|  |   |
|--|---|
| <b>clinical appointment?</b>   | <p>Select 'Yes, visit was combined with a clinical appointment' if the visit happened the same day as a clinical appointment</p> <p>Select 'No, parent came in for a research-only visit' if there was no clinical appointment on that date and the parent came in only for research purposes</p>   |
| <b>Date participant attended visit:</b>  | <p>If 'No, collected partial age 1-year/2-year visit data during a previous visit' (i.e., this is NOT the initial visit) AND if participant travelled &gt;25 miles to attend visit OR if parent came in for a research-only visit</p> <p>Enter date visit was attended in MM/DD/YYYY format</p>   |
| <b>Reason for not attending</b>  | <p>If 'No' to 'After the date of this visit has occurred, please indicate if the child and parent/legal guardian attended the visit:'</p> <p>Please comment on the reason parent did not attend the visit and any other relevant information:</p>   |
| <b>Reason for return</b>   | <p>If "Yes, but participant needs to return in order to complete visit" to 'After the date of this visit has occurred, please indicate if the child and parent/legal guardian attended the visit:'</p> <p>Please specify reason why parent needs to return.</p>   |
| <b>Please indicate the reason the enrollment visit was not successfully re-scheduled</b> | <p>If 'No' was selected for 'Were you able to re-schedule the visit?':</p> <p>Select 'Parent/legal guardian not reachable' if parent/legal guardian was not reachable by phone or e-mail after multiple attempts.</p> <p>Select 'Parent/legal guardian changed mind and would no longer like to participate in this visit' if parent/legal guardian no longer wants to participate in this specific in-person visit.</p> <p>Select 'Parent/legal guardian withdrew from study' if parent/legal guardian no longer wants to participate in the study. Please update the Tracking Form as needed.</p> <p>Select 'Other (specify)' if there is another reason (not specified above) that the enrollment visit was not successfully re-scheduled.</p> |
| <b>Please specify 'other' reason the visit was not re-schedule</b>                       | <p>If 'Other (specify)' was selected for 'Please indicate the reason the enrollment visit was not successfully re-scheduled,' use the text box to describe the reason.</p>  |

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**Comments**

Enter any relevant information in this text box

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## Age 1-yr/2-yr Visit Form

This form should be filled for all participants who show up to their age 1-yr/2-yr visit.

|   |  |  |
|---|--|--|
|   | <b>Confirm Child's First Name</b>                              | See <a href="#">Contact Form Child's Name</a> .  |
|   | <b>Confirm Child's Last Name</b>                               | See <a href="#">Contact Form Child's Name</a> .  |
|   | <b>Confirm Study ID</b>  | Re-enter the child's 6-digit Study ID.   |
|   | <b>Enrollment date</b>   | Re-enter date parent enrolled in study (signed consent form).  |
|   | <b>Did the participant attend the age 1-year/2-year visit?</b> | Select 'Yes' if age 1-year/2-year visit was attended   |
|   | <b>Date of initial Age 1-yr/2-yr visit</b>                     | Enter date of initial visit attendance in MM/DD/YYYY format  |
| <p>Ask parent questions about change's to child's health since the last time you spoke on the phone, so that we can better understand how your child is feeling around the time when the specimens are collected.</p> |  |  |
| 1   | <b>Stomach symptoms past 24 hrs</b>                            | <p>Check "2 or more watery or much loose stools" if child has had 2 or more watery or much loose stools in the past 24 hours</p> <p>Check "any episode of vomiting, not including spit-ups" if child has vomited at least once in the past 24 hours</p> <p>Check "any fever (or felt hot or had chills)" if child has had a fever, felt hot, or had chills in the past 24 hours</p> <p>Check "None" if child has had none of the above symptoms in the past 24 hours</p> <p>Check ALL that apply</p> |
| 2   | <b>Cough</b>   | <p>Enter "Yes" if child has a cough. Continue with question 2a.</p> <p>Enter "No" if child doesn't have a cough.</p>   |

|    |                            |  |
|----|----------------------------|--|
| 2a | <b>Cough severity</b>      | <p>Indicate the severity of this cough.</p> <p>Enter “Mild” if cough caused mostly gagging.</p> <p>Enter “Moderate” if cough was significant, but did not wake the child at night</p> <p>Enter “Severe” if cough caused the child to vomit or woke the child at night.</p>   |
| 3  | <b>Runny Nose</b>          | <p>Enter “Yes” if the child has a runny nose and go to Q3a.</p> <p>Enter “No” if the child does not have a runny nose.</p>   |
| 3a | <b>Runny nose severity</b> | <p>Indicate the severity of this runny nose.</p> <p>Enter “Mild” if the runny nose had to be suctioned 0-4 times per day or wiped every 2 hours or less.</p> <p>Enter “Severe” if runny nose had to be suctioned 5 or more times per day or wiped 1 or more times per hour.</p>  |
| 4  | <b>Fever</b>               | <p>Enter “Yes, temp <math>\geq 100^{\circ}\text{F}</math>” if the child has a fever of <math>100^{\circ}\text{F}</math> or higher.</p> <p>Enter “No” if the child has temperature(s) lower than <math>100^{\circ}\text{F}</math>.</p>  |
| 5  | <b>Hoarse Voice</b>        | <p>Enter “Yes” if the parent indicates that the child has a muffled, scratchy voice.</p> <p>Enter “No” if the child does not have a muffled, scratchy voice. Also enter “No” if the parent reports that the child doesn’t make enough sounds to make this determination (i.e., the child is too young to have reached the developmental milestone of make sounds that could be described as “hoarse”).</p> |
| 6  | <b>Breathing Faster</b>    | <p>Enter “Yes” if the parent indicates that the child is breathing faster than normal.</p> <p>Enter “No” if the child is breathing with the usual frequency.</p>   |
| 7  | <b>Wheezing</b>            | <p>After reading the question, explain to the parent what wheezing means by stating that it is a high-pitched whistling sound that the child might make when breathing out.</p> <p>Enter “Yes” if the parent indicates that he/she hears a wheezing sound.</p>   |

|              |                            |  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
|--------------|----------------------------|--|-------------|--------|--------------|------------|------------------|------------|-----------|---------------|--------|--------------|----------------|--------------|---------|-------------|------------|----------|-------|------------|--------------|-----------|--|
|              |                            | Enter "No" if the parent denies hearing a wheezing sound.  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 8            | <b>Medical problems</b>    | <p>Enter "Yes" if child has been diagnosed with any medical problems since the last time you spoke with them.<br/>If "Yes", specify the problem</p> <p>Enter "No" if child has not be diagnosed with any medical problems since the last time you spoke with them</p> <p>Enter "UKN" if the parent does not know if the child has been diagnosed with any medical problems since the last time you spoke with them</p>   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9            | <b>Antibiotic use</b>      | <p>Enter "Yes" if during the past month the child took any oral, intravenous, or intramuscular antibiotics. See the chart below for some common antibiotics. If "Yes" continue to question 9a and 9b</p> <table border="1"> <tr> <td>Amoxicillin</td> <td>Biaxin</td> <td>Erythromycin</td> </tr> <tr> <td>Ampicillin</td> <td>Cipro Cephalexin</td> <td>Gentamicin</td> </tr> <tr> <td>Augmentin</td> <td>Ciprofloxacin</td> <td>Keflex</td> </tr> <tr> <td>Azithromycin</td> <td>Clarithromycin</td> <td>Levofloxacin</td> </tr> <tr> <td>Bactrim</td> <td>Doxycycline</td> <td>Penicillin</td> </tr> <tr> <td>Rifampin</td> <td>Septa</td> <td>Vancomycin</td> </tr> <tr> <td>Streptomycin</td> <td>Zithromax</td> <td></td> </tr> </table> <p>Enter "No" if the child did not receive any antibiotics during this period.</p> <p>Enter "UKN" if the parent does not know if the child received any antibiotics during this period.</p> | Amoxicillin | Biaxin | Erythromycin | Ampicillin | Cipro Cephalexin | Gentamicin | Augmentin | Ciprofloxacin | Keflex | Azithromycin | Clarithromycin | Levofloxacin | Bactrim | Doxycycline | Penicillin | Rifampin | Septa | Vancomycin | Streptomycin | Zithromax |  |
| Amoxicillin  | Biaxin                     | Erythromycin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Ampicillin   | Cipro Cephalexin           | Gentamicin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Augmentin    | Ciprofloxacin              | Keflex   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Azithromycin | Clarithromycin             | Levofloxacin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Bactrim      | Doxycycline                | Penicillin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Rifampin     | Septa                      | Vancomycin   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| Streptomycin | Zithromax                  |  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9a           | <b>Name of antibiotics</b> | <p>Select type of antibiotic from options listed.</p> <p>Enter "others" if antibiotic is taken is not listed and specify the antibiotic name</p> <p>Enter "UNK" if the parent does not know name of antibiotic received during this period.</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 9b           | <b>Date of antibiotic</b>  | Enter date that child most recently took an antibiotic in MM/DD/YYYY format.   |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |
| 10           | <b>Probiotics</b>          | <p>Enter "Yes" if child took probiotics in the past month. If "Yes" continue with question 10a</p> <p>Enter "No" if child did not take probiotics in the past month</p> <p>Enter "UKN" if parent does not know if child took probiotics in the past month</p>  |             |        |              |            |                  |            |           |               |        |              |                |              |         |             |            |          |       |            |              |           |  |

|      |                                    |   |
|------|------------------------------------|---|
| 10a  | <b>Date of probiotics</b>          | Enter date that child most recently took probiotics in MM/DD/YYYY format.   |
| 11   | <b>Over the counter medicines</b>  | <p>Check all the over the counter medicines that the child received during the past week.</p> <p>If the child was given any specific vitamin(s) or dietary supplement(s) during this period, specify the type of vitamin(s) or supplement(s).</p> <p>If the medicine is not listed, check “Other OTC medicine” and specify the type of medicine.</p> <p>Check “None” if the child did not receive any over the counter medicines.</p>   |
| 12   | <b>Diaper with stool</b>           | <p>Enter “Yes” if parent brought in a diaper with the child’s stool in it. If “Yes” continue to question 12b1-12b4</p> <p>Enter “No” if parent did not bring in a diaper with the child’s stool in it. If “No” continue to question 12a1</p>  |
| 12a1 | <b>Stool needed</b>                | <p>Select parent’s preference for giving us a stool sample</p> <p>Select “come back to clinic” if the parent would like to bring in a diaper to the clinic and specify the date/time when parent can come to the office</p> <p>Select “study staff to visit house” if parent would like study staff to pick up the diaper from the parent’s house and specify the date and time of pick up. Verify that the home address on file is correct and if it isn’t, ask for correct address</p> <p>Select “stool collection kit” if parent would like to take home a stool collection kit and then mail it to EMNet with a specimen inside</p> <p>Select “Other” if parent would like to give us a sample using a method other than the ones listed and specify.</p> |
| 12b1 | <b>Date and time of collection</b> | Enter date and time that diaper was collected at home in MM/DD/YYYY and HH:MM format  |
| 12b2 | <b>Diaper frozen</b>               | Enter “Yes” if diaper was frozen at home after collection and enter date and time it was placed into freezer in MM/DD/YYYY and HH:MM format   |

|      |   |  |
|------|---|--|
|      |   | Enter "No" if diaper was not frozen at home after collection and specify reason(s) diaper was not frozen   |
| 12b3 | <b>Diaper rash creams, pastes, or ointments</b> | <p>Enter "Yes" if diaper rash creams, pastes, or ointments were used on the child before the diaper was removed and specify what was used</p> <p>Enter "No" if diaper rash creams, pastes, or ointments were <u>not</u> used on the child before the diaper was removed</p>  |
| 12b4 | <b>Urine present</b>                            | <p>Enter "No" if no urine was present in the diaper (stool only).</p> <p>Enter "Yes, urine present but diaper not saturated" if urine was present in the diaper but not a significant amount. Use your best judgment in determining saturated vs. not saturated.</p> <p>Enter "Yes, diaper saturated" if a significant amount of urine was present. Again, use your best judgment in determining saturated vs. not saturated.</p> <p>Enter "Unknown" if you are unable to tell if any urine was present in the diaper.</p> |
| 13   | <b>Feeding before visit</b>                     | Enter the date and time of the last feeding/meal in MM/DD/YYYY and HH:MM format  |

# Protocol Deviation Report Form

Protocol deviations are reported using the Protocol Deviation Report Form in REDCap. Protocol deviation reports must include the deviation date, subject number, a brief description of the event, the reason for the deviation, and steps taken to resolve or avoid recurrence of the deviation.

A major protocol deviation is any change, divergence or departure from the study design or procedures of a research protocol that affects the study participant's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data. Changes or alterations in the conduct of the study which do not have a major impact on the study participant's rights, safety, or well-being, or the completeness, accuracy and reliability of the study data are considered non-major protocol deviations. The deviation may be either on the part of the participant, the investigator, or the study site staff.

If there is a major protocol deviation, notify Ashley Sullivan ([afsullivan@partners.org](mailto:afsullivan@partners.org)) immediately. She will work with you to notify the NIH

The following are examples of noncompliance with the protocol, Good Clinical Practice, or Manual of Procedure guidelines that must be reported:

- Forms or procedures not done or not completed as required;
- NPA specimen storage errors (e.g., supposed to be frozen, but was left sitting out);
- Informed consent not obtained prior to enrollment;
- Failure to use the current approved version of the informed consent;
- Consent form is missing, or consent form was not signed and dated by the subject or appropriate legal guardian; and
- Protocol never approved by IRB or other IRB violations.

## *Protocol Deviation Report Form*

| <b>Question</b>                   | <b>Instructions</b>   |
|-----------------------------------|---|
| <b>Study ID</b>                   | Re-enter the Study ID previously assigned to the child.<br>This Study ID must match the Study ID assigned on the Tracking Form. |
| <b>Report Date</b>                | Enter the date in which the protocol deviation was reported. Use the MM/DD/YYYY format.   |
| <b>Protocol Deviation Date</b>    | Enter the date in which the protocol deviation occurred.<br>Use the MM/DD/YYYY format.  |
| <b>Site Name</b>                  | Select your site's name.  |
| <b>Investigator Name</b>          | Enter the site principal investigator's name.   |
| <b>Grant Number:</b>              | UG3OD023253   |
| <b>Alternate Protocol Number:</b> | If applicable, enter alternate protocol number here   |

## Protocol Deviation Report Form

| Question   | Instructions  |
|--|---|
| <b>Protocol Title:</b>   | Airway microbiome and age 6-year asthma phenotypes in a healthy infant cohort   |
| <b>Adverse Event result</b>  | <p>Enter “Yes” if the protocol deviation resulted in an adverse event. If so, complete an <a href="#">Adverse Event Form</a>.</p> <p>Enter “No” if the protocol deviation did not result in an adverse event.</p>   |
| <b>Serious Adverse Event result</b>  | <p>Enter “Yes” if the protocol deviation resulted in a serious adverse event. If so complete a <a href="#">Serious Adverse Event Form</a>.</p> <p>Enter “No” if the protocol deviation did not result in a serious adverse event.</p>   |
| <b>Termination of study Follow-up</b>  | <p>Enter “Yes” if the protocol deviation resulted in a termination of study follow-up for the subject. If so, notify Ashley Sullivan (<a href="mailto:afsullivan@partners.org">afsullivan@partners.org</a>) of the termination.</p> <p>Enter “No” if the protocol deviation did not result in termination of the study follow-up for the subject.</p> |
| <b>Brief deviation description</b>   | Describe the protocol deviation. To learn more about examples of protocol deviations, please see section 8 of the protocol.   |
| <b>Descriptions to avoid recurrence of deviation</b>                                 | Describe the steps taken to resolve or avoid this deviation in the future, as well as the procedures put in place to make sure that the protocol is followed.   |
| <hr/> <p>This section is to be updated by site and kept in site regulatory file.</p> |   |
| <b>IRB reporting requirements</b>  | <p>Enter “Yes” if the deviation meets IRB reporting requirements <u>outside of continuing review</u> (i.e. a major protocol deviation).</p> <p>Enter “No” if the deviation does not meet IRB reporting requirements or only needs to be reported at continuing review.</p>  |
| <b>Date IRB is notified</b>  | If IRB reporting requirements are met, enter the date in which the IRB was notified in MM/DD/YYYY format.   |
| <b>Signature/Date</b>  | Download a pdf of the form (upper right-hand corner of REDCap). Sign and date the form for your files. You do not need to send a signed/dated   |

*Protocol Deviation Report Form*

| <b>Question</b>        | <b>Instructions</b>  |
|------------------------|--|
|                        | form to the EMNet Coordinating Center unless the deviation is a major protocol deviation.  |
| <b>Form Completion</b> | All fields are required in this form. Please enter the interviewer's initials to certify that the form is complete. If you need to return to this form at a later date, change the status to "Unverified." |

# Adverse Event Case Report Form

## Definitions

**Adverse Event (AE)** - Any occurrence or worsening of an undesirable or unintended sign, symptom, laboratory finding, or disease that is experienced during participation in the study and is related to a study procedure. If a medical condition is present at the time that the study participant is screened will be considered as baseline and not recorded as an adverse event.

**Serious Adverse Event (SAE)** - Any adverse event that suggests a significant hazard, contraindication, side effect, or precaution.

Throughout the study all adverse events (serious and non-serious) will be recorded on reported on the Adverse Event Form. The following tables explain what is required on every field for these forms. Please see Section 7 of the protocol for an explanation of what is considered an AE or SAE.

An adverse event will be followed until any of the following takes place:

- a) it is resolved
- b) participant is stable
- c) a minimum of 30 days after participant is terminated from the study and the NIAID Medical Officer and the study investigators determine that follow-up is complete

## *Adverse Event Form*

| <b>Question</b>                     | <b>Instructions</b>  |
|-------------------------------------|--|
| <b>Study ID</b>                     | Re-enter the Study ID previously assigned to the child.  |
| <b>Report Date</b>                  | Enter the date in which the AE report was completed.<br>Use the MM/DD/YYYY format.   |
| <b>Date of event</b>                | Enter the date in which the AE occurred.<br>Use the MM/DD/YYYY format.   |
| <b>Site Name</b>                    | Select your site's name.   |
| <b>Site Investigator Name</b>       | Write the site investigator's name. The site investigator will apply his/her clinical judgment as to whether an adverse event is severe enough to require that the participant immediately be removed from further participation in the study. |
| <b>Grant Number</b>                 | UG3OD023253  |
| <b>Protocol Title or Short Name</b> | Airway microbiome and age 6-year asthma phenotypes in a healthy infant cohort  |

## *Attribution of an adverse event*

This is determined by the site investigator or designated physician co/sub-investigator. He/she will attribute the adverse event to the following.

|                        |   |
|------------------------|---|
| <b>Study Procedure</b> | Enter "Nasal Swab" if the AE is attributed to the performance of the nasal swab. An example of an AE is epistaxis within 24 hours of the procedure in which |
|------------------------|---|

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bleeding does not subside spontaneously within five minutes.

Enter "Blood collection" if the AE is attributed to the performance of the blood draw. Examples could be: bruising at puncture site larger than 2 cm diameter, bleeding from puncture site lasting more than 5 minutes or swelling at puncture site larger than 2 cm.

Enter "Other" if the AE is attributed to something else. Specify the type of AE.

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*Description*

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**Complete description of event** Describe the AE in detail.

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*Action*

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**Steps planned as a result of adverse event reported** Identify all steps taken as a result of the AE. Check ALL that apply.

Check "No action taken" if the AE does not result in any actions taken.

Check "Amend protocol" if the protocol will be changed.

Check "Amend consent document" if the consent forms will be modified.

Check "Inform current subjects" if the participants will be told that there was an AE.

Check "Terminate or suspend protocol" if the study will be terminated or suspended.

Check "Other" if another type of action is taken. Specify the action.

---

Severity of adverse events will be graded according to the criteria from the National Cancer Institute's common terminology criteria.

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*Investigator assessment of severity*

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| Grade    | Descriptor      | Definition (guidelines)  |
|----------|-----------------|--|
| <b>1</b> | <b>Mild</b>     | Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. |
| <b>2</b> | <b>Moderate</b> | Minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL.     |

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|   |                         |  |
|---|-------------------------|--|
| <b>3</b>                                  | <b>Severe</b>           | Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.   |
| <b>4</b>                                  | <b>Life threatening</b> | Life-threatening consequences; or urgent intervention indicated.   |
| <b>5</b>                                  | <b>Death</b>            | Death related to AE.   |
| <i>Relationship to study procedure(s)</i> |                         |  |
| Code                                      | Descriptor              | Definition (guidelines)  |
| UNRELATED CATEGORY                        |                         |  |
| <b>1</b>                                  | <b>Unrelated</b>        | The adverse event is clearly not related to study. The event is completely related to an etiology other than the study procedures (the alternative etiology must be documented in the study participant's medical record)  |
| <b>2</b>                                  | <b>Unlikely</b>         | The adverse event is doubtfully related to study and likely to be related to factors other than study procedures.  |
| RELATED CATEGORIES                        |                         |  |
| <b>3</b>                                  | <b>Possible</b>         | The adverse event may be related to study procedure. There is an association between the event and study procedure and there is a plausible mechanism for the event to be related to the study procedure; there may be also an alternative etiology, such as characteristics of the study participant's clinical status and/or underlying disease.                                   |
| <b>4</b>                                  | <b>Probable</b>         | The adverse event is likely related to study procedure. There is (1) an association between the event and the study procedure, (2) a plausible mechanism for the event to be related to the study procedure, and (3) the event could not be reasonably explained by known characteristics of the study participant's clinical status and or an alternative etiology is not apparent. |
| <b>5</b>                                  | <b>Definite</b>         | The adverse event is clearly related to study procedure. There is (1) an association between the event and the study procedure (2) a plausible mechanism for the event to be related to the related to the study procedure, and (3) causes other than the study procedure have been ruled out.   |
|   | <b>Resolution</b>       | Enter "pending" if the event has not been resolved. If the event is still pending, return to the form and insert the date of resolution after the event is resolved.   |

|   |  |
|---|--|
|   | Enter "complete" if the event has been resolved.<br>Enter the date on which this event was resolved or stabilized.   |
| <i>Expectedness</i>   |  |
| An adverse event is considered "unexpected" when its nature, severity or frequency is not consistent with the information that is provided in the Protocol and is related to a study procedure. |  |
| <b>Was adverse event unexpected</b>   | Enter "Yes" if the adverse event is unexpected.<br><br>Enter "No" if the adverse event is not expected.  |
| <i>Change in the Severity</i>   |  |
| <b>Change in severity</b>   | If after completing this form the severity of adverse event changes, return and record the change in this section.   |
| <b>IRB reporting requirements</b>   | The Principal Investigator will ensure the timely dissemination of AE/SAE information, including expedited reports, to the IRB in accordance with IRB regulations and guidelines.<br><br>Enter "Yes" if the adverse event meets IRB reporting requirements.<br><br>Enter "No" if the adverse event does not meet IRB reporting requirements. |
| <b>Date IRB notified</b>  | Enter the date that the IRB was notified in MM-DD-YYYY format.   |
| <b>Serious AE</b>   | Enter "Yes" if the AE qualifies as a serious AE (SAE). If the event is a SAE, it must be reported immediately to Ashley Sullivan ( <a href="mailto:afsullivan@partners.org">afsullivan@partners.org</a> ). Follow the other reporting responsibilities outlined in REDCap.<br><br>Enter "No" if the event does not qualify as a serious AE.  |
| <b>Signature</b>  | The site principal investigator must sign the form.  |
| <b>Date</b>   | Date on which the form was signed.   |
| <b>Form Completion</b>  | All fields are required in this form. Please enter the interviewer's initials to certify that the form is complete. If you need to return to this form at a later date, change the status to "Unverified."   |

## **SPECIMEN MANUAL OF PROCEDURES**

Please see Appendix E of the protocol for specific instructions on how to collect the nasal and saliva swabs, stools samples, and blood samples.