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4 PROTOCOL SPECIFIC FORMS AND INSTRUCTIONS

This section provides information about two types of forms: data collection forms and administrative forms. Data collection forms are used to collect data from or about the participant. These forms are entered into the AsthmaNet database and submitted to the DCC. Administrative forms facilitate the processing of the participant and the visit flow by the performance sites and the DCC. Administrative forms are not entered into the AsthmaNet database and they are not submitted to the DCC in most cases.

These instructions are divided into two parts—instructions for data collection forms followed by instructions for administrative forms. The instructions for both parts are in alphabetical order based on the full form name found in the header of the form. Forms with a 'P7' prefix are specific to the STICS protocol.

For each form, the following information is provided: the purpose of the form, who completes the form, when the form should be completed, and form instructions. Most forms have a comments section (Q6000) at the bottom of the form. The coordinator can record additional information related to the form in this section. This information is entered into the AsthmaNet database management system. If you are unable to find the specific information needed to complete a form, please contact the STICS Primary or Secondary Data Manager at (717) 531-3663.

4.1 Data Collection Forms

Packet data forms are found in visit-specific packets, and they are submitted to the DCC as packets. Individual data forms (single forms) are submitted on an as-needed basis. Concurrent forms (AECLIN, CMED) are completed at each study visit and can be updated throughout the STICS study. All concurrent forms should be submitted when the participant concludes his or her participation in the STICS study. Some forms (e.g., STICS Medications (P7_MED)) can be submitted as part of a visit packet or as a single form, depending on the specific circumstances. The schematic of the STICS visit structure is posted as a sub-item to this section on the website.

4.1.1 Childhood Asthma Control Test for Children 4 - 11 years old (CACT)

Purpose: To determine how well a pediatric participant's asthma is controlled.

Who: Participant and Participant's Parent/Legal Guardian complete this form.

When: All Visit and Phone Contacts

Form Instructions:

The parent/guardian will be given the CACT at Visits 2 – 7 along with a preaddressed, psotage paid envelope.

During the phone contact visit (2A – 7A) the coordinator will instruct the parent to complete the CACT and mail the form to the site.

When the form is received at the site, the coordinator should enter the form as a single form in the database.

If the site does not receive the CACT phone contact form either via mail or at the next study visit, no data entry is required. A note to file may be made in the participant file to document the form was not received. The DCC may query the site to document the form was not received and data entry will not be completed.

If there is a discrepancy between what is circled and what is indicated in the Score box for an individual question, and the parent/guardian is not available in the clinic to make the correction to the form, the coordinator should enter the circled response in the database during entry of CACT

4.1.2 Pediatric Methacholine Challenge Testing Checklist (METHACHK_PED)

Purpose: To determine if a pediatric participant is eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine testing.

Who: The Pulmonary Function Technician completes the form.

When: Visit 2.

Form Instructions:

Complete this form only if the participant is eligible according to the protocol-specific Pulmonary Procedure Checklist and successfully completed baseline spirometry session(s).

Question 1030-Q1040. If Q1030 is answered 'Yes', Q1040 must be completed. If the participant has had a cold during the past 2 weeks, he/she would be ineligible to complete the Methacholine Challenge.

If the participant does not meet all of the requirements, skip the methacholine challenge and complete the rest of Visit 2 procedures.

4.1.3 **Pre-Bronchodilator IOS (IOS_PRE)**

Purpose: To record the outcome measurements from the pre-bronchodilator IOS procedure.

Who: The Pulmonary Technician completes the form.

When: Refer to Visit Procedure Checklists.

Form Instructions:

The Jaeger systems from the CARE Network will be used to measure IOS. Since there are a limited number of machines remaining, only selected sites will be performing IOS as part of the visit procedures. Any individual who participates in IOS collection must be certified in the IOS procedure. See Appendix 9 of the AsthmaNet General Manual of Operations for details regarding certification and QC procedures.

Participating Sites

112 – Boston Children's Hospital
126 – University of Illinois at Chicago
132 – National Jewish
133 – University of New Mexico
141 – University of Wisconsin
162 – Washington University
181 – University of Arizona
194 – Emory University

The IOS_PRE form will appear as part of visit packets in the data entry application, if a site is not performing IOS procedures the IOS_PRE will be set to missing and the IOS_RPT will be marked 'No'.

4.1.4 Prior Asthma/Allergy Treatment (PRIOR_TRT)

Purpose: To record a participant's medications used to treat asthma or allergies over the last 12 months.

Who: An AsthmaNet coordinator completes the form while interviewing the participant or participant's parent/legal guardian.

When: Visit 1

Form Instructions:

If the participant was randomized in the INFANT study and the treatment assignment is unknown at the time this form is completed, assume the participant was on active medications. Indicate Yes for Leukotriene Antagonist / 5LO inhibitors (Q1260) and Steroids by inhaler (Q1430) and record the date last taken as the INFANT termination date. The instruction will apply if the medication use was in the year prior to enrollment in STICS and if medications were not used since termination from INFANT.

When the INFANT study treatment assignment is revealed, the PRIOR_TRT may be updated to reflect actual use.

4.1.5 STICS Biome Mechanistic Study Medication History (P7_BIOME_HX)

Purpose: To collect the antibiotic and nasal steroid use over the past 12 months for the STICS Biome Mechanistic Study.

Who: An AsthmaNet Coordinator completes the form.

When: Visit 2

Form Instructions:

This form is a short medication history form designed to collect the use of antibiotics and nasal steroids for the STICS mechanistic study. The form is completed as a single form at Visit 2.

If the participant is randomized at Visit 2, this form is required.

Questions 1000-1030. If the participant has used antibiotics during the past 12 months, record the most recent date prior to randomization.

Record 'Don't Know' if the participant does not know or is unsure if he or she has used antibiotics during the past 12 months. If the participant did use antibiotics during the past 12 months but does not know the exact date the medication was last taken, prompt the participant for the month and the year. If the participant cannot recall the day, leave the day blank; if the participant cannot recall the month, leave the month and day blank.

When entering these dates during data entry, the month, day, and year are each represented by a separate entry field. The first box represents the month. Only enter the month into this box. The leading zeros can be left out. The second box represents the day. Only enter the day of the month into this box. The leading zeros can be left out. The third box represents the year. Only enter the year into this box. The year must be entered as four digits. For example, when entering 01/10/2010, enter 01 or 1 into the first box, enter 10 into the second box, and enter 2010 into the third box.

Partial dates can also be entered during data entry for these fields by leaving the box for the unknown information blank. If the day is missing, the month and year can be entered. If both the month and day are missing, the year can be entered. If at least the year is not known, change the leading question to Don't Know.

Questions 1040-1070. If the participant has used antibiotics during the past 12 months, complete Q1a – 1d.

If an antibiotic is prescribed as a loading dose on day one, followed by a lower dose, record the starting dose in Q1060 and record that the lower dose regimen in Q6000.

For example, Azithromycin is prescribed as 10mg/kg/day on day one, following by 5 mg/kg/day on day 2-5.

Record the code – 106 for azithromycin (P7_BIOME_HX_CARD reference card) in Q1050, and the starting dose 180mg on Day 1 for question 1C.

In Q6000 record the child received 92mg on day 2-5.
Question 1050. Refer to the STICS Biome Mechanistic Study Medication History (P7_BIOME_HX_CARD) Reference Card to find the corresponding code for the antibiotic taken. If the antibiotic taken is not listed, record '999' and specify the name of the medication in Q1050D

4.1.6 STICS Coordinator Study Treatment Questionnaire (P7_CC_TXQX)

Purpose: To assess which treatment the Clinic Coordinator thinks the child was receiving during the study.

Who: AsthmaNet Coordinator completes the form.

When: Visits 2 - 8, 2A - 7A, and 90 - 92 when a participant completes or leaves the study.

Form Instructions:

The STICS Coordinator Study Treatment Questionnaire (P7_CC_TXQX) should be completed when the participant completes the study at Visit 8, or when he or she terminates prior to Visit 8. The form can be entered as a packet form at Visit 8, and as a single form at Visits 2 - 8, 2A - 7A, and Visits 90 - 92.

If completed between scheduled visits, record the last completed visit in the **Visit Number** field and the current date in the **Visit Date** field.

Question 1000. If the participant did not use the Yellow Zone Inhaler during the course of the study, skip Q1010 - Q1030D and complete the source documentation box.

Question 1010. Q1010 should be answered with the option that most closely represents the coordinator's feelings about the contents of the Yellow Zone Inhaler the participant received during the study.

Question 1020. Q1020 should be answered with the option that most closely represents how sure the coordinator feels about his/her answer to Q1010.

Question 1030D. Any comments with respect to any other observations the coordinator may have made that helped him/her make a choice in Q1010 should be recorded in Q1030D and entered into the AsthmaNet database (up to 250 characters).

To verify that the information collected on this form is correct, the coordinator who completed the form should initial and date the form in the shaded source documentation box provided (Q1040 - Q1050) at the bottom of the page.

4.1.7 STICS Compliance Checklist (P7_COMPLY)

Purpose: The participant's compliance with the green inhaler, yellow inhaler, as well as the participant's diary compliance is recorded on this form

Who: An AsthmaNet Coordinator completes the form.

When: Visits 2 - 8.

Form Instructions:

The STICS Spirotel® Participant Compliance Report (P7_COMPLY) prints as a report after a participant's spirotel® data are downloaded and converted into Breeze at each visit (see General MOP appendix 6 for instructions on downloading and viewing spirotel® data). The report should be completed by the coordinator, inserted into the visit packet, and data entry should occur directly from the report.

After the report is printed the coordinator **must** complete the Visit, Visit Date and Coordinator ID in the header of the report. If no prior downloads for the same participant are on the laptop that generated the report, a warning will be printed prior to Q1000, as the compliance data may not be accurate. The coordinator will need to contact the primary Data Manager (AsthmaNet_STICS_DM@phs.psu.edu) to obtain the correct report for the visit.

Questions 1000-1020. These questions will populate on the report based on the downloaded spirotel® data. If the compliance value in Q1020 is less than 75% at Visit 2, the participant is ineligible. If the compliance value in Q1020 is less than 75% at Visits 3-7, the coordinator should re-emphasize the importance of completing scheduled diary assessments.

Questions 1030-1060. These questions are completed at Visit 2 only. *These questions will not populate on the report.* The coordinator should complete each question based on the participant's green inhaler counter(s). After priming the inhaler, the number of doses on an inhaler will be 120.

Question 1030. The number of scheduled puffs since the last visit is calculated by counting the calendar days starting with Visit 1 visit date up to and including the Visit 2 visit date. This will yield the number of calendar days. Next, subtract 1 day to account for the half doses scheduled on the visit dates. Take the number of days and multiply times 4, this will yield the number of scheduled doses since the last visit. Record this value in Q1030.

Question 1040. Review the counter on the green inhaler and record the number of doses remaining. If only one inhaler was used, the number of puffs used is a simple subtraction of 120 – counter.

Question 1050. If one inhaler was used, the number of doses taken should be calculated by subtracting the number of does remaining on the counter (Q1040) from the number of doses in the canister (120).

If more than one inhaler was used, complete the STICS Compliance Worksheet (P7_COMPLY_WKS).

Questions 1040–1050. Record these values using the STICS Compliance Worksheet (P7_COMPLY_WKS).

- Q1040. Record the value from the (A) cell on the P7_COMPLY_WKS administrative form.
- Q1050. Record the value from the (B) cell on the P7_COMPLY_WKS administrative form.

Question 1060. Calculate percent compliance by using the formula Q1050/Q1030 x 100. If the percent compliance is less than 75%, the coordinator may consider contacting the DCC to extend the run-in or grant an exception to continue with randomization.

Questions 1070-1130. These questions are completed at Visits 3-8. *These questions will not populate on the report.* The coordinator should complete each question based on the participant's green and yellow inhaler counter(s).

Question 1070. The number of scheduled puffs since the last visit is calculated by counting the calendar days starting with the previous visit date and counting days up to and including the current visit date. Subtract 1 day to account for partial dosing on the visit dates. Take the number of days and multiply times 4, this will yield the number of scheduled doses since the last visit. Record this value in Q1070.

Questions 1080–1120. Record these values using the STICS Compliance Worksheet (P7_COMPLY_WKS).

- Q1080. Record the value from the (A) cell on the P7_COMPLY_WKS administrative form.
- Q1090. Record the value from the (B) cell on the P7_COMPLY_WKS administrative form.
- Q1100. Record the value from the (C) cell on the P7_COMPLY_WKS administrative form.
- Q1110. Record the value from the (D) cell on the P7_COMPLY_WKS administrative form.
- Q1120. Record the value from the (E) cell on the P7_COMPLY_WKS administrative form.

Question 1130. Calculate percent compliance by using the formula Q1120/Q1070 x 100. If the compliance value in Q1130 is less than 75% the coordinator should re-emphasize the importance of maintaining the daily dosing schedule.

Refer to the Dosing Compliance discussion in section 2 of this MOP for further details on calculating inhaler compliance.

4.1.8 STICS Eligibility Checklist 1 (P7_ELIG1)

Purpose: The form consists of basic interview questions, which assist in the determination of a participant's eligibility to enter the study.

Who: An AsthmaNet Coordinator completes the form.

When: Visit 1

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2 of the STICS MOP.

Informed Consent/Assent section. Do not ask the parent/guardian these questions. Data can only be collected if the participant has signed an informed consent form for the STICS study. See the Informed Consent discussion in section 2 for further details.

Questions 1000-1010. The child's parent or guardian must provide informed consent for the STICS study. The signature date should be the date the participant signed the consent document. If the consent was signed prior to the Visit 1, the consent should be reviewed by the parent/guardian on the day Visit 1 takes place. The date the consent form was signed should not be updated.

Questions 1020-1030. The participant must provide informed assent for the STICS study. Assent should be reviewed and signed, or verbally given on the day Visit 1 is performed. If the assent was signed/given prior to the Visit 1, the assent should be reviewed by the participant on the day Visit 1 takes place. The date the assent was signed/given should not be updated. Check N/A if the participant is less than the local age of assent.

Questions 1040-1060. The participant must be able to take the study medications. If the participant has an intolerance or allergy to any of the study medications, he/she is not eligible for STICS.

Question 1070. The participant must be 5 to 11 years old at time of enrollment. Persons who are less than 5 years old **OR** 12 years old or older at the time of *enrollment* are not eligible for STICS. A participant is eligible as long as he/she is enrolled before his/her 12^{th} birthday.

Questions 1090-1100. The participant must be up-to-date with immunizations to be eligible for STICS. The parent/guardian's word is sufficient.

Chicken pox immunization must be acquired by the participant (unless the participant has already had chicken pox). If the participant needs the chicken pox vaccine, this will

be arranged with the primary AsthmaNet physician and must be received prior to randomization.

Question 1170. If the participant has significant developmental delay or failure to thrive, he/she is not eligible to participate in STICS. Significant developmental delay/failure to thrive is defined as height or weight <2nd percentile for age and gender.

Question 1300. If any of the shaded boxes are selected, the participant is ineligible. ***Stop*** completion of the form.

When a participant is ineligible at Visit 1, the packet is not entered into the database, however the study forms should be filed at the site.

Question 1310. Indicate if the participant has been treated with a controller therapy in the past 4 weeks. This question should be answered 'No' if the participant has not been on a controller therapy for at least 4 weeks prior to Visit 1. If the response to Q1310 is 'No' skip to the Naïve to Controller Therapy section (Q1840).

Questions 1320-1810. If the participant has been treated with a controller therapy during the past 4 weeks, complete the table checking all controller therapies that apply and record the dose per day.

Question 1820. If any of the doses are greater than the medium dose defined in column 7 of the table (Step 3 Controller Therapy) for any medication, he/she is ineligible to participate in STICS. If Q1820 is answered 'Yes', ***stop*** completion of the form. When a participant is ineligible at Visit 1, the packet is not entered into the database, however the study forms should be filed at the site.

Question 1830. Based on the responses to Q1320 – Q1810, determine the participant's current dose. If the participant is currently on Step 2 Controller Therapy, SKIP to Q1930. If the participant is currently on Step 3 Controller Therapy, SKIP to Q32.

Note: Participants taking ICS + LTRA should be considered Step 3 Controller Therapy.

Question 1890. Record the participant's Visit 1 C-ACT score in Q32 (this value is not entered into the database). If the C-ACT score is less than or equal to 19 he/she is not eligible to participate in STICS. If any of the responses are blank on the C-ACT form those values should be counted as zero.

Question 1920. Record the participant's Visit 1 pre-bronchodilator FEV_1 % predicted (Q1040 from the SPIRO form) in Q34 (this value is not entered into the database). If the participant's FEV_1 % predicted is less than 80, he/she is not eligible to participate in STICS. If the participant's FEV_1 % predicted is greater than or equal to 80, the participant is eligible, but current controller therapy must be stepped down.

See Section 2 of the STICS MOP for further details.

Question 1930. If any of the shaded boxes are selected, the participant is ineligible. ***Stop*** completion of the form.

When a participant is ineligible at Visit 1, the packet is not entered into the database, however the study forms should be filed at the site.

General Instructions:

If an eligibility protocol exception was granted through the DCC, complete the question(s) that the exception was granted for accurately (i.e. complete the shaded box). The applicable eligibility question(s) should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

4.1.9 STICS Eligibility Checklist 2 (P7_ELIG2)

Purpose: The form consists of basic interview questions, which assist in the determination of a participant's eligibility to enter the study.

Who: An AsthmaNet Coordinator completes the form.

When: Visit 1

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2 of the STICS MOP.

Question 1000. If the participant is male, answer Q1000 'N/A' and skip to Q1030. If the participant is female and pre-menarche answer Q1000 'No.'

Questions 1010-1020. If the participant is currently pregnant or lactating, or she is not willing to use one of the approved methods indicated on the Birth Control Methods (BIRTH_CTRL) reference card for the duration of the study, she is not eligible to participate in STICS.

Question 1040. The participant's pre-bronchodilator FEV1 (% predicted) value should be obtained from Q1040 on the Spirometry Testing (SPIRO) form completed at Visit 1.

Question 1050. The **parent** must demonstrate the ability to use the spirotel® e-diary correctly by achieving a score of 9 on the STICS spirotel® Performance Checklist (P7_SPIRTEL_PERF).

Question 1060. The **participant** must be able to demonstrate the ability to use the metered dose inhaler properly by achieving a score of 12 on the MDI Inhalation Technique Checklist With Spacer (TECH_MDI_SP). The parent should help the child follow the instructions on the TECH_MDI_SP.

Question 1070. If there is any other reason why the participant cannot be included in the study and the response to Q1070 is 'Yes', please provide a description of the reason in Q1070D.

Question 1080. If any of the shaded boxes are selected, the participant is ineligible.

When a participant is ineligible at Visit 1, the packet is not entered into the database and the study forms are filed at the site.

General Instructions:

If an eligibility protocol exception was granted through the DCC, complete the question(s) that the exception was granted for accurately (i.e. complete the shaded box). The applicable eligibility question(s) should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

4.1.10 STICS Eligibility Checklist 3 (P7_ELIG3)

Purpose: This form consists of questions that assist in determining if a participant is eligible to continue in the STICS study.

Who: An AsthmaNet Coordinator completes the form.

When: Visit 2.

Form Instructions:

For detailed information regarding eligibility criteria, see the Eligibility Criteria discussion in Section 2 of the STICS MOP.

Questions 1000-1040. These questions refer to the time since Visit 1, to assess whether the participant is eligible to continue in the study.

Question 1000. If the participant had an asthma exacerbation that required medication and hospitalization, please complete the Serious Adverse Event Reporting (SERIOUS) form.

Question 1030. Refer to Q1020 on the Participant Compliance Report (P7_COMPLY) to determine if the participant completed at least 75% of scheduled PM sessions on the spirotel®.

Question 1040. Refer to Q1060 on the Participant Compliance Report (P7_COMPLY) to determine if the participant took at least 75% of the required puffs from his/her green inhaler.

Question 1050. Record the participant's Visit 2 C-ACT score in Q5 (this value is not entered into the database). If the C-ACT score is less than 20, he/she is not eligible to participate in STICS. If any of the responses are blank on the C-ACT form those values should be counted as zero.

Question 1070. If there is any other reason why the participant cannot be included in the study and the response to Q1070 is 'Yes', please provide a description of the reason in Q1090D.

Question 1080. If any of the shaded boxes are selected, the participant is ineligible. A STICS termination of study participation (P7_TERM) form should be entered.

General Instructions:

If an eligibility protocol exception was granted through the DCC, complete the question(s) that the exception was granted for accurately (i.e. complete the shaded box). The applicable eligibility question(s) should be answered 'Yes' to indicate the

participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

4.1.11 STICS Laboratory Results (P7_LAB)

Purpose: To record local blood test results and sample collection for immunocap, genetics and nasal samples.

Who: An AsthmaNet Coordinator completes the form.

When: Visits 2 - 8, 90 - 92.

Form Instructions:

The Laboratory Tests (P7_LAB) form is entered into the database as a packet form at Visit 2. If the coordinator is unable to collect enough blood at Visit 2 and your Consent Form indicates that blood can be drawn at a later time, samples can be collected at a later visit and the form entered as a single form. A nasal sample is collected at Visit 2 and is recorded on the Visit 2 form (Q1030). Nasal Samples that are collected by the parent/guardian at home between visits do not get recorded on a P7_LAB form.

Visit Date. Record the visit date as the date the blood is drawn (should match collection date on lab report).

Question 1000. Indicate if a blood sample was collected. If Q1000 is answered 'No' and it is Visit 2, skip to Q1050.

Question 1010. Record the White Blood Count (WBC) result. If the units are 'x10E9/L', 'TH/mm3' or 'THOU/UL', then multiply by 1000 and record the calculated value on the P7_LAB form. For example if the lab report indicates a value of 8.0 the calculated value of 8000/cu.mm is recorded in Q1010.

Question 1020. Record the Eosinophil result. If the eosinophil count is not reported as a percentage, it can be calculated. To convert the eosinophil to a percent, divide the eosinophil result by the WBC value and multiple by 100. For example 0.23/8.0 X 100 = 2.9%.

Submit the original local lab report with the participant's visit packet. The coordinator should record the participant's ID number in the upper right-hand corner of the report. **All identifying information (name, medical record number, etc.) should be blackened-out prior to forwarding the report to the DCC with the packet. If the DCC receives a report for which the identifying information has not been blackened-out, a protocol violation may be assigned.**

Question 1030. If a sample was collected at the visit, record the sample on the STICS Immunocap/Ige (P7_IGE_LOG) log and enter the sample into the Biological Sample Tracking (BST) module.

Question 1040. If a sample was collected at the visit, record the sample on the AsthmaNet Genetic Sample (GEN_SAMP_LOG) log and enter the samples into the Genetics Tracking module on the day the sample was collected..

Questions 1050. (VISIT 2 ONLY) Indicate if a nasal sample was collected. If a nasal sample was collected record the sample on the P7_NASAL_COL_LOG and enter the sample into the BST.

4.1.12 STICS Medications (P7_MED)

Purpose: To record the dispensation of study drugs.

Who: An AsthmaNet Coordinator completes the form.

When: Visits 2, 3 – 7, 2A - 7A, 90 - 92.

Form Instructions:

The STICS Medications form must be completed ***every*** time study drugs are dispensed at scheduled or unscheduled visits.

An unscheduled visit is a visit which occurs between two scheduled visits. The Scheduled Medications (P7_MED) form should be entered into the database as a single form. The visit date should be the date the form is completed and the visit number should be the last visit number completed.

Label. Affix the label to the STICS Scheduled Medications (P7_MED) form and copy the drug label number onto the spaces provided in Question 1000.

After affixing the label, the coordinator should sign and date the source documentation box provided (Q1010-1020).

4.1.13 STICS Microbial Exposure Questionnaire (P7_MEQ)

Purpose: To record information on exposures that may affect the participant's lung microbiome.

Who: An AsthmaNet coordinator completes the form.

When: Visit 1

Form Instructions:

If a field only accepts whole numbers, round up to the nearest whole number for decimal values greater than or equal to 0.5 and round down to the nearest whole number for decimal values less than 0.5.

'House' is defined as the place where the participant lives most of the time.

Question 1000. Check only one box. If Q1000 is answered 'Other', Q1000D should be completed.

Question 1050. If Q1050 is answered 'Yes', complete Q1050D.

Question 1060. Check only one box. If Q1060 is answered 'Other', Q1060D should be completed.

Question 1080. Record the number of days per month the participant has used the wood burning fireplace/stove in his or her house during the past three months. For example, if the participant used the fireplace or stove for 10 full days each month out of the past 3 months, record 10 for Q1080. If unsure of the number of days per month, estimate to the nearest number of days.

Question 1130. Record the number of hours per week the participant spends in the yard. For example, if the participant responds that he/she spends 2 hours per day in the yard, record 14 for Q1130. If unsure of the number of hours per week, estimate to the nearest number of hours.

Question 1140. If Q1140 is answered 'No', skip to Q1200.

Questions 1150-1180. Record the number of hours per week the participant spends gardening during each of the four seasons. For example, if the participant responds that he/she spends 2 hours per day in the yard in the Spring, record 14 for Q1150. If unsure of the number of hours per week, estimate to the nearest number of hours.

Question 1190. Record the number of hours per week the participant spent gardening in the past month. For example, if the participant responds that he/she typically spends 1

hour per week gardening, record 1 for Q1190. If unsure of the number of hours per week, estimate to the nearest number of hours.

Question 1200. If Q1200 is answered ‘No’, skip to Q1230.

Question 1210. Record the number of children who spend time in the participant’s houshold. For example, if the participant has two children and also babysits another child frequently, record 3 for Q1210.

Question 1220. Record the number of children who spend time in the participant’s household that are not “potty-trained”. Potty-trained is defined as able to use a toilet and no longer in need of diapers. For example, if the participant has a three month old infant, record 1 for Q1220.

Question 1240. If Q1240 is answered ‘No’, skip to Q1280.

Question 1250. Record the number of months per year the participant works on a farm. For example, if the participant responds that he/she only works on a farm during the months of June and July, record 2 for Q1250. If unsure of the number of months per year, estimate to the nearest number of months.

Question 1260. Record the number of hours per week the participant works on a farm during the months recorded in Q1250. For example, if the participant responds that he/she works on the farm 8 hours a day every day of the week, record 56 for Q1260. If unsure of the number of hours per week, estimate to the nearest number of hours.

Question 1270. Record the number of hours per week the participant worked on a farm in the past month. For example, if the participant responds that he/she worked on the farm 8 hours a day every day of the week, record 56 for Q1270. If unsure of the number of hours per week, estimate to the nearest number of hours.

Question 1300. If Q1300 is answered ‘Yes’, complete Q1310-Q1340.

Question 1340. If Q1340 is answered Yes, complete Q1340D.

Review the form prior to the participant leaving the clinic to ensure that the participant completed the form correctly.

The parent/guardian must complete the source documentation box (using 2 or 3 initials) on page 4 (Q1360 and Q1370). Enter the Date field in the database in the format mm/dd/yyyy.

4.1.14 STICS Participant Study Treatment Questionnaire (P7_PART_TXQX)

Purpose: This form helps to determine whether the blind on the scheduled inhaler was effective from the parent's perspective.

Who: The parent/legal guardian completes the form.

When: Visits 2 - 8, 2A - 7A, and Visits 90 - 92

Form Instructions:

The STICS Participant Study Treatment Questionnaire (P7_PART_TXQX) should be completed when the participant completes the study at Visit 8, or when he or she terminates prior to Visit 8. The form can be entered as a packet form at Visit 8, and as a single form at Visits 2 - 8, 2A - 7A, and 90 - 92.

If completed between scheduled visits, record the last completed visit in the **Visit Number** field and the current date in the **Visit Date** field.

Question 1000. Check only one box. If Q1000 is answered 'Other', Q1000D should be completed.

Question 1010. If the participant did not use the Yellow Zone Inhaler during the course of the study, skip Q1020 - Q1040D and complete the source documentation box.

Question 1020. Q1020 should be answered with the option that most closely represents the parent/guardian's feelings about the contents of the Yellow Zone Inhaler the participant received during the study.

Question 1030. Q1030 should be answered with the option that most closely represents how sure the participant/guardian feels about his/her answer to Q1020.

Question 1040. If the participant/guardian answers Q1040 with option 2 ('I noticed the following'), he/she should comment further on observations made regarding the Yellow Zone Inhaler in Q1040D.

Question 1040D. Any comments with respect to any other observations the parent/guardian may have made regarding the participant's Yellow Zone Inhaler should be recorded in Q1040D and entered into the AsthmaNet database (up to 250 characters).

Parent/guardian-completed forms should always be reviewed by the coordinator upon completion. If a correction is noted, the parent/guardian should make the correction and initial and date next to the change. Coordinators should not alter parent/guardian completed forms.

To verify that the information collected on this form was provided by the parent/guardian, have the parent/guardian initial and date the form in the shaded source documentation box provided (Q1050-Q1060) at the bottom of the page.

See the Study Treatment Questionnaire discussion in section 2 of this MOP for further details.

4.1.15 STICS Phone Symptom Assessment (P7_PHONE_CONTACT)

Purpose: This form assesses the participant's status at scheduled phone calls during the study to assist in the identification of breathing problems, albuterol use, progression to the yellow zone inhaler and use of prednisone.

Who: An AsthmaNet Coordinator completes the form.

When: As a packet form at Visits 2A - 7A.

Form Instructions:

Please complete the information in the shaded box to track the date and time that the phone call was attempted. This data is not entered into the database.

Questions 1000-1010. If the participant has been to the doctor for breathing problems since the last visit or phone call and the answer to Q1000 is 'Yes' complete Q1010. Otherwise, skip to Q1020.

Questions 1020-1030. If the participant has been to the an ER or urgent care facility for breathing problems since the last visit or phone call and the answer to Q1020 is 'Yes' complete Q1030. Otherwise, skip to Q1040.

Question 1040. If the participant has been hospitalized for breathing problems since the last visit or phone call, determine if he/she is a treatment failure by completing the STICS Treatment Failure (P7_TRTFAIL) form and complete the SERIOUS form, if needed.

Questions 1050-1060. If the participant has experienced coughing or wheezing during the past 2 weeks and the answer to Q1050 is 'Yes' complete Q1060.

Questions 1070-1120. If the participant has had night time awakenings due to asthma symptoms requiring albuterol during the past 2 weeks and the answer to Q1070 is 'Yes' complete Q1080 – Q1120 following the skip patterns outlined on the form. If the response to Q1120 is 'Yes' and prednisone was started, please complete the Prednisone Medication (P7_PRED) form. If the response to Q1070 is 'No', skip to Q1130.

Questions 1130-1140. If the participant has taken albuterol during the past 2 weeks (excluding pre-exercise) and the answer to Q1120 is 'Yes' complete Q1130. Otherwise, skip to Q1140.

Questions 1150. If the parent/guardian indicates he/she has not been completing the spirotel® Diary daily, review adherence.

Questions 1160–1180. If the participant has been using the GREEN inhaler every morning and evening (with the exception of YELLOW inhaler use) complete the number of AM and PM puffs in Q1170 - Q1180. If necessary, review adherence with the parent/guardian.

Questions 1190-1200. If the participant has had any Yellow Zones since the last study contact which required the use of the YELLOW inhaler, record the number of zones in Q1200. If the parent/guardian gave the wrong inhaler for a day (non-intentional), that YELLOW inhaler use should not count toward the total number of Yellow Zones. Remind the parent/guardian that they must use the YELLOW inhaler for 7 days. Determine if he/she is a treatment failure by completing the STICS Prednisone and Yellow Zone Tracking (P7_TRK) form. Complete a STICS Treatment Failure (P7_TRTFAIL) form, if necessary.

Questions 1210-1220. If the participant has used prednisone since the last visit or phone contact, complete the Prednisone Medication (P7_PRED) form and record the number of courses (1 course = 4 days) used in Q1220. Determine if he/she is a treatment failure by completing the STICS Prednisone and Yellow Zone tracking (P7_TRK) form. Complete a STICS Treatment Failure (P7_TRTFAIL) form, if necessary.

4.1.16 STICS Prednisone Medication (P7_PRED)

Purpose: To record prednisone medication use during study.

Who: An AsthmaNet Coordinator completes the form.

When: As a single form at Visits 2 - 8, 2A - 7A, and 90 - 92

Form Instructions:

The STICS Prednisone Medication (P7_PRED) form should be completed each time the participant receives a course of oral/systemic corticosteroids for treatment of asthma. A dose of dexamethasone will be considered the equivalent to a prednisone course.

Instruct the parent/guardian to call if the participant's condition worsens while taking prednisone.

If completed between scheduled visits, record the last completed visit in the **Visit Number** field and the current date in the **Visit Date** field. If the last completed visit was a phone visit, the form can be entered with the visit number of the last completed phone call (i.e., if the last completed visit was 5A, the form can be entered using 5A as the visit number).

Question 1000. Record the start date of the prednisone course or dose of dexamethasone. The prednisone course should be recorded on the CMED form using the drug code 382796. A treatment of dexamethasone should be recorded on the CMED form using the drug code 382792 or 382869. Remember to document the prednisone course/dexamethasone treatment on the STICS Prednisone and Yellow Zone Tracking (P7_TRK) administrative form.

Question 1010. Indicate the reason prednisone/dexamethasone was prescribed. If Q1010 is answered 'Physician discretion', please provide an explanation in Q6000.

Question 1020. Indicate if this course of prednisone is the second prednisone course for treatment of asthma within 6 months since randomization. A dose of dexamethasone is considered the equivalent to 1 course of prednisone.

Question 1030. Indicate if this course of prednisone is the third prednisone course for treatment of asthma within 12 months since randomization. A dose of dexamethasone is considered the equivalent to 1 course of prednisone.

4.1.17 STICS Pulmonary Procedure Checklist (P7_PULMONARYCHK)

Purpose: This form assists the coordinator in determining if the participant is eligible to proceed with pulmonary function testing.

Who: The Pulmonary Function Technician or an AsthmaNet coordinator interviews the participant/guardian and completes the form. The coordinator **must possess STICS protocol certification**.

When: Visits 1 - 8, and 90 - 92

Form Instructions:

If any medications other than the study or rescue albuterol were used, record the medications on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

Question 1050. Completed at Visit 1 only.

Question 1140. The participant is ineligible to perform spirometry, exhaled nitric oxide and IOS testing if any of the shaded boxes is completed.

If the participant is not eligible to proceed with spirometry and is willing to reschedule the visit, file the collected data in his or her study folder; do not enter the data or forward it to the DCC.

If a spirometry eligibility protocol exception was granted through the DCC, complete the question(s) for which the exception was granted accurately (i.e. complete the shaded box). Q1140 should be answered 'Yes' to indicate the participant is eligible to proceed and any entry errors that result from the exception should be marked unresolvable. In the unresolvable comment section, indicate that a protocol exception was granted, who granted it, and the justification for the exception. Also, complete the comment field (Q6000) provided on the last page of the form with additional information on the exception.

4.1.18 STICS Red Zone Phone Assessment (P7_RED_PC)

Purpose: The form is completed to assess the status of the participant following an exacerbation treated with prednisone. The phone call is completed for safety purposes and if the participant is not improving on prednisone, a follow up phone call or study visit should be scheduled.

Who: An AsthmaNet Coordinator completes the form.

When: Completed 5 days after an exacerbation onset (+/- 2 days)

Form Instructions:

Parents should be instructed to call before starting prednisone. If prednisone is warranted, the Red Zone Phone Assessment Call should be scheduled for 5 days later, after the 4 day course is finished. This form is completed during that call. This form can only be entered as a single form. The visit number should be the last completed visit and the visit date is the date that the phone call occurred.

Question 1000. Record the related concomitant medication number from the CMED form.

Question 1010. If the participant is still having asthma symptoms, complete Q1020 - Q1050. If they are no longer having asthma symptoms, skip to Q1060.

Questions 1020-1050. If the response to any of these questions is 'Yes', the study physician should be consulted. Additional treatment and a follow-up phone call or visit may be required. If a follow-up visit is required, schedule and complete the red zone clinic visit (Visit 90 - 92 Red Visit).

4.1.19 STICS Termination of Study Participation (P7_TERM)

Purpose: To record the date and the primary reason for the participant's termination of STICS study participation.

Who: An AsthmaNet Coordinator completes the form.

When: May be completed at Visits 1 - 7, 2A - 7A, and 90 - 92 as a single form, or at Visit 8 as a packet form.

Form Instructions:

A participant should be terminated from the study when the participant is a run-in failure, the parent/guardian wishes to withdraw the participant early, or the participant completes the study. The study investigator can also determine using physician discretion that it is in the best interest of the participant to discontinue participation in the trial.

If completed between scheduled visits, record the last completed visit in the **Visit Number** field and the current date in the **Visit Date** field. If the last completed visit was a phone visit, the form can be entered with the visit number of the last completed phone call (i.e., if the last completed visit was 5A, the form can be entered using 5A as the visit number).

Question 1000. If Q1000 is answered 'Yes' and the participant was a Run-In failure, indicate the primary reason in Q1010. If the participant is not a Run-In failure, skip to Q1020.

Question 1010. If the participant experienced a serious adverse event, complete the Serious Adverse Event Reporting (SERIOUS) form. If the response to Q1010 is 10 or 11, complete Q1010D with an additional explanation. SKIP to the Signatures section and complete Q1060 - Q1090.

Question 1020. If the participant has completed the study through Visit 8, answer 'Yes' and skip to the signatures section. If 'No', complete Q1030.

Question 1030. Complete indicating who initiated the termination of the participant from the study. If the termination was initiated by clinical staff, select 2 and skip to Q1050. If the termination was initiated by the parent/guardian, complete Q1040 indicating the primary reason the participant has withdrawn from the study. If the response to Q1040 is 1, 2, 6, 7, 8, or 10 please provide an additional explanation in Q1040D. Skip to the Signatures section and complete Q1060 - Q1090.

Question 1050. If the termination was initiated by the clinical staff, indicate the primary reason for the termination. If the response is 'other', please provide an additional explanation in Q1050D. Complete Q1060 - Q1090.

4.1.20 STICS Treatment Failure (P7_TRTFAIL)

Purpose: To record the date and the events that occurred when a participant is deemed a treatment failure.

Who: An AsthmaNet Coordinator completes the form.

When: This form is completed as a packet form at Visits 3-8 and all phone Visits 2A - 7A, and as a single form at Visits 2 - 8, and Visits 90 - 92 to assess if the participant has met the treatment failure criteria.

Form Instructions:

For more details on Treatment Failures, see the Treatment Failure discussion in Section 2.49 of the STICS MOP.

If completed between scheduled visits, record the last completed visit in the **Visit Number** field and the current date in the **Visit Date** field in the key variable information.

Questions 990 – Q995D. The Spirotel® Participant Visit report will be used by the coordinator to interview the parent/guardian and complete the Yellow Zone Follow Up section. These questions were added in an attempt to re-educate the parent about starting the yellow zones, and to capture information when the yellow zones are not started.

Q995. As soon as the participant qualifies for a yellow zone the yellow inhaler should be used for 7 days, however yellow inhaler use for greater than or equal to 2 days, regardless of the number of doses taken, will be counted as starting yellow zone treatment.

If more than 1 yellow alert is present on the Spirotel® Participant Visit report and each alert was treated, answer Yes. Otherwise answer No and provide a reason for each yellow alert without yellow inhaler treatment.

Questions 1000-1030. The questions are designed to assess the treatment failure status of the participant.

Question 1000. A yellow zone is defined as yellow inhaler use for greater than or equal to 2 days, regardless of the number of doses taken, when following the STICS action plan. The coordinator should reference the STICS spirotel Participant Visit (P7_SPIROTEL_RPT) report and the STICS Prednisone and Yellow Zone Tracking (P7_TRK) form to evaluate the criteria. Yellow inhaler use is identified on the STICS spirotel Participant Visit (P7_SPIROTEL_RPT) report by the word ‘YELLOW’ printed in the ‘Yellow Inhaler?’ column.

Questions 1010, 1020. Prednisone use is recorded on the STICS Prednisone Medcation (P7_PRED) form, the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form and the STICS Prednisone and Yellow Zone Tracking (P7_TRK) form. If a participant is treated with 1 dose of dexamethasone, this will be viewed as the equivalent to 1 prednisone course.

Question 1030. If the participant was hospitalized for more than 24 hours due to an asthma exacerbation, please complete a Serious Adverse Event Reporting (SERIOUS) form.

Question 1040. If any of the shaded boxes are selected, the participant is a treatment failure. Please complete the STICS Termination of Study Participant (P7_TERM) form, and the STICS Study Treatment Questionnaires (P7_CC_TXQX, P7_PART_TXQX) forms. Collect the study medications and supplies as soon as possible.

Question 1050. Record the date that the treatment failure occurred.

4.1.21 STICS Yellow Zone Phone Assessment (P7_YELLOW_PC)

Purpose: This form collects information on the start of the yellow zone and assesses the severity of the participant's asthma symptoms. The participants' clinical status should be assessed and their action plan review, including the criteria for initiating red zone therapy.

Who: An AsthmaNet Coordinator completes the form.

When: Completed within 72 hours of starting the yellow zone medication.

Form Instructions:

The form is completed when the parent/guardian calls within 72 hours of initiating the yellow zone medication. This form can be entered as a single form at Visits 2 - 8, 2A - 7A, and 90 - 92. The visit number should be the last completed visit and the visit date is the date that the phone call occurred.

Questions 1000-1010. Record the date and time of day the parent reports starting treatment with the yellow inhaler when following the action plan.

Question 1020. Record the reason the yellow zone was started. If the response to Q1020 is 'other', please complete Q1020D with a description in the space provided.

Question 1030. If the participant is no longer having asthma symptoms, skip to Q1080.

Questions 1040-1070. These questions assess the severity of the asthma symptoms and if any one of these questions is answered 'Yes', the participant may meet criteria for starting prednisone. Please consult the study physician. The parent/guardian should also be instructed to contact the site if the participant continues to meet yellow zone criteria at the end of the 7 day yellow zone period.

Questions 1090-1100. These questions refer to the nasal sample collection performed by the parent/guardian since the start of the illness. If the parent/guardian indicates that the nasal sample was not collected and the answer to Q1130 is 'No', instruct them to collect a nasal sample immediately.

4.2 Administrative Forms

Administrative forms facilitate processing of the participant and visit flow by the clinical centers and the DCC, but they are not entered into the study database and they are not submitted to the DCC in most cases. The following is a list of all STICS study administrative forms, the corresponding form code and related instructions[1]:

Administrative Form Name	Form Code
STICS Compliance Worksheet	P7_COMPLY_WKS
STICS Immunocap/IgE Log	P7_IGE_LOG
STICS Participant Assignment Log	P7_LOG
STICS Nasal Mucus Collection Log	P7_NASAL_COL_LOG
STICS Nasal Sample Kit Dispensation Log	P7_NASAL_DISP_LOG
STICS spirotel® Performance Checklist	P7_SPIROTEL_PERF
STICS Prednisone and Yellow Zone Tracking Form	P7_TRK
STICS Visit Procedure Checklists	P7_VISIT1, P7_VISIT2, P7_VISIT3_7, P7_VISIT8, P7_VISIT_PC, P7_VISIT_RED

[1] Drug logs and related procedures are covered in the **STICS** Pharmacy MOP

4.2.1 STICS Compliance Worksheet (P7_COMPLY_WKS)

Purpose: To organize the inhaler compliance information from multiple inhalers at each regular in-person visit.

Who: An AsthmaNet Coordinator completes the form.

When: Visits 2-8.

Form Instructions:

The first table records the doses remaining/taken for each Green inhaler. The sum of these values is recorded in the total row at the bottom of the table. Note: At Visit 1, only two green inhalers will be distributed.

The second table records the doses remaining/take from the Yellow Inhaler. If the participant did not experience any yellow zones, this inhaler may not be used. This table will only be completed at Visits 3-8.

The third table provides a space to add the total doses taken from both the Green and Yellow inhalers.

4.2.2 STICS Immunocap/IgE Log (P7_IGE_LOG)

Purpose: To record a participant's biological specimen collection for Immunocap and IgE.

Who: An AsthmaNet Coordinator completes the log.

When: This log is completed every time a biological specimen sample is collected.

Form Instructions:

When a sample is collected, the Coordinator must complete a row on the appropriate log for the participant ID. All biological samples collected during the study must be recorded on a log.

A P7_LAB form should be completed and entered into the database for the visit during which a clinic sample has been collected, typically Visit 2.

Note: For the Visit Number column, use the Visit Number of the current visit.

If multiple aliquots are produced for one sample type, multiple barcodes can be recorded in the Cryovial Barcode # column.

This log will be reviewed during AsthmaNet site visits.

For use only at the Clinical Center, this form is not data entered.

DO NOT forward to the DCC when completed.

4.2.3 STICS Participant Assignment Log (P7_LOG)

Purpose: To track all participants enrolled in the STICS studies by their study-specific Participant ID numbers.

Who: An AsthmaNet Coordinator completes the form.

When: Visits 1 - 7.

Form Instructions:

A Participant Assignment Log (P7_LOG) has been developed for Clinical Sites to record the assignment of Participant ID numbers. It includes columns for unique participant ID numbers, participant initials, participant's name, box to check to indicate if the participant has been randomized (to be completed at Visit 2) and Yellow Inhaler assignments.

The first digit is the number of the AsthmaNet protocol. For STICS this digit is 7.

The second set of numbers (3 digits) is the AsthmaNet Clinical Site identifier which will pre-fill with the Site ID when printed from the website.

The last three digits constitute the participant identification number, which is unique within the Clinical Site. The first participant is assigned 001, the second 002, and so on.

The Participant Assignment Log (P7_LOG) **must** be used every time a **new** Participant ID number is assigned. The Participant Assignment Log (P7_LOG) is pre-numbered, so a new Participant ID number is assigned by selecting the next available blank entry on the log. This number will be the primary participant identifier used during the study; it should be used in all communications with the DCC. The participant ID number should also be labeled on the participant's study folder at the Clinical Site.

Once assigned, an ID number cannot be assigned to any other participant.

If a participant has withdrawn during the assessment/characterization period and later re-enrolls in the study, he or she should be assigned a new participant ID number; that is, the next available blank entry on the Participant Assignment Log.

A participant's three-letter initials will be used as a secondary identifier. All participants ***must*** have three initials for use during this study. Use the letter "X" if there is no middle initial and select three letters if there are 4 or more letters in the initials. These initials must remain constant throughout the study and throughout any future studies the participant is involved in.

Visit 1: Complete the Participant initials and Participant name columns for the new participants.

The participant's name should be written last name first, followed by first name on the STICS Participant Assignment Log (P7_LOG).

Visit 2: If the participant is randomized, check the box in the Randomized column and complete the first yellow inhaler assignment.

Visits 3-7: Record the yellow inhaler assignments.

Since the participant's name is recorded on this log, DO NOT forward this log to the DCC during the study. After the study, mail a copy to the DCC in a sealed envelope. The DCC will retain this sealed log for historical and safety purposes. The site needs to retain the original log in a secure and confidential location.

This log will be reviewed during Asthmanet site visits.

For use only at the Clinical Site, this form is not data entered.

DO NOT forward to the DCC.

4.2.4 STICS Nasal Mucus Collection Log (P7_NASAL_COL_LOG)

Purpose: To record a participant's nasal mucus collection.

Who: An Asthmanet Coordinator completes the log.

When: This log is completed every time a nasal mucus sample is collected.

Form Instructions:

When a sample is collected, the Coordinator must complete a row on the P7_NASAL_COL_LOG for the participant ID. All samples collected during the study must be recorded on this log, whether collected in clinic or at home.

A P7_LAB form should be completed and entered into the database for the visit during which a clinic sample has been collected (Visit 2). The samples collected at home visits will not be recorded on a data collection form.

Note: For the Visit Number column, use the Visit Number of the current visit.

This log will be reviewed during AsthmaNet site visits.

For use only at the Clinical Center, this form is not data entered.

DO NOT forward to the DCC when completed.

4.2.5 STICS Nasal Sample Kit Distribution Log (P7_NASAL_DISP_LOG)

Purpose: To record dispensation of nasal sample kits.

Who: An Asthmanet Coordinator completes the log.

When: This log is completed every time a nasal sample kit is dispensed and sample is collected.

Form Instructions:

When a nasal sample kit is dispensed to a parent/guardian for home nasal mucus collection, the Coordinator must complete a row on the P7_NASAL_DISP_LOG. Sample kits used in the clinic do not need to be recorded on this log. An individual log should be kept for each participant and should be stored in the participant's binder.

Note: For the Visit Number column, use the Visit Number of the current visit.

This log will be reviewed during AsthmaNet site visits.

For use only at the Clinical Center, this form is not data entered.

DO NOT forward to the DCC when completed.

4.2.6 STICS spirotel® Performance Checklist (P7_SPIROTEL_PERF)

Purpose: To assess the parent/guardian's ability to correctly use the spirotel® device.

Who: An AsthmaNet Coordinator completes the form.

When: Visit 1

Form Instructions:

The parent/guardian must demonstrate the ability to coordinate use of the spirotel® device for entering diary information before leaving the performance site. These skills are assessed using the site demo device and completing the spirotel® Performance Checklist (P7_SPIROTEL_PERF).

After the parent/guardian has had a chance to experiment with the STICS demo device, he/she should undergo a formal spirotel® performance assessment using the steps on the spirotel® Performance Checklist (P7_SPIROTEL_PERF). He/she must pass the performance check with a score of 9 to remain eligible for the study. Results of the performance check are recorded in Q1050 on STICS Eligibility Checklist 2 (P7_ELIG2) form.

If a parent/guardian fails to perform all the steps on the performance checklist correctly, he/she may be retrained and undergo another assessment. There is no limit on the number of times the participant may attempt to pass the checklist. Store all completed P7_SPIROTEL_PERF forms in the participant's STICS study folder at the performance site; they should not be forwarded to the DCC.

Train with the demo spirotel® for the protocol in which the participant is enrolled.

For use only at the Clinical Center, this form is not data entered.

DO NOT forward to the DCC when completed.

4.2.7 STICS Prednisone and Yellow Zone Tracking Form (P7_TRK)

Purpose: To track prednisone and yellow zone courses taken by the participant during the STICS Treatment Phase.

Who: An AsthmaNet Coordinator completes the form.

When: Whenever the participant is prescribed a prednisone course or begins yellow zone treatment.

Form Instructions:

Record the date the prednisone course started and was completed. If a participant is treated with 1 dose of dexamethasone, this will be viewed as the equivalent to 1 prednisone course.

If 2 prednisone courses are taken within 6 months OR 3 courses are taken within 12 months, the participant is a treatment failure. The STICS Treatment Failure (P7_TRTFAIL) form should be completed.

Record the date the yellow zone course started and was completed. If the yellow inhaler was used for at least one day in response to the STICS action plan, this will count as a yellow zone.

If 6 Yellow Zone courses are taken since randomization, the participant is a treatment failure. The STICS Treatment Failure (P7_TRTFAIL) form should be completed.

This form will be reviewed during AsthmaNet site visits.

For use only at the Clinical Center, this form is not data entered.

DO NOT forward to the DCC when completed.

4.2.8 STICS Visit Procedure Checklists (P7_VISIT1, P7_VISIT2, P7_VISIT3_7, P7_VISIT8, P7_VISIT_PC, P7_VISIT_RED)

Purpose: To provide the coordinator with a checklist of all procedures and forms that must be completed during a visit

Who: An AsthmaNet Coordinator completes the form.

When: At the specified visit.

Form Instructions:

These checklists serve as a guide for the coordinator and should be sent to the DCC, in front of the visit packet, with the other forms in the packet.

For all procedures and forms, indicate whether or not the procedure or form was completed. If it was not completed, indicate the reason in the comment field.

Procedures should be followed in the order they are presented on the visit checklist for applicable visits.

These forms are not entered during data entry, but should be sent to the DCC with the rest of the packet forms.