"Attach Registry Form Label Here"	**AsthmaNet REGISTRY FORM**	Participant's Last Name: _____ Participant's First Name: _____ Participant's Initials: __ __ __ Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Search the AsthmaNet Registry. If the participant has incomplete status or is not found in the registry, complete the Registry form and enter/update the participant's information appropriately.

ADMINISTRATIVE

1. Three-digit ID for site registering participant and maintaining source documentation: **(SITE_REG)** __ __ __

2. Is the participant ≥ 18 years old? **(1000)** ❑1 Yes ❑0 No
   ➔ If **NO**, skip to Q3.

   2a. IF **YES**: Did the participant sign and date an AsthmaNet Protocol Informed Consent and a HIPAA Authorization Form? **(1010)** ❑1 Yes ❑0 No
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.

   2ai. IF **YES**: Record the date the consent form was signed. **(1020)** __ __ / __ __ / __ __ __ __
   ➔ Skip to Q5.

3. If the participant is < 18 years old, did the parent/legal guardian sign and date an AsthmaNet Protocol Informed Consent and a HIPAA Authorization Form? **(1030)** ❑1 Yes ❑0 No
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.

   3a. If **YES**: Record the date the consent form was signed. **(1040)** __ __ / __ __ / __ __ __ __

4. Did the participant sign and date an AsthmaNet Protocol Informed Assent and HIPAA Authorization form according to local IRB rules and regulations? **(1050)** ❑1 Yes ❑0 No ❑2 Not required by IRB
   ➔ If **NO**, STOP HERE. Data cannot be entered into the AsthmaNet Registry.
   ➔ If **NOT REQUIRED**, skip to Q5.

   4a. If **YES**: Record the date assent was given. **(1060)** __ __ / __ __ / __ __ __ __

DEMOGRAPHICS

5. Participant's date of birth **(1070)** __ __ / __ __ / __ __ __ __
   (Ask the participant his/her date of birth.)

6. Participant's gender **(1080)** ❑1 Male ❑2 Female

7. Participant's ethnic background
(Ask the participant to identify his/her ethnic background.)

(1090) ❑1 Hispanic or Latino
❑2 Not Hispanic or Latino

8. Participant's racial background
(Ask the participant to identify all that apply. Check at least one Yes.)

8a. American Indian or Alaskan Native	**(1100)**	❑1 Yes	❑0 No
8b. Asian	**(1110)**	❑1 Yes	❑0 No
8c. Black or African American	**(1120)**	❑1 Yes	❑0 No
8d. White	**(1130)**	❑1 Yes	❑0 No
8e. Native Hawaiian or Other Pacific Islander	**(1140)**	❑1 Yes	❑0 No

9. Participant's primary racial identification (Ask the parent/guardian or participant which category best describes the participant, and check only one box.)

(1150) ❑1 American Indian or Alaskan Native
❑2 Asian or Pacific Islander
❑3 Black or African American
❑4 White
❑5 Hispanic or Latino
❑6 Other

(1160) _____

Registry Form Storage Instructions:

Print the participant's Registry Report with his/her name on the report. Registry Reports and completed Registry forms should be stored alphabetically by participant's last name in the AsthmaNet *Registry binder.*

REGISTRY FORMS AND REPORTS SHOULD <u>NOT</u> BE SENT TO THE DCC.

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __
Date: __ __ / __ __ / 20 __ __
MM DD YYYY

REGISTRY

AsthmaNet

STICS BIOME MECHANISTIC STUDY MEDICATION HISTORY

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Antibiotics

1. During the past 12 months, has the participant used antibiotics? **(1000)** ❑1 Yes ❑0 No ❑8 Don't Know __ __ / __ __ / 20 __ __ **(1010) (1020) (1030)**
   - ➔ If **YES**, record the most recent date of use prior to randomization
   - ➔ If **YES**, complete Q1a – Q1d

1a. How many courses of antibiotics has your child had over the past 12 months? **(1040)** __ __ courses

1b. Indicate most recent type of antibiotic taken prior to randomization (refer to P7_BIOME_HX_CARD reference card) **(1050)** __ __ __ code

1bi. If **Other**, specify the name of the medication **(1050D)** _____

1c. Indicate number of milligrams per day used during the most recent use prior to randomization **(1060)** __ __ __ __ __ mg

1d. Indicate the number of days used during the most recent use prior to randomization **(1070)** __ __ days

Intranasal Steroids

2. Is the participant currently using nasal steroids? **(1080)** ❑1 Yes ❑0 No

COMMENTS: **(6000)**

_____

_____

_____

P7 BIOME HX

AsthmaNet

STICS COORDINATOR STUDY TREATMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

This questionnaire is to be completed at Visit 8 by the AsthmaNet coordinator who was primarily responsible for the participant's STICS visits. If a randomized participant terminates prior to the end of the study, this form should be completed at the time of the termination visit.

Yellow Inhaler Contents

1. Did the participant use the Yellow Zone inhaler? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, stop here and complete the source documentation box below.

2. Participants in the STICS study are randomized to receive either a low-dose inhaled corticosteroid or a high-dose inhaled corticosteroid used during Yellow Zones. Please check the box next to the treatment that you believe the participant received during the study. **(1010)**
   ❑$_1$ fluticasone 44 mcg/puff
   ❑$_2$ fluticasone 220 mcg/puff

3. How sure are you about your answer in Question 2? **(1020)**
   ❑$_1$ Absolutely sure – I know what the Inhaler contains
   ❑$_2$ Moderately sure
   ❑$_3$ Somewhat sure
   ❑$_4$ Not sure at all – purely guess

4. Please comment with respect to any observations you made that helped you make your choice in Question 2. **(1030D)**

_____

_____

_____

Coordinator Source Documentation
Coordinator's Initials: __ __ __ **(1040)**
Date: __ __ / __ __ / 20 __ __ **(1050)**
MM DD YYYY

AsthmaNet

STICS ELIGIBILITY CHECKLIST 1

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Informed Consent/Assent

1. Has the parent/legal guardian appropriately signed and dated the STICS Informed Consent? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, record the date the consent form was signed. **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)
   ➔ Consent should be reviewed and signed on the day Visit 1 is performed.

2. Has the participant provided informed assent? Check N/A if the participant is less than the local age of assent. **(1020)** ☐1 Yes ☐0 No ☐9 N/A

   2a. If ***YES***, record the date the assent was given. **(1030)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)
   ➔ Assent should be reviewed and signed or verbally given on the day Visit 1 is performed.

Study Medicines

3. Does the participant have an intolerance or allergy to fluticasone? **(1040)** ☐1 Yes ☐0 No ☐8 Don't know

4. Does the participant have an intolerance or allergy to oral corticosteroids (e.g. Decadron, Dexamethasone, Orapred, Prelone, Pediapred or prednisone)? **(1050)** ☐1 Yes ☐0 No ☐8 Don't know

5. Is the participant able to take albuterol (e.g. Proventil and Ventolin)? **(1060)** ☐1 Yes ☐0 No

Medical History Criteria

6. Is the participant 5 to 11 years old? **(1070)** ☐1 Yes ☐0 No

7. Was the participant born before 35 weeks gestation? **(1080)** ☐1 Yes ☐0 No

8. Does the parent report that the participant is up-to-date with immunizations? **(1090)** ☐1 Yes ☐0 No

9. Has the participant ever had chicken pox or received one dose of the chicken pox vaccine? (Refer to MOP for discussion on immunization records) **(1100)** ☐1 Yes ☐0 No

10. Is the participant receiving allergy shots? **(1110)** ☐1 Yes ☐0 No

    10a. If ***YES***, has the dose been changed in the past 3 months? **(1120)** ☐1 Yes ☐0 No

11. Has the participant used any medications known to significantly interact with corticosteroid disposition in the past 2 weeks (including but not limited to carbamazepine, erythromycin, phenobarbital, phenytoin, rifampin, and ketoconazole)? **(1130)** ☐1 Yes ☐0 No

12. Does the participant have a chronic or active lung disease other than asthma (cystic fibrosis, BPD, etc.)? **(1140)** ☐1 Yes ☐0 No

13. Does the participant have a significant medical illness other than asthma or concurrent medical problem that could require oral or injectable corticosteroids during the study (including by not limited to thyroid disease, diabetes mellitus, Cushing's disease, Addison's disease, and hepatic disease)? **(1150)** ☐1 Yes ☐0 No

14. Does the participant have a history of cataracts, glaucoma, or any other medical disorder associated with an adverse effect to corticosteroids? **(1160)** ☐1 Yes ☐0 No

15. Does the participant have significant developmental delay/failure to thrive (defined as below the 2nd percentile)? **(1170)** ☐1 Yes ☐0 No

16. Does the participant have a significant medical illness other than asthma (refer to P7_EXCLMED)? **(1180)** ☐1 Yes ☐0 No

Medication History

17. During the past 12 months, how many oral/systemic corticosteroid courses has the participant had? **(1190)** __ __ courses

17a. Is Q17 ≥ 1? **(1200)** ☐1 Yes ☐0 No

17b. Is Q17 ≥ 6? **(1210)** ☐1 Yes ☐0 No

18. Has the participant used an oral/systemic corticosteroid for any reason in the past 2 weeks? **(1220)** ☐1 Yes ☐0 No

19. Is the participant currently taking any medications listed on the Exclusionary Drugs for STICS (P7_EXCLDRUG) reference card? **(1225)** ☐1 Yes ☐0 No

19a. If ***Yes***, list: **(1225D)** _____

Other Criteria

20. If this participant was re-enrolled due to an asthma exacerbation during the Run-In, has it been at least 4 weeks since the exacerbation was resolved? **(1230)** ☐1 Yes ☐0 No ☐9 N/A

21. During the past 12 months, how many times has the participant been hospitalized for asthma (hospitalization lasting > 24 hours)? **(1240)** __ __ times

    21a. Is Q21 ≥ 2? **(1250)** ❑1 Yes ❑0 No

22. Has the participant ever had a near-fatal asthma exacerbation requiring intubation, mechanical ventilation, or resulting in a hypoxic seizure? **(1260)** ❑1 Yes ❑0 No

23. Currently, or within the past month, has the participant been involved in another therapeutic drug trial? **(1270)** ❑1 Yes ❑0 No

24. Does the participant's family have plans to move out of the area before the end of the study? **(1280)** ❑1 Yes ❑0 No

25. Is there any other reason for which this participant should not be included in this study? **(1290)** ❑1 Yes ❑0 No

    If ***YES***, describe **(1290D)** _____

    _____

26. Is the participant eligible? **(1300)** ❑1 Yes ❑0 No

    If any of the shaded boxes is selected, the participant is ineligible.
    ➔ ***If NO, STOP HERE***.

27. During the past 4 weeks, has the participant been treated with a controller therapy? **(1310)** ❑1 Yes ❑0 No
    *(If the participant has not been on a controller therapy for at least 4 weeks prior to Visit 1, answer **NO**.)*
    ➔ If ***NO***, skip to Q30.

    27a. If ***YES***, which controller therapies was the participant taking during the last 4 weeks?
    CHECK ONLY THOSE THAT APPLY.

Medication			Taking?	If ***YES***, number of puffs/nebs/ inhalations per day	Low Dose (Step 2 Controller Therapy)	Medium Dose (Step 3 Controller Therapy)
Advair (fluticasone-salmeterol)	DPI: 100/50 mcg/inh DPI: 250/50 mcg/inh DPI: 500/50 mcg/inh	**(1320 - 1330)**	❑1 Yes	_ _ inhs/day	None	1-2 inh 1 inh None
Advair (fluticasone-salmeterol)	HFA: 45/21 mcg/inh HFA: 115/21 mcg/inh HFA: 230/21 mcg/inh	**(1340 - 1350)**	❑1 Yes	_ _ inhs/day	None	1-4 inh 1-2 inh 1 inh

Medication			Taking?	If ***YES***, number of puffs/nebs/ inhalations per day	Low Dose (Step 2 Controller Therapy)	Medium Dose (Step 3 Controller Therapy)
Symbicort (budesonide-fomoterol)	80/4.5 mcg/inh 160/4.5 mcg/inh	**(1360 - 1370)**	❑1 Yes	_ _ inhs/day	None	1-4 inh 1-2 inh
Dulera (mometasone-formoterol)	100/5 mcg/inh 200/5 mcg/inh	**(1380 - 1390)**	❑1 Yes	_ _ inhs/day	None	1-2 inh 1 inh
Beclomethasone	HFA: 40 mcg/puff	**(1400 - 1410)**	❑1 Yes	_ _ puffs/day	1-4 puffs	5-8 puffs
Beclomethasone	HFA: 80 mcg/puff	**(1420 - 1430)**	❑1 Yes	_ _ puffs/day	1-2 puffs	3-4 puffs
Budesonide	Nebulizer 0.25mg suspension	**(1440 - 1450)**	❑1 Yes	_ _ nebs/day	1-2 nebs	3-4 nebs
Budesonide	Nebulizer 0.5mg suspension	**(1460 - 1470)**	❑1 Yes	_ _ nebs/day	1 neb	2 nebs
Budesonide	Nebulizer 1mg suspension	**(1480 - 1490)**	❑1 Yes	_ _ nebs/day	None	1 neb
Budesonide	Flexhaler: 90 mcg/inh	**(1500 - 1510)**	❑1 Yes	_ _ inhs/day	1-4 inh	5-8 inh
Budesonide	Flexhaler: 180 mcg/inh	**(1520 - 1530)**	❑1 Yes	_ _ inhs/day	1-2 inh	3-4 inh
Ciclesonide	HFA: 80 mcg/puff	**(1540 - 1550)**	❑1 Yes	_ _ puffs/day	1-2 puffs	3-4 puffs
Ciclesonide	HFA: 160 mcg/puff	**(1560 - 1570)**	❑1 Yes	_ _ puffs/day	1 puff	2 puffs
Flunisolide	HFA: 80 mcg/puff	**(1580 - 1590)**	❑1 Yes	_ _ puffs/day	1-3 puffs	4-6 puffs
Fluticasone	HFA: 44 mcg/puff	**(1600 - 1610)**	❑1 Yes	_ _ puffs/day	1-4 puffs	5-8 puffs
Fluticasone	HFA: 110 mcg/puff	**(1620 - 1630)**	❑1 Yes	_ _ puffs/day	1 puff	2-3 puffs

Medication			Taking?	If ***YES***, number of puffs/nebs/ inhalations per day	Low Dose (Step 2 Controller Therapy)	Medium Dose (Step 3 Controller Therapy)
Fluticasone	HFA: 220 mcg/puff	**(1640 - 1650)**	❑1 Yes	_ _ puffs/day	None	1 puff
Fluticasone	DPI: 50 mcg/inh	**(1660 - 1670)**	❑1 Yes	_ _ inhs/day	1-4 inh	5-8 inh
Fluticasone	DPI: 100 mcg/inh	**(1680 - 1690)**	❑1 Yes	_ _ inhs/day	1-2 inh	3-4 inh
Fluticasone	DPI: 250 mcg/inh	**(1700 - 1710)**	❑1 Yes	_ _ inhs/day	None	1 inh
Mometasone	DPI: 110 mcg/inh	**(1720 - 1730)**	❑1 Yes	_ _ inhs/day	1 inh	2-4 inh
Mometasone	DPI: 220 mcg/inh	**(1740 - 1750)**	❑1 Yes	_ _ inhs/day	None	1-2 inh
Singulair	4 or 5 mg/tablet	**(1760 - 1770)**	❑1 Yes	_ _ tablets/ day	1-2 tablets	1 tablet + Step 2 ICS therapy
Singulair	4 mg/packet	**(1780 - 1790)**	❑1 Yes	_ _ packet/ day	1-2 packets	1 packet + Step 2 ICS therapy
Triamcinolone	MDI: 75 mcg/puff	**(1800 - 1810)**	❑1 Yes	_ _ puffs/day	1-8 puffs	9-12 puffs

28. Are any of the doses greater than the medium dose? **(1820)** ❑1 Yes ❑0 No
    ➔ If ***YES***, STOP HERE. The participant is ineligible for STICS.

29. What is the participant's current dose? **(1830)** ❑1 Step 2 Controller Therapy ❑2 Step 3 Controller Therapy
    ➔ If **Step 2 Controller Therapy**, Skip to Q36.
    ➔ If **Step 3 Controller Therapy,** Skip to Q33.

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

Naïve to Controller Therapy

30. On average over the past 4 weeks, how many days per week did the participant have asthma symptoms or use albuterol (excluding pre-medication prior to exercise) **(1840)** __ days

    30a. Is Q30 > 2? **(1850)** ❑1 Yes ❑0 No

31. How many nights in the past 4 weeks did the participant have nighttime awakenings due to asthma? **(1860)** __ __ nights

31a. Is Q31 > 2? **(1870)** ❑1 Yes ❑0 No

32. Is the response to Q30a or Q31a ***YES***? **(1880)** ❑1 Yes ❑0 No
➔ Skip to Q36.

Step 3 Controller Therapy

Clinic Use Only

33. What is the participant's Visit 1 C-ACT score? __ __ score

33a. Is Q33 > 19? **(1890)** ❑1 Yes ❑0 No

34. How many asthma exacerbations requiring oral or systemic corticosteroids has the participant had in past 6 months? **(1900)** __ __ exacerbations

34a. Is Q34 <= 2? **(1910)** ❑1 Yes ❑0 No

Clinic Use Only

35. What is the participant's Visit 1 pre-bronchodilator FEV_1 % predicted? __ __ %

35a. Is Q35 >= 80%? **(1920)** ❑1 Yes ❑0 No

➔ If **YES**, the participant is eligible but current controller therapy must be stepped down. See MOP for further details.

36. Is the participant eligible? **(1930)** ❑1 Yes ❑0 No

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

➔ **If *NO, STOP HERE*.**

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

STICS ELIGIBILITY CHECKLIST 2

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Pregnancy

1. Is the participant potentially able to bear children? (If the participant is Male, check N/A and go to Q2.) **(1000)** ❑1 Yes ❑0 No ❑9 N/A

   1a. If ***YES***, is the participant currently pregnant or lactating? **(1010)** ❑1 Yes ❑0 No

   1b. If ***YES***, does the participant agree to use one of the approved methods indicated on the Birth Control Methods reference card (BIRTH_CTRL) for the duration of the study? **(1020)** ❑1 Yes ❑0 No

Spirometry

2. Is the participant able to perform reproducible spirometry according to ATS criteria? **(1030)** ❑1 Yes ❑0 No

3. Is the participant's pre-bronchodilator FEV_1 >= 60% of predicted? **(1040)** ❑1 Yes ❑0 No

Spirotel®/MDI Technique

4. Is the parent able to use the spirotel® e-diary correctly as evidenced by achieving a score of 9 on the STICS spirotel® Performance Checklist (P7_SPIROTEL_PERF)? **(1050)** ❑1 Yes ❑0 No

5. Is the participant able to use a metered dose inhaler properly, as evidenced by achieving a score of 12 on the MDI Inhalation Technique Checklist With Spacer (TECH_MDI_SP)? **(1060)** ❑1 Yes ❑0 No

6. Is there any other reason for which this participant should not be included in this study? **(1070)** ❑1 Yes ❑0 No
   If ***YES***, describe **(1070D)** _____

   _____

7. Is the participant eligible? **(1080)** ❑1 Yes ❑0 No
   If any of the shaded boxes is selected, the participant is ineligible.

   ➔ **If *NO, STOP HERE*.**

COMMENTS: (6000)

_____

P7 ELIG2

AsthmaNet

STICS ELIGIBILITY CHECKLIST 3

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

1. Since Visit 1, did the participant have any exacerbations requiring systemic corticosteroids? **(1000)** ☐1 Yes ☐0 No
   ➔ If **YES**, the participant is ineligible.

   1a. If **YES**, was the participant hospitalized? **(1010)** ☐1 Yes ☐0 No
   ➔ If **YES**, complete the SERIOUS form.
   ➔ Skip to Q8.

2. Since Visit 1, did the participant take any medication for asthma other than study medications? **(1020)** ☐1 Yes ☐0 No

3. Did the participant complete at least 75% of scheduled PM sessions? **(1030)** ☐1 Yes ☐0 No
   ➔ Use Q1c from the spirotel® Participant Compliance Report (P7_COMPLY) to answer this question.

4. Did the participant take at least 75% of the required puffs from his or her green inhaler? **(1040)** ☐1 Yes ☐0 No
   ➔ Use Q2d from the spirotel® Participant Compliance Report (P7_COMPLY) to answer this question.

Clinic Use Only

5. C-ACT score at visit 2 __ __ score

   5a. Is the Visit 2 C-ACT score <20? **(1050)** ☐1 Yes ☐0 No

6. Is the participant's pre-bronchodilator $FEV_1 \geq 80\%$ of predicted at Visit 2? **(1060)** ☐1 Yes ☐0 No

7. Is there any other reason for which this participant should not be included in this study? **(1070)** ☐1 Yes ☐0 No
   7a. If ***YES***, describe: **(1070D)** _____

   _____

8. Is the participant eligible? **(1080)** ☐1 Yes ☐0 No

   If any of the shaded boxes is selected, the participant is ineligible.
   ➔ **If *NO, STOP HERE*.**

COMMENTS: **(6000)**

_____

_____

* P 7 E L I G 3 *

AsthmaNet	STICS LABORATORY RESULTS	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

If unable to collect blood at Visit 2, samples can be collected at a later visit. Only collect samples once.

BLOOD TESTS and SPECIMEN COLLECTIONS (VISIT 2 – 8)

1. Were you able to collect a blood sample from the participant today? **(1000)** ❑1 Yes ❑0 No
   ➔ If **NO and Visit 2**, skip to Q6.

Local Laboratory Results

2. Total WBC **(1010)** __ __ __ __ __ /cu.mm

3. Eosinophils **(1020)** __ __ . __ %

External Laboratory Samples

4. Were you able to collect a sample for allergen-specific IgE and total IgE? **(1030)** ❑1 Yes ❑0 No

5. Were you able to collect a sample for genetic analysis? **(1040)** ❑1 Yes ❑0 No

   ➔ If Visit 3-8, **STOP HERE.**

NASAL SAMPLING (VISIT 2 ONLY)

6. Were you able to collect a nasal sample from the participant today? **(1050)** ❑1 Yes ❑0 No

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

STICS MICROBIAL EXPOSURE QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

To the Parent/Guardian: The purpose of this questionnaire is to collect information on exposures that may affect the microbiome, or microscopic environment, of your child's lungs. When answering these questions, "you" is referring to your child who is the study participant.

GENERAL HOUSE CHARACTERISTICS

('House' is meant to refer to the place where you live most of the time.)

1. What type of dwelling do you live in?

(1000)
- ❑$_1$ Detached house
- ❑$_2$ Attached house (e.g., row home/townhouse)
- ❑$_3$ Lower apartment/condo (1st-2nd floor)
- ❑$_4$ Higher apartment/condo (3rd+ floors)
- ❑$_5$ Mobile home/trailer
- ❑$_6$ Other (specify) (e.g., dorm room, hotel)

(1000D) _____

2. Do you live within a mile of a:

2a. Port **(1010)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A

2b. Farm **(1020)** ❑$_1$ Yes ❑$_0$ No

2c. Power plant **(1030)** ❑$_1$ Yes ❑$_0$ No

2d. Major highway **(1040)** ❑$_1$ Yes ❑$_0$ No

2e. Other source of airborne particulate matter (e.g., factory, airport, industrial plant, etc.) **(1050)** ❑$_1$ Yes ❑$_0$ No

2ei. If ***YES***, please specify source **(1050D)** _____

3. What is the main heating source in your house?

(1060)
- ❑1 Radiators (steam or hot water)
- ❑2 Forced air or central heating (vents)
- ❑3 Electric baseboard heating
- ❑4 Kerosene space heater
- ❑5 Open stove or oven
- ❑6 Natural gas fireplace
- ❑7 Other (specify)

(1060D) _____

4. In the past 3 months, did you use a wood burning fireplace or a wood burning stove in your house? **(1070)** ❑1 Yes ❑0 No ❑8 Don't Know

   4a. If ***YES***, on average, how many days per month did you use the wood burning fireplace or wood burning stove in your house during the past 3 months? **(1080)** __ __ days per month

5. Do you have a gas stove, gas range, gas oven, or gas fireplace in your house? **(1090)** ❑1 Yes ❑0 No ❑8 Don't Know

6. Of the area around your home, about 100 yards in each direction, what proportion is "natural" (e.g., grass, dirt, shrubs and trees, garden, etc.)? **(1100)**
- ❑1 Less than 25%
- ❑2 25-50%
- ❑3 51-75%
- ❑4 More than 75%

7. On average, how much time per week do you spend in a yard? **(1130)** __ __ hours per week

8. Does the home you live in have a yard? **(1110)** ❑1 Yes ❑0 No

   8a. If ***YES***, what proportion of the yard is "natural" (e.g., grass, dirt, shrubs and trees, garden, etc.)? **(1120)**
- ❑1 Less than 25%
- ❑2 25-50%
- ❑3 51-75%
- ❑4 More than 75%

9. Do you garden at home? **(1140)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q10.

   9a. On average, how many hours per week do you spend gardening in the...?

      9ai. Spring **(1150)** __ __ hours per week

      9aii. Summer **(1160)** __ __ hours per week

9aiii. Fall **(1170)** __ __ hours per week

9aiv. Winter **(1180)** __ __ hours per week

9b. On average, how many hours per week have you gardened in the past month? **(1190)** __ __ hours per week

CHILDREN

('Children' defined as less than 18 years old.)

10. During the past 3 months, have children spent an average of more than 2 hours a day in your household? **(1200)** ❑1 Yes ❑0 No

➔ If ***NO***, skip to Q11.

10a. How many children spend time in your household? **(1210)** __ __ children

10b. How many children spend time in your household that are not "potty-trained"? **(1220)** __ __ children

ANIMAL EXPOSURE

11. Do you currently live on a farm? **(1230)** ❑1 Yes ❑0 No

12. Do you work on a farm? **(1240)** ❑1 Yes ❑0 No

➔ If ***NO***, skip to Q13.

12a. On average, how many months per year do you work on a farm? **(1250)** __ __ months per year

12b. On average, how many hours per week do you work on a farm during those months? **(1260)** __ __ hours per week

12c. On average, how many hours per week have you worked on a farm in the past month? **(1270)** __ __ hours per week

13. Do you visit a farm frequently (at least 2 days per week)? **(1280)** ❑1 Yes ❑0 No

14. Do you have frequent contact (at least 2 days per week) with farm animals (e.g., hoofed livestock or poultry)? **(1290)** ❑1 Yes ❑0 No

15. Have you been around animals outside your home at least 2 days per week in the past 3 months? **(1300)** ❑1 Yes ❑0 No

15a. If ***YES***, have you been around animals at a…?

15ai. Zoo **(1310)** ❑1 Yes ❑0 No

15aii. Farm **(1320)** ❑1 Yes ❑0 No

15aiii. Park **(1330)** ❑1 Yes ❑0 No

15aiv. Other location outside your home **(1340)** ❑1 Yes ❑0 No

(1340D) _____

TOBACCO EXPOSURE

16. Are you frequently exposed (2 or more days per week) to tobacco smoke outside of your home, such as in restaurants, other homes, workplace, or other locations? **(1350)** ❑1 Yes ❑0 No

Participant/Guardian Source Documentation

Participant/Guardian Initials: __ __ __ **(1360)**

Date: __ __ / __ __ / 20 __ __ **(1370)**
MM DD YYYY

Coordinator Completed

COMMENTS

(6000):_____

_____

_____

AsthmaNet

STICS PARTICIPANT STUDY TREATMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Legal Guardian Completed)

This questionnaire is to be completed by the parent/guardian at Visit 8. If a randomized participant terminates prior to the end of the study, please ask the parent/guardian to complete this form during the termination visit.

1. Who is the respondent?

(1000) ❑1 Parent/Guardian
❑2 Other (specify)

(1000D) _____

2. Did your child use the Yellow Zone inhaler?
   ➔ If ***NO***, stop here and complete the source documentation box below.

(1010) ❑1 Yes ❑0 No

Yellow Inhaler Contents

3. As a STICS study participant, your child was randomized to receive either a low-dose inhaled corticosteroid or a high-dose inhaled corticosteroid used during Yellow Zones. Please check the box next to the treatment that you believe you received **during the study.**

(1020) ❑1 fluticasone 44 mcg/puff
❑2 fluticasone 220 mcg/puff

4. How sure are you about your answer to Question 3?

(1030) ❑1 Absolutely sure – I know what the Inhaler contains
❑2 Moderately sure
❑3 Somewhat sure
❑4 Not sure at all – purely a guess

5. Please comment with respect to any observations you made that helped you make your choice in Question 3 (for example: **taste, smell, or physical sensations** related to your Yellow Inhaler).

(1040) ❑1 I have no comments
❑2 I noticed the following: *(Describe below)*

(1040D) _____
_____
_____
_____

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __ **(1050)**
Date: __ __ / __ __ / 20 __ __ **(1060)**
MM DD YYYY

AsthmaNet

PHONE SYMPTOM ASSESSMENT

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Guardian Interview Completed)

Contact Attempt	***Coordinator ID***	***Date***	***Time***	***Contact Occurred?***
1	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
2	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
3	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No
4	__ __ __ __	__ __ / __ __ / __ __ __ __	__ __ : __ __ AM ❑ PM ❑	❑ Yes ❑ No

1. Since the last visit or phone contact, has your child been to a doctor for breathing problems? **(1000)** ❑$_1$ Yes ❑$_0$ No
   1a. If ***YES***, how many times? **(1010)** __ __ times

2. Since the last visit or phone contact, has your child been to an ER/urgent care facility for breathing problems? **(1020)** ❑$_1$ Yes ❑$_0$ No
   2a. If ***YES***, how many times? **(1030)** __ __ times

3. Since the last visit or phone contact, has your child been hospitalized for breathing problems? **(1040)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, assess whether the participant is a treatment failure and complete the SERIOUS form, if needed.

4. During the past 2 weeks, did your child have wheezing or cough? **(1050)** ❑$_1$ Yes ❑$_0$ No
   4a. If ***YES***, how many days? **(1060)** __ __ days

5. During the past 2 weeks, did your child awaken from sleep due to asthma symptoms requiring albuterol? **(1070)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, skip to Q6.
   5a. If ***YES***, how many nights? **(1080)** __ __ nights
   5b. If ***YES***, was the Yellow Zone started? **(1090)** ❑$_1$ Yes ❑$_0$ No
   5c. If ***YES***, is Q5a > 1? **(1100)** ❑$_1$ Yes ❑$_0$ No
   5ci. If ***YES***, was there at least 2 consecutive nights? **(1110)** ❑$_1$ Yes ❑$_0$ No

5cii. Was prednisone started? **(1120)** ❑1 Yes ❑0 No
➔ If ***YES***, complete the Prednisone Medication (P7_PRED) form.

6. During the past 2 weeks, did your child take any albuterol (excluding pre-exercise)? **(1130)** ❑1 Yes ❑0 No

6a. If ***YES***, how many days? **(1140)** __ __ days

7. Have you been completing the spirotel® Diary daily? **(1150)** ❑1 Yes ❑0 No
➔ If **NO**, please review adherence with parent.

8. Has your child been using the GREEN inhaler every morning and evening (except when using the YELLOW inhaler)? **(1160)** ❑1 Yes ❑0 No

8a. If ***YES***, how many puffs are taken in the AM? **(1170)** __ puffs

8b. If ***YES***, how many puffs are taken in the PM? **(1180)** __ puffs

➔ Please review adherence with parent, if necessary.

9. Has your child had any Yellow Zones (during which your child used the YELLOW inhaler)? **(1190)** ❑1 Yes ❑0 No

9a. If ***YES***, how many Yellow Zones did your child have? **(1200)** __ zones
➔ Check for treatment failure.

10. Since the last visit or phone contact, has your child used prednisone? **(1210)** ❑1 Yes ❑0 No
➔ If ***YES***, complete the Prednisone Medication (P7_PRED) form.

10a. If ***YES***, how many courses (1 course = 4 days) of prednisone were used? **(1220)** __ courses
➔ Check for treatment failure.

COMMENTS: **(6000)**

AsthmaNet

STICS PREDNISONE MEDICATION

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form each time a STICS participant receives oral/systemic corticosteroids for treatment of asthma.

Prednisone Checklist

1. Administer prednisone at 2 mg/kg per day for 2 days (maximum 60 mg) followed by 1 mg/kg per day for 2 days (maximum 30 mg).

   1a. Start date of prednisone **(1000)** __ __ / __ __ / 20 __ __
   MM DD YYYY

   ➔ **Record prednisone course on the CMED form**

2. Why was the prednisone course prescribed? The STICS protocol specifications are to prescribe oral steroids if: **(1010)**

   - ❑1 >3 albuterol nebulizer treatments or 6 puffs albuterol in past 4 hours for asthma
   - ❑2 12 or more puffs of albuterol in past 24 hours for asthma
   - ❑3 Nighttime awakenings requiring albuterol due to cough, shortness of breath, chest tightness, or wheezing on 2 of the last 3 nights
   - ❑4 8 or more puffs of albuterol per day on 2 of the last 3 days for asthma
   - ❑5 Physician discretion **(If Physician discretion, please explain in the comments section below)**
   - ❑6 Other (specify)

   (1010D) _____

3. Is this the second prednisone course for treatment of asthma within 6 months since randomization? **(1020)** ❑1 Yes ❑0 No
   ➔ **If *YES*, the participant is a treatment failure. Complete the P7_TRTFAIL form.**

4. Is this the third prednisone course for treatment of asthma within 12 months since randomization? **(1030)** ❑$_1$ Yes ❑$_0$ No
   ➔ **If *YES*, the participant is a treatment failure. Complete the P7_TRTFAIL form.**

5. Instruct the parents to call if the child's condition worsens.

6. A Red Zone phone call should be made to the parents 5 days (+-2 day window) after initiation of prednisone to reassess the participant's symptoms. Complete the Red Zone Phone Assessment Form (P7_RED_PC)

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

STICS PULMONARY PROCEDURE CHECKLIST

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Parent/Guardian Interview Completed)

Complete this form at all visits where baseline spirometry is required. If any medications other than study or rescue albuterol were used, record the medication(s) on the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

1.	Have you consumed caffeine in the past **4** hours? **Examples:** Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull, 5-hour ENERGY	**(1000)**	☐ 1 Yes	☐ 0 No
2.	Have you used medications with caffeine in the past **4** hours? **Examples:** Anacin, Darvon compound, Esgic, Excedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin	**(1010)**	☐ 1 Yes	☐ 0 No
3.	Have you used any weight loss medications in the past **4** hours? **Examples:** Belviq, bitter orange, Xenadrine, EFX, Thermorexin, Qsymia	**(1020)**	☐ 1 Yes	☐ 0 No
4.	Have you consumed any food containing alcohol or beverages containing alcohol in the past **4** hours?	**(1030)**	☐ 1 Yes	☐ 0 No
5.	Have you used a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? **Examples:** albuterol (Proventil), study RESCUE (ProAir®)	**(1040)**	☐ 1 Yes	☐ 0 No
6.	***(Visit 1 only)*** Have you used a short-acting anticholinergic in the past **6** hours? **Examples:** ipratropium (Atrovent, Combivent)	**(1050)**	☐ 1 Yes	☐ 0 No
7.	Have you used any ophthalmic antihistamines in the past **6** hours? **Examples:** Alaway, Elestat, Emadine, Optivar, Pataday, Patanol, Zaditor	**(1060)**	☐ 1 Yes	☐ 0 No
8.	Have you used any nasal antihistamines in the past **6** hours? **Examples:** Astelin, Astepro, Livostin, Patanase	**(1070)**	☐ 1 Yes	☐ 0 No
9.	Have you used any nasal decongestants in the past **6** hours? **Examples:** oxymetazoline (Afrin)	**(1080)**	☐ 1 Yes	☐ 0 No
10.	Have you used any oral antihistamines in the past **48** hours? **Examples:** Allegra, Benadryl, Chlor-Trimeton, Clarinex, Claritin, Tylenol PM	**(1090)**	☐ 1 Yes	☐ 0 No

11. Have you used any oral decongestants or cold remedies in the past **48** hours? **(1100)** ☐1 Yes ☐0 No
Examples: pseudoephedrine (Sudafed), Tylenol Allergy

12. Have you used any smokeless tobacco products today? **(1110)** ☐1 Yes ☐0 No
Examples: chewing tobacco, snuff

13. At this time, is your asthma worse because of recent exposure to triggers? **(1120)** ☐1 Yes ☐0 No
Examples: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection

14. Is there any other reason you should not proceed with spirometry testing? **(1130)** ☐1 Yes ☐0 No

If ***YES,*** explain: **(1130D)** _____

_____

15. Is the participant eligible to proceed with the spirometry testing? **(1140)** ☐1 Yes ☐0 No

If any of the shaded boxes is selected, the participant is ineligible for spirometry, exhaled nitric oxide and IOS testing.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

RED ZONE PHONE ASSESSMENT

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Guardian Interview Completed)

1. ***(Coordinator Completed)*** Record related Concomitant Medication Number **(1000)** __ __

2. Is the participant still having asthma symptoms? **(1010)** ❑1 Yes ❑0 No
   ➔ If **NO**, Skip to Q3.

   2a. Has the participant used more than 3 nebulizer treatments with albuterol or 6 puffs of albuterol (3 treatments of 2 puffs each) in 4 hours for relief of asthma symptoms? **(1020)** ❑1 Yes ❑0 No

   2b. Has the participant used 12 or more puffs of albuterol in 24 hours for relief of asthma symptoms? **(1030)** ❑1 Yes ❑0 No

   2c. Has the participant had nighttime awakenings on 2 out of 3 consecutive nights due to cough, shortness of breath, chest tightness, or wheezing and used albuterol? **(1040)** ❑1 Yes ❑0 No

   2d. Has the participant used 8 or more puffs of albuterol per day on 2 out of 3 consecutive days for relief of asthma symptoms? **(1050)** ❑1 Yes ❑0 No

   ➔ **If 2a, 2b, 2c, or 2d is** '***Yes***', the study physician should be consulted. Additional treatment, a follow-up phone call or a visit may be required.

3. Have you been completing the spirotel® Diary daily? **(1060)** ❑1 Yes ❑0 No
   ➔ If **NO**, please review adherence with the parent.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

STICS TERMINATION OF STUDY PARTICIPATION

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 1.

1. Is the participant a Run-In failure? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ ***If No, skip to Q2***

   1a. Indicate the **primary** reason the participant was a Run-In failure.

   - ❑$_1$ inability to demonstrate adherence with spirotel® **(1010)**
   - ❑$_2$ inability to demonstrate adherence with study medications
   - ❑$_3$ too few asthma symptoms during Run-In
   - ❑$_4$ too many asthma symptoms during Run-In
   - ❑$_5$ asthma exacerbation during Run-In
   - ❑$_6$ participant required an asthma medication other than study medications since Visit 1
   - ❑$_7$ parent withdrew consent
   - ❑$_8$ participant lost to follow up
   - ❑$_9$ participant experienced a serious adverse event*
   - ❑$_{10}$ physician initiated termination of study participation**
   - ❑$_{11}$ other**

*** Please complete the Serious Adverse Event Reporting (SERIOUS) form.**
****Additional explanation required: (1010D)**

_____

_____

_____

   ➔ ***Skip to SIGNATURES section.***

2. Has the participant completed the study through Visit 8? **(1020)** ❑$_1$ Yes ❑$_0$ No
   ➔ ***If YES, skip to SIGNATURES section.***

3. Who initiated termination of the participant? **(1030)** ❑$_1$ Parent/Guardian ❑$_2$ Clinical Staff

   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***

   ➔ ***If Clinical Staff, skip to Q5.***

4. Indicate the **primary** reason the participant has withdrawn from the study.

- ❑1 no longer interested in participating* **(1040)**
- ❑2 no longer willing to follow protocol*
- ❑3 difficult access to clinic (location, transportation, parking)
- ❑4 unable to make visits during clinic hours
- ❑5 moving out of the area
- ❑6 unable to continue due to personal constraints*
- ❑7 unable to continue due to medical condition unrelated to asthma*
- ❑8 side effects of study medications*
- ❑9 dissatisfied with asthma control
- ❑10 other*

***Additional explanation required: (1040D)**

_____

_____

➔ ***Skip to SIGNATURES section.***

5. Indicate the **primary** reason the participant was terminated by clinical staff.

- ❑1 pregnancy **(1050)**
- ❑2 lost to follow up
- ❑3 an asthma-related adverse event
- ❑4 a medication-related adverse event
- ❑5 an adverse event not related to asthma or medications
- ❑6 treatment failure
- ❑7 other reason*

***Additional explanation required: (1050D)**

_____

_____

SIGNATURES
Please complete the following section regardless of the reason for termination of study participation.

I verify that all information collected on the AsthmaNet STICS data collection forms for this participant is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the study protocol.

_____ **(1060)** __ __ / __ __ / 20 __ __ **(1070)**
Coordinator Signature MM DD YYYY

_____ **(1080)** __ __ / __ __ / 20 __ __ **(1090)**
Principal Investigator Signature MM DD YYYY

AsthmaNet

STICS TREATMENT FAILURE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Yellow Zone Follow Up

1. Since the last visit or phone contact, did the spirotel device or action plan alert you to start a yellow zone? **(990)** ❑1 Yes ❑0 No
   ➔ If **NO**, skip to Q3.

2. If Yes, did you start it when alerted? **(995)** ❑1 Yes ❑0 No

   2a. If No, what was the reason that you didn't start it? **(995D)**

   _____

   _____

   _____

(Coordinator Completed)

Treatment Failure Assessment

3. Has the participant experienced 6 yellow zone courses since randomization? **(1000)** ❑1 Yes ❑0 No

4. Has the participant required 2 courses of prednisone for treatment of asthma within 6 months since randomization? **(1010)** ❑1 Yes ❑0 No

5. Has the participant required 3 courses of prednisone for treatment of asthma within 12 months since randomization? **(1020)** ❑1 Yes ❑0 No

6. Has the participant been hospitalized for more than 24 hours due to an asthma exacerbation? **(1030)** ❑1 Yes ❑0 No

7. Is the participant a treatment failure? If any of the shaded boxes is selected, the participant is a treatment failure. **(1040)** ❑1 Yes ❑0 No

   ➔ **If NO, continue with remaining visit procedures.**
   ➔ **If YES, record the treatment failure date. Complete the STICS Termination of Study Participation (P7_TERM) form, STICS Study Treatment Questionnaire (P7_CC_TXQX, P7_PART_TXQX) forms, and collect study medications and supplies as soon as possible.**

8. Date treatment failure occurred. **(1050)** __ __ / __ __ / 20 __ __
   MM DD YYYY

P7 TRTFAIL

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

YELLOW ZONE PHONE ASSESSMENT

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Guardian Interview Completed)

Update the STICS Prednisone and Yellow Zone Tracking (P7_TRK) form and complete a Treatment Failure (P7_TRTFAIL) form, if necessary.

1. When was the Yellow Zone started? **(1000)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Did you start the Yellow Zone in the morning or the evening? **(1010)** ❑1 AM ❑2 PM

3. Why was the Yellow Zone started? **(1020)**
   - ❑1 Albuterol given two times (4 puffs) in 6 hours
   - ❑2 Albuterol given three times (6 puffs) in 24 hours
   - ❑3 A nighttime awakening with albuterol use
   - ❑4 Other (please describe)

   (1020D) _____

   _____

4. Is the participant still having asthma symptoms? **(1030)** ❑1 Yes ❑0 No
   ➔ If **NO**, Skip to Q5.

   4a. Has the participant used more than 3 nebulizer treatments with albuterol or 6 puffs of albuterol (3 treatments of 2 puffs each) in 4 hours for relief of asthma symptoms? **(1040)** ❑1 Yes ❑0 No

   4b. Has the participant used 12 or more puffs of albuterol in 24 hours for relief of asthma symptoms? **(1050)** ❑1 Yes ❑0 No

   4c. Has the participant had nighttime awakenings on 2 out of 3 consecutive nights due to cough, shortness of breath, chest tightness, or wheezing and used albuterol? **(1060)** ❑1 Yes ❑0 No

   4d. Has the participant used 8 or more puffs of albuterol per day on 2 out of 3 consecutive days for relief of asthma symptoms? **(1070)** ❑1 Yes ❑0 No

   ➔ **If 4a, 4b, 4c, or 4d is '*Yes*'**, the participant may meet criteria for starting prednisone. The study physician should be consulted.

   ➔ Parent should 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.

5. Have you been completing the spirotel® Diary daily? **(1080)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **NO**, please review adherence with the parent

6. Was a nasal sample collected? **(1090)** ❑$_1$ Yes ❑$_0$ No
   ➔ If **NO**, instruct the parent/guardian to collect a nasal sample immediately.

   6a. If ***YES***, date nasal sample was collected? **(1100)** __ __ / __ __ / 20 __ __
   MM DD YYYY

COMMENTS: **(6000)**

AsthmaNet

CLINICAL ADVERSE EVENTS

(Coordinator completed)

Part. ID: __ __ - __ __ __ - __ __ __

Part. Initials: __ __ __

Visit: __ __ __

Complete this log if the participant experienced any clinical adverse events (including intercurrent events) since the last visit. Check the "None" box if the participant has not experienced any clinical adverse events since the last visit.

❑0 None

* Please complete a Serious Adverse Event Reporting (SERIOUS) form. ** Please complete the appropriate Change in Medications form. *** Please complete the Concomitant Medications (CMED) form.		2. DATE STARTED (Top Line) **(1020)** 3. DATE STOPPED (Bottom Line) **(1030)**	4. ONGOING at current visit **(1040)**	5. TYPE **(1050)**	6. SEVERITY **(1060)**	7. SERIOUS **(1070)**	8. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG(S) **(1080)**	9. CHANGE IN STUDY DRUG(S) **(1090)**	10. OUTCOME (Skip if #3 is missing.) **(1100)**	11. TREATMENT REQUIRED **(1110)**	12. ONGOING at final visit **(1120)**
DESCRIPTION OF ADVERSE EVENT **(1000)**	1. ICD9 CODE **(1010)**	MONTH / DAY / YEAR		1 – INTERMITTENT 2 – CONTINUOUS	1 – MILD 2 – MODERATE 3 – SEVERE	1 – YES* 0 – NO	1 – NONE 2 – UNLIKELY (REMOTE) 3 – POSSIBLE 4 – PROBABLE	1 – UNCHANGED 2 – ALTERED**	1 – COMPLETELY RECOVERED 2 – RECOVERED, BUT WITH LASTING EFFECTS 3 – DEATH*	1 – NONE 2 – MEDICATION*** 3 – HOSPITALIZATION* 4 – OTHER	
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1
__ __	_ _ _ . _ _	_ _ / _ _ / 20 _ _ _ _ / _ _ / 20 _ _	❑1								❑1

AsthmaNet

PEDIATRIC ASTHMA AND ALLERGY HISTORY

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

ASTHMA HISTORY

1. Approximately how old was the participant when chest symptoms suggesting asthma first appeared? **(1000-1010)** __ __ years__ __ months

2. Has a doctor diagnosed the participant with asthma? **(1065)** ❑1 Yes ❑0 No
   2a. If ***YES***, how old was the participant when a doctor first diagnosed him/her with asthma? **(1070-1080)** __ __ years__ __ months

3. Have any of the participant's immediate blood relatives been told by a physician that they have asthma? *(Check the 'N/A' box if the participant does not have biological siblings or children.)*
   3a. Mother **(1090)** ❑1 Yes ❑0 No ❑8 Don't Know
   3b. Father **(1100)** ❑1 Yes ❑0 No ❑8 Don't Know
   3c. Brother(s) or Sister(s) **(1110)** ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A
   3d. Child(ren) **(1120)** ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A

ASTHMA SYMPTOMS

4. How do you categorize the participant's asthma symptoms throughout the course of the year? **(1130)** ❑1 Relatively the same all year ❑2 Vary by season(s)
   ➔ If 'Vary by season(s)', do the participant's asthma symptoms worsen during the…
   4a. Winter? **(1140)** ❑1 Yes ❑0 No
   4b. Spring? **(1150)** ❑1 Yes ❑0 No
   4c. Summer? **(1160)** ❑1 Yes ❑0 No
   4d. Fall? **(1170)** ❑1 Yes ❑0 No

5. In the last 12 months, how many... *(Enter '00' if none)*

5a. Asthma episodes has the participant had that required emergency care or an unscheduled office visit? **(1180)** __ __ episodes

5b. Overnight hospitalizations has the participant had due to asthma? **(1190)** __ __ hospitalizations

5c. Courses of systemic corticosteroid therapy (e.g., prednisone, IM, IV) for asthma has the participant taken? **(1200)** __ __ courses

5d. Days of work, school/daycare, or housework has the participant missed due to asthma? **(1210)** __ __ __ days
➔ If Q5d > 0, complete Q5di.

5di. In the past 3 months, how many days of work, school/daycare, or housework has the participant missed due to asthma? **(1220)** __ __ days

5e. Days of work, school, or housework has the participant's parent/guardian or another caretaker missed because of the participant's asthma symptoms? **(1230)** __ __ __ days
➔ If Q5e > 0, complete Q5ei.

5ei. In the past 3 months, how many days of work, school, or housework has the participant's parent/guardian or another caretaker missed due to asthma? **(1240)** __ __ days

6. Has the participant ever been admitted to an intensive care unit for asthma? **(1250)** ❑$_1$ Yes ❑$_0$ No
➔ If ***NO***, skip to Q7.

6a. How many times has the participant been admitted to an intensive care unit for asthma? **(1260)** __ __

6b. Has the participant ever had invasive mechanical ventilation? **(1270)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know

6c. Has the participant ever had non-invasive mechanical ventilation? **(1280)** ❑$_1$ Yes ❑$_0$ No ❑$_8$ Don't Know

ASTHMA TRIGGERS

7. Do any of the following currently provoke the participant's asthma?

7a.	Exercise/Sports/Play	(1290)	❑1 Yes	❑0 No	❑8 Don't Know
7b.	Menstrual cycle *(If participant is male or a pre-menarche female, leave blank.)*	(1300)	❑1 Yes	❑0 No	❑8 Don't Know
7c.	Aspirin or non-steroidal anti-inflammatory drugs (e.g., Aleve, Motrin)	(1310)	❑1 Yes	❑0 No	❑8 Don't Know
7d.	Respiratory infections (e.g., colds)	(1320)	❑1 Yes	❑0 No	❑8 Don't Know
7e.	Irritants (e.g., pollution, odors, perfumes, chemicals, household cleaners)	(1330)	❑1 Yes	❑0 No	❑8 Don't Know
7f.	Weather conditions (e.g., change in weather, humidity)	(1340)	❑1 Yes	❑0 No	❑8 Don't Know
7g.	Exposure to cold air	(1350)	❑1 Yes	❑0 No	❑8 Don't Know
7h.	Emotional factors (e.g., stress, laughing)	(1360)	❑1 Yes	❑0 No	❑8 Don't Know
7i.	Tobacco smoke	(1370)	❑1 Yes	❑0 No	❑8 Don't Know
7j.	Food additives/preservatives (e.g., MSG, sulfites)	(1380)	❑1 Yes	❑0 No	❑8 Don't Know
7k.	Allergies (e.g., dust, animals, pollens)	(1390)	❑1 Yes	❑0 No	❑8 Don't Know
7l.	Other	(1400)	❑1 Yes	❑0 No	
	If ***YES***, please specify	(1400D)	_____		

ALLERGIES

8. To which of the following did a doctor or other health practitioner say the participant was allergic?

8a.	Medicines	(1410)	❑1 Yes	❑0 No	❑8 Don't Know
	If ***YES***, please list:	(1410D)	_____		
			_____		

8b. Foods (1420) ❑1 Yes ❑0 No ❑8 Don't Know

If ***YES***, please list: (1420D) _____

_____

8c. Things the participant breathes in or is exposed to (e.g., dust, pollens, molds, animal fur, feathers, dander) (1430) ❑1 Yes ❑0 No ❑8 Don't Know

8d. Stinging insects such as bees or wasps (1440) ❑1 Yes ❑0 No ❑8 Don't Know

8e. Latex (1450) ❑1 Yes ❑0 No ❑8 Don't Know

8f. Other (1460) ❑1 Yes ❑0 No

If ***YES***, describe: (1460D) _____

_____

9. Has the participant ever had eczema / atopic dermatitis (i.e., prolonged itchy, scaly skin rash)? (1470) ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO*** or ***DON'T KNOW***, skip to Q10.

9a. At what age did the participant FIRST have eczema? (1480-1490) __ __ years__ __ months

9b. Was the eczema diagnosed by a doctor? (1500) ❑1 Yes ❑0 No

9c. During the past 12 months, how would you generally describe the participant's eczema? (1510)
➔ If ***NONE***, skip to Q10.
❑1 None
❑2 Mild
❑3 Moderate
❑4 Severe

9d. Which parts of the participant's body were ever affected by eczema in the past 12 months?

9di. Head (1520) ❑1 Yes ❑0 No

9dii. Arms/Hands (1530) ❑1 Yes ❑0 No

9diii. Trunk (mid-section or torso) (1540) ❑1 Yes ❑0 No

9div. Legs/Feet (1550) ❑1 Yes ❑0 No

9dv. Other **(1560)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1560D)** _____

10. Have any of the participant's immediate blood relatives been told by a physician that they have allergies/eczema/hay fever?
(Check the 'N/A' box if the participant does not have biological siblings or children.)

10a. Mother **(1570)** ❑1 Yes ❑0 No ❑8 Don't Know

10b. Father **(1580)** ❑1 Yes ❑0 No ❑8 Don't Know

10c. Brother(s) or Sister(s) **(1590)** ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A

10d. Child(ren) **(1600)** ❑1 Yes ❑0 No ❑8 Don't Know ❑9 N/A

SMOKING HISTORY

11. Did the participant's mother smoke while she was pregnant with the participant? **(1610)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO or DON'T KNOW***, skip to Q13.

12. During which part(s) of the pregnancy did the participant's mother smoke?

12a. First 3 months **(1620)** ❑1 Yes ❑0 No ❑8 Don't Know

12b. Middle 3 months **(1630)** ❑1 Yes ❑0 No ❑8 Don't Know

12c. Last 3 months **(1640)** ❑1 Yes ❑0 No ❑8 Don't Know

13. Between the time the participant was born and when he/she turned 5 years of age, or present if less than 5 years of age, were there any smokers in any household in which the participant spent time? (Include any households the participant regularly spent time in.) **(1650)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If ***NO or DON'T KNOW***, skip to Q14.

13a. Did the participant's mother (or stepmother or female guardian) smoke? **(1660)** ❑1 Yes ❑0 No ❑8 Don't Know

13b. Did the participant's father (or stepfather or male guardian) smoke? **(1670)** ❑1 Yes ❑0 No ❑8 Don't Know

13c. Were there any other smokers in the household? **(1680)** ❑1 Yes ❑0 No ❑8 Don't Know

14. At the present time, are there any smokers in any household in which the participant spends time? (Include any households the participant regularly spends time in.) **(1690)** ❑1 Yes ❑0 No ❑8 Don't Know

➔ If ***NO or DON'T KNOW***, ***STOP HERE***.

14a. Does the participant's mother (or stepmother or female guardian) smoke? **(1700)** ❑1 Yes ❑0 No ❑8 Don't Know

14b. Does the participant's father (or stepfather or male guardian) smoke? **(1710)** ❑1 Yes ❑0 No ❑8 Don't Know

14c. Are there any other smokers in the household? **(1720)** ❑1 Yes ❑0 No ❑8 Don't Know

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS

(Coordinator completed)

Part. ID: __ __ - __ __ __ - __ __ __

Part. Initials: __ __ __

Visit: __ __ __

Instructions: Since signing the informed consent or last study visit, list all prescription and over-the-counter (OTC) concomitant medications used to treat asthma/allergy symptoms and adverse events. Do not list routine use of study drugs or rescue medications. Check the "None" box if the participant has not started taking any medications since signing the informed consent or last study visit. If the medication is not related to an adverse or laboratory event, leave the event number missing and check the "N/A" box. If the participant is still taking the medication at the end of the current visit, check the "ongoing at current visit" check box and leave the stop date missing. All ongoing medications should be reviewed at subsequent visits to document the stop date of a medication. At the last study visit or an early termination visit, review all ongoing medication and indicate a stop date or check the "ongoing at final visit" check box on the data collection forms and update the medication data in the AsthmaNet data entry application.

At the final study visit or early termination visit, forward all concomitant medications for asthma/allergy and adverse event-related medications forms to the DCC.

❑0 None

NAME OF MEDICATION **(1000)**	CODE **(1010)**	RELATED EVENT **(1020)**	DOSE **(1030)**	UNITS **(1040)**	FREQUENCY **(1050)**	ROUTE **(1055)**	START DATE (MM/DD/YYYY) **(1060)**	STOP DATE (MM/DD/YYYY) **(1070)**	ONGOING AT CURRENT VISIT **(1080)**	ONGOING AT FINAL VISIT **(1090)**
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1
__ __		Event __ __ ❑0 NA					__ / __ / ____	__ / __ / ____	❑1	❑1

AsthmaNet

HOME ENVIRONMENT QUESTIONNAIRE

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent?

(1000) ❑1 Self/Participant
❑2 Parent/Guardian
❑3 Other (specify)
(1000D) _____

GENERAL HOUSE CHARACTERISTICS

('House' is meant to refer to the place where you live most of the time.)

2. How long have you lived in the current house? *(Estimate if uncertain.)* **(1010-1020)** __ __ years__ __ months

3. Does your house use a wood burning stove as a primary source of heat? **(1030)** ❑1 Yes ❑0 No ❑8 Don't Know

4. Does your house use an air conditioner? **(1040)** ❑1 Yes ❑0 No ❑8 Don't Know

5. Does your house use an evaporative cooler (swamp cooler)? **(1050)** ❑1 Yes ❑0 No ❑8 Don't Know

6. Does your house use a humidifier? *(Include humidifier built into the heating system of your house.)* **(1060)** ❑1 Yes ❑0 No ❑8 Don't Know

7. Does your house use a dehumidifier? *(Include dehumidifier built into the cooling system of your house.)* **(1070)** ❑1 Yes ❑0 No ❑8 Don't Know

8. Has there been water damage to your house, basement, or its contents during the past 12 months? **(1080)** ❑1 Yes ❑0 No ❑8 Don't Know

9. Has there been any mold or mildew, on any surfaces, inside your house in the past 12 months? **(1090)** ❑1 Yes ❑0 No ❑8 Don't Know
➔ If **NO or DON'T KNOW**, skip to Q11.

10. Which rooms have or have had mold or mildew?

10a. Bathroom(s) **(1100)** ❑1 Yes ❑0 No

10b. Basement or attic **(1110)** ❑1 Yes ❑0 No

10c. Kitchen **(1120)** ❑1 Yes ❑0 No

10d. Your bedroom **(1130)** ❑1 Yes ❑0 No

10e. Other bedrooms **(1140)** ❑1 Yes ❑0 No

10f. Living or family room **(1150)** ❑1 Yes ❑0 No

10g. Other **(1160)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1160D)** _____

11. Do you ever see cockroaches in your house? **(1170)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q13.

12. In which room(s) have you seen cockroaches?

12a. Kitchen **(1180)** ❑1 Yes ❑0 No

12b. Basement or attic **(1190)** ❑1 Yes ❑0 No

12c. Bathroom(s) **(1200)** ❑1 Yes ❑0 No

12d. Living or family room **(1210)** ❑1 Yes ❑0 No

12e. Your bedroom **(1220)** ❑1 Yes ❑0 No

12f. Other bedrooms **(1230)** ❑1 Yes ❑0 No

12g. Garage **(1240)** ❑1 Yes ❑0 No

12h. Other **(1250)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1250D)** _____

13. Do you ever see rodents (mice, rats) or rodent droppings in your house? **(1260)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q15***.***

14. In which room(s) have you seen rodents or rodent droppings?

14a. Kitchen **(1270)** ❑1 Yes ❑0 No

14b. Basement or attic **(1280)** ❑1 Yes ❑0 No

14c. Bathroom(s) **(1290)** ❑1 Yes ❑0 No

14d. Living or family room **(1300)** ❑1 Yes ❑0 No

14e. Your bedroom **(1310)** ❑1 Yes ❑0 No

14f. Other bedrooms **(1320)** ❑1 Yes ❑0 No

14g. Garage **(1330)** ❑1 Yes ❑0 No

14h. Other **(1340)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1340D)** _____

15. Are any of the following located on your property or next to your property?

15a. Barns **(1350)** ❑1 Yes ❑0 No

15b. Hay **(1360)** ❑1 Yes ❑0 No

15c. Woodsheds **(1370)** ❑1 Yes ❑0 No

15d. Firewood **(1380)** ❑1 Yes ❑0 No

15e. Chicken coops **(1390)** ❑1 Yes ❑0 No

15f. Corral **(1400)** ❑1 Yes ❑0 No

CHARACTERISTICS OF THE PARTICIPANT'S BEDROOM
(If the participant does not have a bed or bedroom, answer for the place where the participant sleeps.)

16. What is the floor covering in your bedroom? **(1410)**
❑1 Rug/carpet
❑2 Vinyl tile or linoleum
❑3 Wood
❑4 Ceramic tile
❑5 Other (specify)
(1410D) _____
❑9 Don't know

17. What type of mattress is on your bed? **(1420)**
➔ If ***NONE***, skip to Q19.
❑1 None
❑2 Inner spring mattress
❑3 Foam mattress
❑4 Waterbed
❑5 Air mattress
❑6 Other (specify)
(1420D) _____
❑9 Don't know

18. Is the mattress completely enclosed in an allergy-proof, encasing cover? **(1430)** ❑1 Yes ❑0 No

19. Does your bed have a box spring? **(1440)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q21.

20. Is the box spring completely enclosed in an allergy-proof, encasing cover? **(1450)** ❑1 Yes ❑0 No

21. What type of pillow do you usually sleep with? **(1460)**
➔ If ***NONE***, skip to Q23.
❑1 None
❑2 Feather/down
❑3 Foam/Dacron/synthetic
❑5 Other (specify)
(1460D) _____
❑9 Don't know

22. Is the pillow completely enclosed in an allergy-proof, encasing cover? **(1470)** ❑1 Yes ❑0 No

PETS

23. Does your household have any pets? **(1480)** ❑1 Yes ❑0 No
➔ If ***NO***, skip to Q25.

24. Enter the number of pets that the household has. (*Enter '00' if none. If none to Q24a – Q24d, skip to the next question.*)

24a. Cat	**(1490)** __ __	**(1500)**	❑1 Indoor	❑2 Outdoor	❑3 Both
24b. Dog	**(1510)** __ __	**(1520)**	❑1 Indoor	❑2 Outdoor	❑3 Both
24c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1530)** __ __	**(1540)**	❑1 Indoor	❑2 Outdoor	❑3 Both
24d. Bird	**(1550)** __ __	**(1560)**	❑1 Indoor	❑2 Outdoor	❑3 Both

25. In general, and on a regular basis, are you exposed to any of the following animals?

25a. Cat	**(1570)**	❑1 Yes	❑0 No
25b. Dog	**(1580)**	❑1 Yes	❑0 No
25c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1590)**	❑1 Yes	❑0 No
25d. Bird	**(1600)**	❑1 Yes	❑0 No
25e. Farm animals	**(1610)**	❑1 Yes	❑0 No

25f. Other **(1620)** ❑1 Yes ❑0 No

If ***YES***, please specify **(1620D)** _____

➔ ***If participant is 6 years of age or older, STOP HERE and complete the source documentation box.***

DAY CARE

26. Did the participant attend day care during the 1st year of life? **(1630)** ❑1 Yes ❑0 No

26a. If ***YES***, at what age did the day care attendance begin? **(1640)** __ __ months

27. Does the participant currently attend day care? **(1650)** ❑1 Yes ❑0 No
➔ ***If No, STOP HERE and complete the source documentation box.***

27a. Is the day care… **(1660)** ❑1 In home day care
❑2 Nonresidential
❑3 Mixed

27b. How many children are in the participant's day care room? **(1670)** __ __ children

27c. How many hours per day is the participant at day care? **(1680)** __ __ hours

27d. How many days per week is the participant at day care? **(1690)** __ days

27e. How many months per year is the participant at day care? **(1700)** __ __ months

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __ **(1710)**
Date: __ __ / __ __ / 20 __ __ **(1720)**
MM DD YYYY

Coordinator Completed
COMMENTS
(6000):_____

_____

_____

AsthmaNet

HOUSEHOLD SOCIO-ECONOMIC INFORMATION

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Parent/Legal Guardian or Participant Completed)

Please answer the following questions about your primary household. If you're a college student living away from home during the school year, the questions pertain to your parents' household.

1. Who is the respondent? **(1000)**
   - ❑1 Self/Participant
   - ❑2 Parent/Guardian
   - ❑3 Other (specify) **(1000D)** _____

2. Which category best describes the **highest** grade or educational level that **any member of your household** has achieved? (Check one box only.) **(1010)**
   - ❑0 No High School diploma
   - ❑1 GED
   - ❑2 High School diploma
   - ❑3 Technical training
   - ❑4 Some college, no degree
   - ❑5 Associate degree
   - ❑6 Bachelors degree
   - ❑7 Masters degree
   - ❑8 MD/PhD/JD/PharmD
   - ❑9 Decline to answer
   - ❑10 Don't know

3. To help us characterize the economic status of our study participants, please indicate which category best describes the **combined annual income**, before taxes, of **all members of your household** for the last year. (Check one box only.) **(1020)**
   - ❑1 Less than $25,000
   - ❑2 $25,000 - $49,999
   - ❑3 $50,000 - $99,999
   - ❑4 $100,000 or more
   - ❑9 Decline to answer
   - ❑10 Don't know

4. How many people (adults and children) are supported by this income reported in Q3? **(1030)** __ __ people

COMMENTS: **(6000)**

_____

_____

_____

* H O U S E H O L D S E I *

AsthmaNet

PEDIATRIC LONG PHYSICAL EXAM

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

PARENTAL HEIGHT – First study visit only or until both are completed

1. Biological mother's height (complete height or check unknown) **(1000-1010)** __ feet __ __ inches
   (1020) ❑9 Don't Know

2. Biological father's height (complete height or check unknown) **(1030-1040)** __ feet __ __ inches
   (1050) ❑9 Don't Know

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

3. What type of height measurement was obtained? **(1060)** ❑1 Standing height ❑2 Length

   3a. First measurement **(1070)** __ __ __ . __ cm

   3b. Second measurement **(1080)** __ __ __ . __ cm

   3c. Third measurement **(1090)** __ __ __ . __ cm

   3d. Average height or length measurement **(1100)** __ __ __ . __ cm

   ➔ ***Plot average height or length on gender- and age-appropriate growth charts. See study MOP for further details.***

   3e. In your judgment, was the participant's height or length measurement acceptable? **(1110)** ❑1 Yes ❑0 No

   3ei. If **NO**, why was it unacceptable? **(1120D)** _____

   _____

4. Weight (shoes off, light clothing) **(1130)** __ __ __ . __ kg

   ➔ ***Plot weight on gender- and age-appropriate growth charts. See study MOP for further details.***

ORAL CANDIDIASIS

5. Does the participant have evidence of oral candidiasis? **(1140)** ❑1 Yes ❑0 No
   ➔ ***If YES, complete the Clinical Adverse Events (AECLIN) form.***

LEXAM PED

DO NOT DATA ENTER THE INFORMATION ON THE REST OF THE FORM EXCEPT THE COMMENTS (IF APPLICABLE)

(Licensed Medical Practitioner Completed)

Please indicate current physical findings by checking the appropriate boxes below. If ABNORMAL, please describe concisely.

		Not Done	Normal	Abnormal	
6.	Hair and Skin	❑	❑	❑	_____
7.	Lymph nodes	❑	❑	❑	_____
8.	Eyes (excluding corrective lenses)	❑	❑	❑	_____
9.	Ears, Nose, and Throat	❑	❑	❑	_____
10.	Respiratory	❑	❑	❑	_____
	10a. If Abnormal:				❑ Wheeze on inspiration or expiration ❑ Adventitious sounds other than wheezing ❑ Other _____ _____ _____
11.	Cardiovascular	❑	❑	❑	_____
12.	Gastrointestinal	❑	❑	❑	_____
13.	Musculoskeletal	❑	❑	❑	_____
14.	Neurological	❑	❑	❑	_____
15.	Mental Status	❑	❑	❑	_____
16.	Other _____ (check Not Done if non-applicable)	❑	❑	❑	_____

Licensed Medical Practitioner Source Documentation

Licensed Medical Practitioner Signature: _____

Printed Name: _____

Date: __ __ / __ __ / 20 __ __
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)*

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

PRIOR CONDITIONS FOR ALL PARTICIPANTS

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent? **(1000)**
   - ❑1 Self/Participant
   - ❑2 Parent/Guardian
   - ❑3 Other (specify) **(1000D)** _____

PRIOR DISEASES, ILLNESSES, AND SURGERIES

Have you had any diseases, illnesses, conditions, or surgeries related to the following areas?

						If Yes, Comment
2.	Skin	**(1010)**	❑1 Yes	❑0 No	**(1010D)**	_____
3.	Ears, Nose, or Throat					
3a.	Have you ever had allergic rhinitis (hay fever)?	**(1020)**	❑1 Yes	❑0 No	❑9 Don't know	
3b.	Have you ever had nasal polyps?	**(1030)**	❑1 Yes	❑0 No	❑9 Don't know	
3c.	Do you have chronic or recurrent sinusitis (treated with antibiotics and/or surgery)?	**(1040)**	❑1 Yes	❑0 No	❑9 Don't know	
3d.	Have you ever been diagnosed with vocal cord dysfunction?	**(1050)**	❑1 Yes	❑0 No	❑9 Don't know	
3e.	Have you ever had other conditions related to the ear, nose, or throat?	**(1060)**	❑1 Yes	❑0 No	**(1060D)**	_____
4.	Lung - other than asthma					
4a.	Have you ever had pneumonia?	**(1070)**	❑1 Yes	❑0 No	❑9 Don't know	

PRIOR COND ALL

If Yes, Comment

4ai. If **YES**, were you diagnosed by chest x-ray? **(1080)** ❑1 Yes ❑0 No ❑9 Don't know

4aii. If **YES**, were you treated with antibiotics? **(1090)** ❑1 Yes ❑0 No ❑9 Don't know

4b. Have you ever had bronchitis? **(1100)** ❑1 Yes ❑0 No ❑9 Don't know

4c. Have you ever had other conditions related to the lungs (besides asthma)? **(1110)** ❑1 Yes ❑0 No **(1110D)** _____

5. Stomach or Intestines

5a. Do you have gastroesophageal reflux disease (GERD)? **(1120)** ❑1 Yes ❑0 No ❑9 Don't know

5b. Have you ever had other conditions related to the stomach or intestines? **(1130)** ❑1 Yes ❑0 No **(1130D)** _____

6. Sleep Disorder

6a. Have you been diagnosed with sleep disordered breathing (sleep apnea)? **(1150)** ❑1 Yes ❑0 No **(1150D)** _____

6ai. If **YES**, are you being treated with CPAP or BiPAP? **(1160)** ❑1 Yes ❑0 No

6b. Have you ever had other sleep disorders? **(1170)** ❑1 Yes ❑0 No **(1170D)** _____

7. Have you ever had other conditions that have not been mentioned on this form? **(1180)** ❑1 Yes ❑0 No **(1180D)** _____

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

PRIOR ASTHMA/ALLERGY TREATMENT

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed by Interview)

Note: If you are a parent or guardian responding for a child, "you" is referring to the child who is the study participant.

1. Who is the respondent?

(1000) ❑1 Self/Participant
❑2 Parent/Guardian
❑3 Other (specify)
(1000D) _____

Next I will read a list of medications that are used to treat asthma and allergies. Please indicate if you have used each medication ***during the past 12 months FOR ASTHMA OR ALLERGIES***. If you have used a particular medication, please indicate to the best of your knowledge the date it was last taken.

During the past 12 months were the following medications used FOR ASTHMA OR ALLERGIES?		**If Yes, indicate date medication was last taken Month / Day / Year**
2. Short-acting Inhaled Beta-Agonists by Inhaler (**e.g., albuterol, Primatene Mist, Maxair, ProAir, Proventil, Ventolin, Xopenex)**	**(1010)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1020) (1030) (1040)**
2a. If **YES**, indicate average weekly puffs in the past month (Enter '000' if none used)	**(1050)** __ __ __ weekly puffs	
3. Rescue treatment via a Nebulizer Machine **(e.g., albuterol, ipratropium, Combivent, Xopenex, levalbuterol)**	**(1060)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1070) (1080) (1090)**
4. Long-acting Inhaled Beta-Agonists **(e.g., Serevent, Foradil, salmeterol, formoterol)** ➔ ***Do not consider combination medications.***	**(1100)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1110) (1120) (1130)**
5. Oral Beta-Agonists **(e.g., albuterol, Brethine, Bricanyl, metaproterenol, Proventil, Ventolin, Repetabs, Volmax)**	**(1140)** ❑1 Yes ❑0 No ❑9 Don't Know	__ __ / __ __ / 20 __ __ **(1150) (1160) (1170)**

PRIOR TRT

6. Oral Theophylline (short-acting or sustained release) **(e.g., Aminophylline, Slo-Phyllin, Slo-bid, Theo-Dur, Uniphyl)** **(1180)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1190) (1200) (1210)

If Yes, indicate date medication was last taken Month / Day / Year

7. Inhaled Anticholinergic by Inhaler (**e.g., Atrovent, Combivent, Spiriva**) **(1220)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1230) (1240) (1250)

8. Leukotriene Antagonist / 5LO Inhibitors (**e.g., Accolate, Zyflo, Singulair**) **(1260)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1270) (1280) (1290)

9. IgE Blocker (**e.g., Xolair**) **(1300)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1310) (1320) (1330)

10. Oral Steroids FOR ASTHMA (**e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone**) **(1340)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1350) (1360) (1370)

10a. If **YES**, in the past 12 months, how many courses of steroids by mouth have you taken FOR ASTHMA? **(1380)**

- ❑1 1 course
- ❑2 2 courses
- ❑3 3 courses
- ❑4 4 courses
- ❑5 5 courses
- ❑6 More than 5 courses

11. Injectable Steroids FOR ASTHMA (**e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV**) **(1390)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ (1400) (1410) (1420)

12. Steroids by Inhaler **(1430)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1440) (1450) (1460)**
(e.g., Asmanex Twisthaler, QVAR, Flovent, Pulmicort Flexhaler)
➔ ***Do not consider combination medications.***
➔ If **YES**, complete Q12a – Q12c

12a. Indicate most recent type of inhaled steroid taken (refer to PRIOR_TRT_CARD reference card) **(1470)** __ __ __ code

12ai. If **Other**, specify the name of the medication **(1470D)** _____

12b. Indicate number of daily puffs used **(1480)** __ __ daily puffs

12c. Indicate the total number of months that you used the inhaled steroid out of the past 12 months **(1490)** __ __ months

If Yes, indicate date medication was last taken Month / Day / Year

13. Steroids by Nebulizer **(1500)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1510) (1520) (1530)**
(e.g., Pulmicort Respules, budesonide)
➔ If **YES**, complete Q13a – Q13c

13a. Indicate most recent type of nebulized steroid taken (refer to PRIOR_TRT_CARD reference card) **(1535)** __ __ code

13ai. If **Other**, specify the name of the medication **(1500D)** _____

13b. Indicate number of daily treatments used **(1540)** __ __ daily treatments

13c. Indicate the total number of months that you used the nebulized steroid out of the past 12 months **(1550)** __ __ months

14. Long-Acting Beta-Agonist and Inhaled Steroid Combination Medications **(1560)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1570) (1580) (1590)**
(e.g., Advair Diskus, Symbicort MDI, Dulera MDI)
➔ If **YES**, complete Q14a – Q14c

14a. Indicate most recent type of combination medication taken (refer to PRIOR_TRT_CARD reference card) **(1600)** __ __ __ __ code

14ai. If **Other**, specify the name of the medication **(1600D)** _____

14b. Indicate number of daily puffs used **(1610)** __ __ daily puffs

14c. Indicate the total number of months that you used the combination medication out of the past 12 months **(1620)** __ __ months

During the past 12 months were the following nasal treatments used FOR ALLERGIES?

15. Nasal Steroids (**e.g., Beconase, Vancenase, Flonase, Nasacort, Nasalide, Nasarel, Omnaris, Rhinocort, Nasonex)** **(1630)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1640) (1650) (1660)**

16. Non-steroidal Anti-allergic Nasal Medications (**e.g., Nasalcrom, Astelin, Astepro, ipratropium**) **(1670)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1680) (1690) (1700)**

During the past 12 months were the following general allergy treatments used?

If Yes, indicate date medication was last taken Month / Day / Year

17. Anti-allergic Oral Medications (**e.g., fexofenadine, loratadine, cetirizine, chlorpheniramine**) **(1710)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1720) (1730) (1740)**

During the past 12 months were the following skin treatments used FOR ECZEMA OR ALLERGIES?

18. Topical Steroids – Prescription (**e.g., Synalar, Lidex, Dermacin, Fluocinonide**) **(1750)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1760) (1770) (1780)**

19. Topical Steroids – OTC (**e.g., Hydrocortisone - multiple strengths and products)** **(1790)** ❑1 Yes ❑0 No ❑9 Don't Know — __ __ / __ __ / 20 __ __ **(1800) (1810) (1820)**

During the past 12 months were there any OTHER medications used FOR ASTHMA OR ALLERGIES?

20. Other Medication FOR ASTHMA OR ALLERGIES **(1830)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1840) (1850) (1860)**

20a. If **YES**, specify the name of the medication **(1830D)** _____

During the past 12 months were the following treatments used for conditions OTHER THAN ASTHMA?

21. Oral Steroids **for Conditions Other Than Asthma** (**e.g., Prednisone, Prelone, Pediapred, Medrol, Orapred, Decadron, dexamethasone**) **(1870)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1880) (1890) (1900)**

21a. If **YES**, specify indication **(1870D)** _____

If Yes, indicate date medication was last taken Month / Day / Year

22. Injectable Steroids **for Conditions Other Than Asthma** (**e.g., Medrol, Solumedrol, Decadron, dexamethasone, triamcinolone, Kenalog, hydrocortisone IV**) **(1910)** ❑1 Yes ❑0 No ❑9 Don't Know __ __ / __ __ / 20 __ __ **(1920) (1930) (1940)**

22a. If **YES**, specify indication **(1910D)** _____

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

SERIOUS ADVERSE EVENT REPORTING FORM

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

This form and a final resolution report (including relevant documents) written by the Principal Investigator should be faxed to the DCC at (717) 531-4359 within 72 hours of notification of a serious event. Also fax the Clinical Adverse Events form (AECLIN), the Concomitant Medications for Asthma and Allergies (CMED) form, and any relevant source documents.

1. Date of Adverse Event **(1000)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Description of Adverse Event (ICD9 Code) **(1010)** __ __ __ . __ __

   Describe: **(1010D)** _____

3. Is the participant currently taking study drug? **(1020)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q6.

4. Time interval between the last administration of the study drug and the Adverse Event **(1030)** __ __ __

5. What was the unit of time for the interval in Question #4? **(1040)**
   ❑1 Second(s)
   ❑2 Minute(s)
   ❑3 Hour(s)
   ❑4 Day(s)

6. Why was the event serious?

   6a. Fatal event **(1050)** ❑1 Yes ❑0 No

   6b. Life-threatening event **(1060)** ❑1 Yes ❑0 No

   6c. Inpatient hospitalization required **(1070)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q6d.

   6ai. Admission date **(1080)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   6aii. Discharge date **(1090)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

   6d. Hospitalization prolonged **(1100)** ❑1 Yes ❑0 No

   6e. Disabling or incapacitating **(1110)** ❑1 Yes ❑0 No

   6f. Overdose **(1120)** ❑1 Yes ❑0 No

6g. Cancer **(1130)** ❑1 Yes ❑0 No

6h. Congenital anomaly **(1140)** ❑1 Yes ❑0 No

6i. Serious laboratory abnormality with clinical symptoms **(1150)** ❑1 Yes ❑0 No

6j. Height failure (per protocol MOP) **(1160)** ❑1 Yes ❑0 No

6k. Pregnancy **(1170)** ❑1 Yes ❑0 No ❑9 N/A

6l. Other **(1180)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1180D)** _____

7. What in your opinion caused the event?

7a. Toxicity of study drug(s) **(1190)** ❑1 Yes ❑0 No

7b. Withdrawal of study drug(s) **(1200)** ❑1 Yes ❑0 No

7c. Concurrent medication **(1210)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1210D)** _____

7d. Other condition or event **(1220)** ❑1 Yes ❑0 No

If ***YES***, describe: **(1220D)** _____

(Investigator Completed)

8. Was the event expected or unexpected? **(1240)** ❑1 Expected ❑2 Unexpected

9. Was the event possibly, probably, or definitely related to study participation? **(1250)** ❑1 Yes ❑0 No

DO NOT ENTER THE FOLLOWING QUESTIONS: FOR REPORTING PURPOSES ONLY.

10. If participant died, cause of death: _____

_____

11. Was an autopsy performed? ❑ Yes ❑ No

If YES, attach report or send as soon as possible.

REPORTING INVESTIGATOR:

Please provide a typed summary of the event including: the participant's status in the study, whether study drugs will be continued, follow-up treatment plans, and communication with the treating physicians and participant or participant's parent/guardian.

COMMENTS: (6000)

_____

_____

_____

Name: _____

Signature:_____

Date: __ __ / __ __ / 20 __ __
MM DD YYYY

AsthmaNet

PEDIATRIC SHORT PHYSICAL EXAM

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

PARTICIPANT MEASUREMENTS – Complete at all applicable study visits

1. What type of height measurement was obtained? **(1060)** ❑$_1$ Standing height ❑$_2$ Length

   1a. First measurement **(1070)** __ __ __ . __ cm

   1b. Second measurement **(1080)** __ __ __ . __ cm

   1c. Third measurement **(1090)** __ __ __ . __ cm

   1d. Average height or length measurement **(1100)** __ __ __ . __ cm

   ➔ ***Plot average height or length on gender- and age-appropriate growth charts. See study MOP for further details.***

   1e. In your judgment, was the participant's height or length measurement acceptable? **(1110)** ❑$_1$ Yes ❑$_0$ No

   1ei. If **NO**, why was it unacceptable? **(1120D)** _____

   _____

2. Weight (shoes off, light clothing) **(1130)** __ __ __ . __ kg

   ➔ ***Plot weight on gender- and age-appropriate growth charts. See study MOP for further details.***

ORAL CANDIDIASIS

3. Does the participant have evidence of oral candidiasis? **(1140)** ❑$_1$ Yes ❑$_0$ No
   ➔ ***If YES, complete the Clinical Adverse Events (AECLIN) form.***

SEXAM PED

DO NOT DATA ENTER THE INFORMATION ON THE REST OF THE FORM EXCEPT THE COMMENTS (IF APPLICABLE)

Please indicate current physical findings by checking the appropriate boxes below. If ABNORMAL, please describe concisely.

		Not Done	Normal	Abnormal	
4.	Hair and Skin	❑	❑	❑	_____
5.	Eyes, Ears, Nose, and Throat	❑	❑	❑	_____
6.	Respiratory	❑	❑	❑	_____

6a. If Abnormal:

- ❑ Wheeze on inspiration or expiration
- ❑ Adventitious sounds other than wheezing
- ❑ Other _____
  _____
  _____
  _____

Coordinator Source Documentation

Coordinator Signature: _____

Printed Name: _____

Date: __ __ / __ __ / 20 __ __
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)*

COMMENTS: (6000)

_____

_____

_____

Part. ID: - -

Part. Initials: Visit: Visit Date: / / Coordinator ID:

Childhood Asthma Control Test for children 4 to 11 years old.

Know the score.

This test will provide a score that may help your doctor determine if your child's asthma treatment plan is working or if it might be time for a change.

How to take the Childhood Asthma Control Test

Step 1 Let your child respond to **the first four questions (1 to 4)**. If your child needs help reading or understanding the question, you may help, but let your child select the response. Complete the remaining **three questions (5 to 7)** on your own and without letting your child's response influence your answers. There are no right or wrong answers.

Step 2 Write the number of each answer in the score box provided.

Step 3 Add up each score box for the total.

Step 4 Take the test to the doctor to talk about your child's total score.

19 or less

If your child's score is 19 or less, it may be a sign that your child's asthma is not controlled as well as it could be. No matter what the score, bring this test to your doctor to talk about your child's results.

Have your child complete these questions.

1. How is your asthma today?

SCORE

 0 Very bad	 1 Bad	 2 Good	 3 Very good

2. How much of a problem is your asthma when you run, exercise or play sports?

 0 It's a big problem, I can't do what I want to do.	 1 It's a problem and I don't like it.	 2 It's a little problem but it's okay.	 3 It's not a problem.

3. Do you cough because of your asthma?

 0 Yes, all of the time.	 1 Yes, most of the time.	 2 Yes, some of the time.	 3 No, none of the time.

4. Do you wake up during the night because of your asthma?

 0 Yes, all of the time.	 1 Yes, most of the time.	 2 Yes, some of the time.	 3 No, none of the time.

Please complete the following questions on your own.

5. During the last 4 weeks, how many days did your child have any daytime asthma symptoms?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

6. During the last 4 weeks, how many days did your child wheeze during the day because of asthma?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

7. During the last 4 weeks, how many days did your child wake up during the night because of asthma?

5 Not at all	4 1-3 days	3 4-10 days	2 11-18 days	1 19-24 days	0 Everyday

TOTAL

Please turn this page over to see what your child's total score means.

AsthmaNet	EXHALED NITRIC OXIDE Supervisor ID: __ __ __ __	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

ENO must be performed prior to any pulmonary function testing. Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form.

1. Has QC procedure been performed on the NIOX MINO® today? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***NO,*** please specify the reason QC was not performed in Q6000.

2. Did the participant eat or drink within the past hour? **(1010)** ❑$_1$ Yes ❑$_0$ No

3. Did the participant take part in strenuous activity/exercise within the past hour? **(1020)** ❑$_1$ Yes ❑$_0$ No

4. Time eNO started *(based on a 24-hour clock)* **(1040)** __ __ __ __

5. ENO Measurement **(1050)** __ __ __ ppb

COMMENTS: **(6000)**

_____

_____

_____

* E N O *

AsthmaNet	PRE-BRONCHODILATOR IOS	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form.

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING

1.	Time IOS started (based on 24-hour clock)	**(1000)**	__ __ __ __

Results of first effort

2.	R_5	**(1010)**	__ __ . __ __ kPa/l/s
3.	R_{10}	**(1020)**	__ __ . __ __ kPa/l/s
4.	R_{15}	**(1030)**	__ __ . __ __ kPa/l/s
5.	R_{20}	**(1040)**	__ __ . __ __ kPa/l/s
6.	R_{35}	**(1050)**	__ __ . __ __ kPa/l/s
7.	X_5	**(1060)**	__ __ . __ __ kPa/l/s
8.	Resonant Frequency	**(1070)**	__ __ . __ __ Hz
9.	Area X_A	**(1080)**	__ __ . __ __ kPa/l

Results of second effort

10.	R_5	**(1090)**	__ __ . __ __ kPa/l/s
11.	R_{10}	**(1100)**	__ __ . __ __ kPa/l/s
12.	R_{15}	**(1110)**	__ __ . __ __ kPa/l/s
13.	R_{20}	**(1120)**	__ __ . __ __ kPa/l/s
14.	R_{35}	**(1130)**	__ __ . __ __ kPa/l/s
15.	X_5	**(1140)**	__ __ . __ __ kPa/l/s
16.	Resonant Frequency	**(1150)**	__ __ . __ __ Hz
17.	Area X_A	**(1160)**	__ __ . __ __ kPa/l

Results of third effort

18.	R_5	**(1170)**	__ __ . __ __ kPa/l/s
19.	R_{10}	**(1180)**	__ __ . __ __ kPa/l/s
20.	R_{15}	**(1190)**	__ __ . __ __ kPa/l/s
21.	R_{20}	**(1200)**	__ __ . __ __ kPa/l/s
22.	R_{35}	**(1210)**	__ __ . __ __ kPa/l/s
23.	X_5	**(1220)**	__ __ . __ __ kPa/l/s
24.	Resonant Frequency	**(1230)**	__ __ . __ __ Hz
25.	Area X_A	**(1240)**	__ __ . __ __ kPa/l
26.	In your judgment, was the participant's pre-bronchodilator technique acceptable?	**(1250)**	❑$_1$ Yes ❑$_0$ No
	26a. If **NO**, why was it unacceptable?		
	26ai. Coherence < 0.80 (for R_{10})	**(1260)**	❑$_1$ Yes ❑$_0$ No
	26aii. Poor repeatability (for R_{10} values vary by more than 20%)	**(1270)**	❑$_1$ Yes ❑$_0$ No
	26aiii. Fewer than 3 good tests	**(1280)**	❑$_1$ Yes ❑$_0$ No
	26aiv. Inconsistent tidal breathing	**(1290)**	❑$_1$ Yes ❑$_0$ No
	26av. Participant refusal during test	**(1300)**	❑$_1$ Yes ❑$_0$ No
	26avi. Other	**(1310)**	❑$_1$ Yes ❑$_0$ No
	If YES, please specify	**(1310D)**	_____
	26b. If **YES**, grade the participant's technique	**(1320)**	❑$_1$ Acceptable, good effort ❑$_2$ Acceptable, questionable effort

IOS Standards

27. How was the participant positioned? **(1330)**
- ❑1 Sitting on a chair
- ❑2 Sitting on a lap
- ❑3 Standing
- ❑4 Other

28. Were the participant's cheeks held? **(1340)** ❑1 Yes ❑0 No

28a. If **YES**, how were the participant's cheeks held? **(1350)**
- ❑1 Parent/guardian held the cheeks
- ❑2 Technician held the cheeks
- ❑3 Participant held his/her own cheeks
- ❑4 Other

29. Were nose clips used? **(1360)** ❑1 Yes ❑0 No

29a. If **YES**, how effective were the nose clips? **(1370)**
- ❑1 The nose clips sealed the nostrils completely
- ❑2 The nose clips sealed the nostrils partially
- ❑3 The nose clips came off during the procedure
- ❑4 Other

29a. If **NO**, was the nose occluded? **(1380)** ❑1 Yes ❑0 No

29ai. If **YES**, how was the nose occluded? **(1390)**
- ❑1 Parent/guardian occluded the nose
- ❑2 Technician occluded the nose
- ❑3 Participant occluded the nose
- ❑4 Other

If a gray box is selected, please explain in the comment section below.

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

METHACHOLINE CHALLENGE TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the Methacholine Challenge Testing Checklist (METHACHK) form.

Clinic Use Only *(Technician Completed)*
Use the FEV_1 value from the appropriate spirometry testing form as the baseline reference.

A. Baseline (pre) FEV_1 prior to methacholine challenge __ . __ __ L

B. Methacholine Reversal Reference Value (Question A x 0.90 = __ . __ __ L)

1. Post Diluent FEV_1 **(1000)** __ . __ __ L

2. Did the participant drop ≥ 20% at the diluent stage? **(1010)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, proceed to Q5. Record 'Yes' for Q5 and 0 for Q5a.

3. Last concentration of methacholine administered **(1020)** __ __ . __ __ __ __ mg/ml

4. FEV_1 after last concentration of methacholine administered **(1030)** __ . __ __ L

5. Did the participant achieve a PC_{20}? **(1040)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***NO***, proceed to Q6.

   5a. PC_{20} **(1050)** __ __ . __ __ mg/ml

6. Time methacholine challenge ended *(based on 24-hour clock)* **(1060)** __ __ __ __

7. Participant's FEV_1 after standard reversal from methacholine challenge

   If participant is continuing with sputum induction, standard reversal = 4 puffs albuterol.
   If participant is not continuing with sputum induction, standard reversal = 2 puffs albuterol.

   7a. FEV_1 **(1070)** __ . __ __ L

   7b. Time of FEV_1 in Q7a (*based on 24-hour clock)* **(1080)** __ __ __ __

   7c. Was the FEV_1 from Q7a ≥ the methacholine reversal reference value (B) in the gray box above? **(1090)** ❑$_1$ Yes ❑$_0$ No

➔ ***If YES, STOP HERE and continue with remaining visit procedures.***
➔ ***If NO, proceed to the Additional Treatment for Methacholine Challenge Testing (METHA_ADD_TRT) form.***

COMMENTS: (6000)

_____

* M E T H A *

AsthmaNet

PEDIATRIC METHACHOLINE CHALLENGE TESTING CHECKLIST

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

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

Exclusions and Confounders

1. Has the participant had any severe acute illness in the past 4 weeks? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing? **(1010)** ☐1 Yes ☐0 No
   Physician's Signature: **(1020)** _____

2. During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1030)** ☐1 Yes ☐0 No

   2a. If ***YES***, during the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1040)** ☐1 Yes ☐0 No

3. Has the participant used 4 or more days of systemic corticosteroid (e.g., prednisolone, prednisone, Solumedrol, Decadron) for the treatment of an asthma exacerbation in the past 4 weeks? **(1050)** ☐1 Yes ☐0 No

4. Does the participant have a baseline (pre-diluent) FEV_1 less than 70% of predicted? **(1060)** ☐1 Yes ☐0 No

5. Pregnancy test results *(Check N/A if the participant is male, or is female and has not started menses.)* **(1070)** ☐1 Positive ☐0 Negative ☐9 N/A

6. **If participant's age is ≥ 12 years:** Is the participant's systolic blood pressure > 200 mm Hg or diastolic blood pressure > 100 mm Hg? **(1080)** ☐1 Yes ☐0 No

7. **If participant's age is < 12 years:** Is the participant's systolic blood pressure > 180 mm Hg or diastolic blood pressure > 90 mm Hg? **(1090)** ☐1 Yes ☐0 No

8. Is there any other reason the participant should not proceed with the methacholine challenge testing? **(1100)** ☐1 Yes ☐0 No
   If ***YES***, explain: **(1100D)** _____

METHACHK PED

9.	Is the participant eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ***If any of the shaded boxes are completed, the participant is NOT eligible for the methacholine challenge testing.*** ➔ ***If YES, proceed to the Methacholine Challenge Testing (METHA) form.***	**(1110)** ☐ 1 Yes ☐ 0 No

COMMENTS: **(6000)**

_____

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AsthmaNet

ADDITIONAL TREATMENT POST METHACHOLINE CHALLENGE TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant did not reverse to 90% of baseline (pre) FEV_1 after the first post-challenge treatment of albuterol.

1. Was an additional treatment used in the first hour? **(1000)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3.

   1a. Additional albuterol by MDI **(1010)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q1b.

   Number of additional puffs of albuterol administered **(1020)** ❑1 2 ❑2 4 ❑3 > 4

   1b. Nebulized Beta-agonist **(1030)** ❑1 Yes ❑0 No

   1c. Subcutaneous epinephrine **(1040)** ❑1 Yes ❑0 No

   1d. Implementation of clinic emergency protocol or algorithm **(1050)** ❑1 Yes ❑0 No

   1e. Other **(1060)** ❑1 Yes ❑0 No

   If ***YES***, specify: **(1060D)** _____

2. Participant's FEV_1 after additional treatment within first hour.

   2a. FEV_1 **(1070)** __ . __ __ L

   2b. Time of FEV_1 in Q2a *(based on 24-hour clock)* **(1090)** __ __ __ __

   2c. Was the FEV_1 from Q2a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? **(1100)** ❑1 Yes ❑0 No
   ➔ If ***YES, STOP HERE*** and continue with remaining visit procedures.

   ➔ If ***NO***, proceed to Q3.

3. Was additional treatment used after one hour? **(1110)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q4.

   3a. Additional albuterol by MDI **(1120)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q3b.

METHA ADD TRT

Number of additional puffs of albuterol administered	**(1130)**	❑$_1$ 2	❑$_2$ 4	❑$_3$ > 4
3b. Nebulized Beta-agonist	**(1140)**	❑$_1$ Yes	❑$_0$ No	
3c. Subcutaneous epinephrine	**(1150)**	❑$_1$ Yes	❑$_0$ No	
3d. Implementation of clinic emergency protocol or algorithm	**(1160)**	❑$_1$ Yes	❑$_0$ No	
3e. Treatment in the emergency room	**(1170)**	❑$_1$ Yes	❑$_0$ No	
3f. Overnight hospitalization ➔ If ***YES***, please complete the Serious Adverse Event (SERIOUS) form.	**(1180)**	❑$_1$ Yes	❑$_0$ No	
3g. Other	**(1190)**	❑$_1$ Yes	❑$_0$ No	
If ***YES***, specify:	**(1190D)**	_____		

4. Participant's final FEV_1 after methacholine challenge

4a. FEV_1	**(1200)**	__ . __ __ L
4b. Time of FEV_1 in Q4a *(based on 24-hour clock)*	**(1220)**	__ __ __ __
4c. Was the FEV_1 from Q4a ≥ the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form? ➔ If ***NO***, complete the source documentation box below.	**(1230)**	❑$_1$ Yes ❑$_0$ No

Physician Source Documentation

Physician's Signature: _____ **(1240)**

Date: __ __ / __ __ / 20 __ __ (MM / DD / YYYY) **(1250)**

Time: __ __ __ __ *(based on a 24-hour clock)* **(1260)**

COMMENTS: **(6000)**

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AsthmaNet

POST-ALBUTEROL (4 puffs) SPIROMETRY TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __

Part. Initials: __ __ __

Visit: __ __ __

Visit Date: __ __ / __ __ / 20 __ __

Technician ID: __ __ __ __

(Technician Completed)

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

➔ ***Administer 4 puffs of albuterol and wait 10 to 15 minutes, then perform spirometry.***

1. Time albuterol administered *(based on 24-hour clock)* **(1000)** __ __ __ __

2. Time post-albuterol spirometry started *(based on 24-hour clock)* **(1010)** __ __ __ __

The reported FEV_1, FVC and FEF Max are the best measurements of all acceptable maneuvers.

3. Highest FVC **(1020)** __ . __ __ L

4. Highest FEV_1 **(1030)** __ . __ __ L

5. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

6. FEF Max **(1050)** __ __ . __ __ L/S

The reported FEF_{25-75} corresponds to the maneuver where FEV_1 + FVC is maximized.

7. FEF_{25-75} **(1060)** __ . __ __ L/S

8. In your judgment, was the participant's spirometry technique acceptable? **(1070)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: (6000)

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PALB4 SPIRO

AsthmaNet

URINE PREGNANCY TEST

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form for female participants ages 6 and older. All female participants ages 6 and older or her parent/guardian must review the completed form and provide source documentation below.

1. Is the participant unable to bear children due to any of the following reasons?

1a. Pre-menarche **(1000)** ☐1 Yes ☐0 No
➔ If **YES**, stop here and have the parent/guardian complete the source documentation box below.

1b. Post-menopausal (at least one year since last menses) **(1010)** ☐1 Yes ☐0 No

1c. Hysterectomy **(1020)** ☐1 Yes ☐0 No

1d. Tubal ligation **(1030)** ☐1 Yes ☐0 No

➔ ***If any of the shaded boxes are filled in, a pregnancy test is not required. Proceed to the source documentation box below.***

2. Pregnancy test results **(1040)** ☐1 Positive ☐0 Negative
➔ ***If pregnancy test results are positive, the participant must be terminated from study participation. Complete the appropriate Termination of Study Participation form and follow study termination procedures.***

Participant/Guardian Source Documentation
Participant/Guardian Initials: __ __ __ **(1050)**
Date: __ __ / __ __ / 20 __ __ **(1060)**
MM DD YYYY

COMMENTS: (6000)

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* P R E G T E S T *

AsthmaNet

SPIROMETRY TESTING

Supervisor ID: __ __ __ __

Part. ID: __ __ - __ __ __ - __ __ __
Part. Initials: __ __ __
Visit: __ __ __
Visit Date: __ __ / __ __ / 20 __ __
Technician ID: __ __ __ __

(Technician Completed)

Complete this form only if the participant is eligible according to the appropriate Pulmonary Procedure Checklist form.

1. Time spirometry started *(based on 24-hour clock)* **(1010)** __ __ __ __

The reported FEV_1, FVC and FEF Max are the best measurements of all acceptable maneuvers.

2. Highest FVC **(1020)** __ . __ __ L

3. Highest FEV_1 **(1030)** __ . __ __ L

4. Highest FEV_1 (% predicted) **(1040)** __ __ __ % predicted

5. FEF Max **(1050)** __ __ . __ __ L/S

The reported FEF_{25-75} corresponds to the maneuver where FEV_1 + FVC is maximized.

6. FEF_{25-75} **(1060)** __ . __ __ L/S

7. In your judgment, was the participant's spirometry technique acceptable? **(1070)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: (6000)

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* S P I R O *