ASTHMA CONTROL QUESTIONNAIRE

ENGLISH FOR NORTH AMERICA VERSION
(QUESTIONS 1 – 6 ONLY: QUESTION 7 (FEV_1) OMITTED)

For further information:

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Part. ID: - -
Part. Initials:
Visit:
Visit Date: / / 2 0
Coordinator ID:

Please answer questions 1 - 6.

Circle the number of the response that best describes how you have been during the past week.

1. On average, during the past week, how often were you woken by your asthma during the night?

0 Never
1 Hardly ever
2 A few times
3 Several times
4 Many times
5 A great many times
6 Unable to sleep because of asthma

2. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?

0 No symptoms
1 Very mild symptoms
2 Mild symptoms
3 Moderate symptoms
4 Quite severe symptoms
5 Severe symptoms
6 Very severe symptoms

3. In general, during the past week, how limited were you in your activities because of your asthma?

0 Not limited at all
1 Very slightly limited
2 Slightly limited
3 Moderately limited
4 Very limited
5 Extremely limited
6 Totally limited

4. In general, during the past week, how much shortness of breath did you experience because of your asthma?

0 None
1 A very little
2 A little
3 A moderate amount
4 Quite a lot
5 A great deal
6 A very great deal

5. In general, during the past week, how much of the time did you wheeze?

0 Not at all
1 Hardly any of the time
2 A little of the time
3 A moderate amount of the time
4 A lot of the time
5 Most of the time
6 All the time

6. On average, during the past week, how many puffs/inhalations of short-acting bronchodilator (e.g. Ventolin/Bricanyl) have you used each day?
(If you are not sure how to answer this question, please ask for help)

0 None
1 1 - 2 puffs/inhalations most days
2 3 - 4 puffs/inhalations most days
3 5 - 8 puffs/inhalations most days
4 9 - 12 puffs/inhalations most days
5 13 - 16 puffs/inhalations most days
6 More than 16 puffs/inhalations most days

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

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

* Please complete a Serious Adverse Event Reporting (SERIOUS) form.
** Please complete the appropriate Change in Medications form.
*** Please complete the Concomitant Medications (CMED) form.

AsthmaNet

ADULT ASTHMA AND ALLERGY HISTORY

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

(Coordinator Completed by Interview)

ASTHMA HISTORY

1. Approximately how old were you when chest symptoms suggesting asthma first appeared? *(Enter '00' if participant was under 1 year.)* **(1000)** __ __ years

   Did these symptoms appear immediately after or as a result of:

   1a. a respiratory infection such as a cold or pneumonia? **(1020)** ❑1 Yes ❑0 No ❑8 Don't Know

   1b. an occupational or job change? **(1030)** ❑1 Yes ❑0 No ❑8 Don't Know

   1c. a household move? **(1040)** ❑1 Yes ❑0 No ❑8 Don't Know

   ➔ If participant is male, skip to Q2.

   1d. a pregnancy? **(1050)** ❑1 Yes ❑0 No ❑8 Don't Know

   1e. a hormonal change (e.g., menopause)? **(1060)** ❑1 Yes ❑0 No ❑8 Don't Know

2. How old were you when a doctor first diagnosed you with asthma? **(1070)** __ __ years

3. Have any of your 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 your 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 your 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 have you had that required emergency care or an unscheduled office visit? **(1180)** __ __ episodes

   5b. Overnight hospitalizations have you had due to asthma? **(1190)** __ __ hospitalizations

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

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

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

6. Have you ever been admitted to an intensive care unit for asthma? **(1250)** ❑1 Yes ❑0 No
   ➔ If ***NO***, skip to Q7.

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

   6b. Have you ever had invasive mechanical ventilation? **(1270)** ❑1 Yes ❑0 No ❑8 Don't Know

   6c. Have you 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 your asthma?

7a.	Exercise/Sports/Play	(1290)	❑1 Yes	❑0 No	❑8 Don't Know
7b.	Menstrual cycle *(If participant is male or a postmenopausal 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 you were 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 you breathe in or are 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. Have you ever had eczema / atopic dermatitis (i.e., prolonged itchy, scaly skin rash)? (1470) ❑1 Yes ❑0 No ❑8 Don't Know

9a. If ***YES***, was your eczema diagnosed by a doctor? (1500) ❑1 Yes ❑0 No

10. Have any of your 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 you grow up in a household where you were exposed to tobacco smoke? **(1730)** ❑$_1$ Yes ❑$_0$ No

12. Do you currently smoke? **(1740)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q13.

    12a. Record smoking history in pack-years*. **(1750)** __ __ . __ pack-years

    ➔ **STOP HERE.**

13. Were you ever a smoker? **(1760)** ❑$_1$ Yes ❑$_0$ No
    ➔ If ***NO***, skip to Q14.

    13a. Record smoking history in pack-years*. **(1770)** __ __ . __ pack-years

14. Do you currently live in a household where you are exposed to tobacco smoke? **(1780)** ❑$_1$ Yes ❑$_0$ No

COMMENTS: **(6000)**

_____

_____

_____

*Pack-years = # packs per day X # years smoked at that quantity (1 pack contains 20 cigarettes)

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

UNITS, FREQUENCY, AND ROUTE CODES FOR USE ON THE CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS FORM (CMED)

AsthmaNet

Codes for Units (Q1040)	
Code	Units
1	mg
2	mcg (µg)
3	ml
4	mg/ml
5	mEq
6	g
7	U
8	teaspoon
9	tablespoon
10	patch
11	puffs (oral inhalation)
12	nasal spray
13	packet
14	1 drop
15	mm
16	percent
98	no units
99	other

Codes for Frequency (Q1050)		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at bedtime
12	PRN	as required
13	qod	every other day
14	qw	once a week
15	biw	2 times per week
16	tiw	3 times per week
17	5 times per week	
18	every 5 days	
19	once a month	
20	taper dose	
99	other	

Codes for Route (Q1055)	
Route	Route Desc
1	Epidural Injection
2	External/Topical
3	Inhalation
4	Intraarterial Injection
5	Intraarticular/Intracapsular Injection
6	Intramuscular Injection – IM
7	Intrathecal Injection
8	Intravenous Injection – IV
9	Medicated Gums
10	Misc. Injection
11	Nasal
12	Nebulization
13	Ophthalmic
14	Oral
15	Otic
16	Patch
17	Rectal
18	Subcutaneous Injection – SQ
19	Sublingual
20	Swallowed
21	Urological
22	Vaginal

AsthmaNet

COLD HISTORY

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.

Please answer the following questions with respect to your cold history over the past 12 months.

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

2. In the past 12 months, how many respiratory tract infections/colds did you experience? (Enter '00' if none.)
   ➔ If **'00'**, STOP HERE.
   (1010) __ __ colds in past 12 months

3. In the past 12 months, how severe were your colds usually?
   (1020) ❑1 Extremely mild
   ❑2 Mild
   ❑3 Moderate
   ❑4 Severe

4. In the past 12 months, has a cold EVER made your asthma worse?
   ➔ If **NO**, STOP HERE.
   (1030) ❑1 Yes ❑0 No

5. In the past 12 months, when you had a cold, how often did it make your asthma worse?
   (1040) ❑1 Rarely
   ❑2 Sometimes
   ❑3 Usually
   ❑4 Always

6. In the past 12 months, when colds made your asthma worse, how severe did your asthma usually get?
   (1050) ❑1 Extremely mild
   ❑2 Mild
   ❑3 Moderate
   ❑4 Severe

COMMENTS: **(6000)**

_____

_____

_____

COLD HX

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

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

ADULT 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. 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

3. Does the participant have a baseline (pre-diluent) FEV_1 less than 55% of predicted or less than 1.0 L? **(1060)** ☐1 Yes ☐0 No

4. Pregnancy test results **(1070)** ☐1 Positive ☐0 Negative ☐9 N/A
   (Check N/A if the participant is male, or is female and is post-menopausal, had a hysterectomy or tubal ligation.)

5. Is the participant's systolic blood pressure > 200 mm Hg or diastolic blood pressure > 100 mm Hg? **(1080)** ☐1 Yes ☐0 No

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

7. Is the participant eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? **(1110)** ☐1 Yes ☐0 No
   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.***

COMMENTS: **(6000)**

_____

METHACHK ADULT

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)**

_____

_____

_____

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)

_____

_____

_____

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)**

_____

_____

_____

* P R E G T E S T *

AsthmaNet

PRIOR CONDITIONS FOR ADULT PARTICIPANTS

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

(Coordinator Completed by Interview)

PRIOR DISEASES, ILLNESSES, AND SURGERIES

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

						If Yes, Comment
1.	Blood, Lymph, or Immune Systems	**(1000)**	❑1 Yes	❑0 No	**(1000D)**	_____
2.	Eyes	**(1010)**	❑1 Yes	❑0 No	**(1010D)**	_____
3.	Breasts	**(1020)**	❑1 Yes	❑0 No	**(1020D)**	_____
4.	Endocrine Systems	**(1030)**	❑1 Yes	❑0 No	**(1030D)**	_____
5.	Heart and Blood Vessels	**(1040)**	❑1 Yes	❑0 No	**(1040D)**	_____
6.	Liver or Pancreas	**(1050)**	❑1 Yes	❑0 No	**(1050D)**	_____
7.	Kidneys or Urinary Tract System	**(1060)**	❑1 Yes	❑0 No	**(1060D)**	_____
8.	Reproductive System	**(1070)**	❑1 Yes	❑0 No	**(1070D)**	_____
9.	Muscles or Bones	**(1080)**	❑1 Yes	❑0 No	**(1080D)**	_____
10.	Nervous System	**(1090)**	❑1 Yes	❑0 No	**(1090D)**	_____
11.	Psychiatric	**(1100)**	❑1 Yes	❑0 No	**(1100D)**	_____
12.	Drug Allergies	**(1110)**	❑1 Yes	❑0 No	**(1110D)**	_____
13.	Other	**(1120)**	❑1 Yes	❑0 No	**(1120D)**	_____

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)**

_____

_____

_____

"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

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

SINONASAL QUESTIONNAIRE

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

(Participant Completed)

Over the last 3 months how often, on average, did you have the following symptoms? Please check one box for each symptom.

		Never	1-4 times per month	2-6 times per week	Daily
Runny Nose	**(1000)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Post nasal drip	**(1010)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Need to blow your nose	**(1020)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Facial pain/pressure	**(1030)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$
Nasal obstruction	**(1040)**	❑$_0$	❑$_1$	❑$_2$	❑$_3$

Participant Source Documentation

Participant Initials: __ __ __ **(1050)**

Date: __ __ / __ __ / 20 __ __ **(1060)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1070)**

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)

_____

_____

_____

* S P I R O *

AsthmaNet

SPUTUM INDUCTION LAB VALUES

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

(Technician Completed)

Processing Sample

1. Processing Date **(1000)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)
2. Time processing started *(based on 24-hour clock)* **(1010)** __ __ __ __
3. Total Cell Count **(1020)** __ __ __ __. __ x 10^4 cells/ml

4. Was the participant's sputum sample processed within 4 hours after collection? **(1030)** ❑1 Yes ❑0 No

   ➔ ***If YES, send the sputum sample for reading.***
   ➔ ***If NO, STOP HERE and mark the samples as excluded in the Biological Sample Tracking module.***

COMMENTS: **(6000)**

_____

_____

_____

SPUTLAB

AsthmaNet

SPUTUM INDUCTION READ

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

(Technician Completed)

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

2. Rate slide's quality: **(1010)**
   - ❑1 Very good
   - ❑2 Good
   - ❑3 Acceptable
   - ❑4 Poor but readable
   - ❑5 Not readable

   ➔ Comment: **(6000)**
   _____
   _____
   _____
   _____

3. Record the number on the slide(s) that was (were) read **(1020)** __ **(1030)** __
   ➔ ***These are numbers that were assigned to the slides at each site.***

4. Total Cell Count **(1040)** __ __ __ __ . __ x 10^4 cells/ml
   ➔ ***Transcribe Total Cell Count from the Sputum Processing Worksheet.***

Differential Cell Counts

5. Squamous Cells **(1050)** __ __ . __ %

The parameters below are calculated following exclusion of squamous cells.

6. Epithelial Cells **(1060)** __ __ . __ %
7. Macrophages **(1070)** __ __ . __ %
8. Neutrophils **(1080)** __ __ . __ %
9. Eosinophils **(1090)** __ __ . __ %
10. Lymphocytes **(1100)** __ __ . __ %

SPUTREAD

AsthmaNet

SPUTUM INDUCTION

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

(Technician Completed)

Complete this form only if the participant is eligible according to the Sputum Induction Checklist (SPUTUMCHK) form.

(If attempting sputum induction for the first time in this protocol or participant has not had an adequate sample at prior attempts, do not complete Q1.)

1. For this protocol, what was the duration of sputum induction the first time the participant's sample was processed within 4 hours after collection? **(1000)** __ __ . __ minutes

   Duration of sputum induction at current visit should not exceed this.

2. Sputum induction start time *(based on 24-hour clock)* **(1010)** __ __ __ __

3. Sputum induction stop time *(based on 24-hour clock)* **(1020)** __ __ __ __

4. Duration of sputum induction collection phase at this visit **(1030)** __ __ . __ minutes

   4a. Was the duration ≥ 4 minutes? **(1040)** ❑1 Yes ❑0 No

5. Volume of sputum sample at this visit **(1050)** __ __ __ . __ ml

   5a. Is the volume adequate for processing? **(1060)** ❑1 Yes ❑0 No

6. Is the sample adequate for laboratory analysis? **(1070)** ❑1 Yes ❑0 No
   If either shaded box in Q4a or Q5a is completed, the sputum sample is not adequate and should not be sent for processing.

   ➔ ***If YES, the technician processing the sample should complete the Sputum Induction Lab Values (SPUTLAB) form.***

SPUTUM

7. Participant's FEV_1 immediately after completion of sputum induction:

7a.	FEV_1	**(1080)**	__ . __ __ L
7b.	FEV_1 (% predicted)	**(1090)**	__ __ __ % predicted
7c.	Time of FEV_1 in Q7a (based on 24-hour clock)	**(1100)**	__ __ __ __
7d.	Percent difference in FEV_1 $\frac{(\text{Reference} - \text{Q7a})}{\text{Reference}}$ X100	**(1110)**	__ __ . __ %

Reference = FEV_1 used for assessment of eligibility for SI.

7e. Did the participant's FEV_1 drop > 10% from reference FEV_1 as indicated in Q7d? **(1120)** ❑$_1$ Yes ❑$_0$ No

➔ ***If NO, STOP HERE and continue with remaining visit procedures.***

➔ ***If YES, proceed to the Additional Treatment for Sputum Induction (SPUTUM_ADD_TRT) form.***

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

SPUTUM INDUCTION CHECKLIST

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).

(Only complete Q1 for participants who completed a methacholine challenge at this visit.)

1. Was the participant's FEV_1 after reversal from the methacholine challenge ≥ 90% of the baseline FEV_1 (i.e., greater than or equal to the methacholine reversal reference value (B) in the gray box on the Methacholine Challenge Testing (METHA) form)? **(1000)** ☐$_1$ Yes ☐$_0$ No

   1a. If ***NO***, has the participant received permission from the supervising physician to proceed with sputum induction testing? **(1010)** ☐$_1$ Yes ☐$_0$ No

   Physician's Signature: **(1020)** _____

2. Participant's FEV_1 used for assessment of eligibility for sputum induction **(1030)** __ . __ __ L

3. Participant's FEV_1 (% predicted) used for assessment of eligibility for sputum induction **(1040)** __ __ __ % predicted

4. Was the participant's FEV_1 (% predicted) from Q3 ≥ 50% predicted? **(1050)** ☐$_1$ Yes ☐$_0$ No

5. Is there any other reason the participant should not proceed with sputum induction? **(1060)** ☐$_1$ Yes ☐$_0$ No

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

   _____

6. Is the participant eligible for sputum induction? **(1070)** ☐$_1$ Yes ☐$_0$ No
   If any of the shaded boxes are completed, the participant is NOT eligible for sputum induction.

   ➔ ***If YES, proceed to the Sputum Induction (SPUTUM) form.***

COMMENTS: **(6000)**

_____

_____

AsthmaNet

ADDITIONAL TREATMENT POST SPUTUM INDUCTION

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

(Technician Completed)

Complete this form only if the participant has experienced > 10% fall in FEV_1 immediately after completion of sputum induction.

Clinic Use Only

Sputum Induction Reversal Reference Value: *Reference X 0.90 = __ . __ __ L*

Reference = FEV_1 used for assessment of eligibility for Sputum Induction.

➔ Administer 2 puffs of albuterol and wait 10-15 minutes, then perform spirometry.

1. Participant's FEV_1 after initial 2 puffs of albuterol

   1a. FEV_1 **(1000)** __ . __ __ L

   1b. FEV_1 (% predicted) **(1010)** __ __ __ % predicted

   1c. Time of FEV_1 from Q1a *(based on 24-hour clock)* **(1020)** __ __ __ __

   1d. Was the FEV_1 from Q1a ≥ the sputum induction reversal reference value in the gray box above? **(1030)** ❑$_1$ Yes ❑$_0$ No
   - ➔ If **YES**, stop here and continue with remaining visit procedures.
   - ➔ If **NO**, administer 2 puffs of albuterol and wait 10-15 minutes, then perform spirometry. Proceed to Q2.

2. Participant's FEV_1 after 2 additional puffs of albuterol

   2a. FEV_1 **(1040)** __ . __ __ L

   2b. FEV_1 (% predicted) **(1050)** __ __ __ % predicted

   2c. Time of FEV_1 from Q2a *(based on 24-hour clock)* **(1060)** __ __ __ __

   2d. Was the FEV_1 from Q2a ≥ the sputum induction reversal reference value in the gray box above? **(1070)** ❑$_1$ Yes ❑$_0$ No
   - ➔ If **NO**, complete the source documentation box below.

Physician Source Documentation

Physician Signature: _____ **(1080)**

Date: __ __ / __ __ / 20 __ __ **(1090)**
MM DD YYYY

Time: __ __ __ __ *(based on a 24-hour clock)* **(1100)**

SPUTUM ADD TRT

AsthmaNet

MICROBIOME ASTHMA MONITORING LOG

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

Part. Initials: __ __ __

Return Visit: __ __

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

Coordinator ID: __ __ __ __

To the Participant: Please record your daily RESCUE Ventolin® inhaler puffs on this log. Please do not include preventive puffs. Use your RESCUE inhaler as instructed in the handout "If Your Asthma Gets Worse." Contact study personnel if you are experiencing extreme symptoms.

If you have taken at least __ __ puffs per 24 hours for the past 48 hours from your RESCUE Ventolin® inhaler, contact study personnel.

Please record any non-study medications you have taken and details of any medical problems you have experienced since your last study visit on the back of this log.

(Visit 2 only) Participant's baseline rescue use value __ __ puffs/day **(1000)**

Date (ddate)	**Total RESCUE Puffs Used** (1010)	**Comments**
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
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__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	

Date (ddate)	**Total RESCUE Puffs Used** (1010)	**Comments**
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	
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__ __/__ __	__ __	
__ __/__ __	__ __	
__ __/__ __	__ __	

Participant Notes

Non-Study Medications

Please indicate any non-study medications (both prescription and over-the-counter) taken for any reason.

Medication Name	Dosage/Frequency	Dates Taken	Reason

Medical Problems

Please indicate any medical problems you experience, as well as the severity of each (mild, moderate, severe). If you experience an asthma attack (refer to the "If Your Asthma Gets Worse" handout) or significant illness, contact study personnel within 72 hours.

Problem Description	Dates/Times	Severity (mild, moderate, severe)	Comments

Coordinator Completed

COMMENTS

(6000):_____

_____

_____

* P 3 A S T H M A L O G *

AsthmaNet

MICROBIOME BRONCHOSCOPY PROCEDURE DOCUMENTATION

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

(Coordinator or RN Completed)

PRE-PROCEDURE

1. Subject is classified as **(1000)** ❑1 Asthmatic ❑2 Non-asthmatic

2. Vital Signs

   2a. Blood pressure **(1010-1020)** __ __ __ / __ __ __ mm Hg (systolic / diastolic)

   2b. Pulse **(1030)** __ __ __ / min

   2c. Respirations **(1040)** __ __ / min

   2d. Temperature **(1050)** __ __ __ . __ °Fahrenheit

   2e. Pulse Oximetry **(1060)** __ __ __ % sat

3. FEV_1

   3a. Pre-bronchodilator % predicted **(1070)** __ __ __ % predicted

   3b. Post-bronchodilator (4 puffs) % predicted **(1080)** __ __ __ % predicted

4. Has participant signed informed consent for bronchoscopy procedure? **(1090)** ❑1 Yes ❑0 No

5. Has participant refrained from eating and drinking for 8 hours? **(1100)** ❑1 Yes ❑0 No

6. Has participant refrained from taking drugs that interfere with clotting (e.g., aspirin or NSAID) for 7 days? **(1110)** ❑1 Yes ❑0 No

7. Has investigator reviewed recent history and physical from Visit 1 and Microbiome Bronchoscopy Checklist? **(1120)** ❑1 Yes ❑0 No

8. Is the name and telephone number (contact information) of the responsible adult to whom the participant will be discharged documented and readily available? **(1130)** ❑1 Yes ❑0 No

➔ ***If any of the questions in Q4 – Q8 are answered <u>NO</u>, STOP HERE. Bronchoscopy should not be performed. Set the P3_BPD form to missing in the database. The form should still be forwarded to the DCC.***

PROCEDURE

9. Coordinator or RN Name* **(1140)** _____

10. Bronchoscopist Name **(1150)** _____

11. Lidocaine Lot Numbers

    11a. 1% Lidocaine **(1160)** __ __ - __ __ __ - __ __

    11b. 2% Lidocaine **(1170)** __ __ - __ __ __ - __ __

12. Saline Lot Numbers

    12a. Saline Bag **(1180)** __ __ __ __ __ __ __

    12b. Saline Syringes **(1190)** __ __ __ __ __ __ __

13. Start Time of Topical Anesthesia *(based on 24-hour clock)* **(1200)** __ __ __ __

14. Total Lidocaine Dose **(1210)** __ __ __ mg

    14a. Lidocaine below Vocal Cords **(1220)** __ __ __ mg

15. Supplemental O_2 **(1230)** __ __ . __ L / min

16. Bronchoscopy Medications:			If ***YES***, indicate route:	If ***YES***, indicate dose:
16a. Atropine	**(1240-1260)**	❑1 Yes	❑1 IM ❑2 IV	__ . __ mg
16b. Glycopyrolate	**(1270-1290)**	❑1 Yes	❑1 IM ❑2 IV	0 . __ mg
16c. Midazolam	**(1300-1320)**	❑1 Yes	❑1 IM ❑2 IV	__ __ . __ mg
16d. Fentanyl	**(1330-1350)**	❑1 Yes	❑1 IM ❑2 IV	__ __ __ mcg
16e. Other (describe and indicate dose)	**(1360-1360D)**	❑1 Yes	_____	

* Individual completing form, present during bronchoscopy

17. Vital Signs Immediately Before Bronchoscope Introduced

17a. Blood Pressure **(1370-1380)** __ __ __ / __ __ __ mm Hg (systolic / diastolic)

17b. Pulse **(1390)** __ __ __ / min

17c. Respirations **(1400)** __ __ / min

17d. Pulse Oximetry **(1410)** __ __ __ % sat

18. Time of Scope Entry *(based on 24-hour clock)* **(1420)** __ __ __ __

19. Time of Scope Withdrawal *(based on 24-hour clock)* **(1430)** __ __ __ __

20. Protected Brushings

20a. Protected Brushings From**: **(1440)**
- ❑1 Right lower lobe
- ❑2 Left lower lobe

20b. Number of Protected Brushings: **(1450)** __ __

21. Bronchoalveolar Lavage

21a. Lavage From**: **(1460)**
- ❑1 Right middle lobe
- ❑2 Lingula, Left upper lobe

21b. Volume In **(1470)** __ __ __ ml

21c. Volume Out **(1480)** __ __ __ ml

** Side of brushings and lavage determined by coin toss at Visit 2; opposite side will be sampled in the asthmatic participants at Visit 5.

ADVERSE EVENTS DURING OR AFTER THE PROCEDURE

22. Did the participant experience any adverse events during or immediately after the procedure? **(1490)** ❑1 Yes ❑0 No

➔ ***If YES, complete Q22a-Q22o and the Clinical Adverse Events (AECLIN) form.***
➔ If ***NO***, skip to Q23.

22a. Allergic reaction	**(1500)**	❑1 Yes	❑0 No
22b. Arrhythmias	**(1510)**	❑1 Yes	❑0 No
22c. Aspiration	**(1520)**	❑1 Yes	❑0 No
22d. Death	**(1530)**	❑1 Yes	❑0 No
22e. Extended recovery: 6+ hours	**(1540)**	❑1 Yes	❑0 No
22f. Hospitalization	**(1550)**	❑1 Yes	❑0 No
22g. Hypotension needing treatment	**(1560)**	❑1 Yes	❑0 No
22h. Laryngeal spasm	**(1570)**	❑1 Yes	❑0 No
22i. Major bleeding (> 50 ml)	**(1580)**	❑1 Yes	❑0 No
22j. Pneumothorax	**(1590)**	❑1 Yes	❑0 No
22k. Hypoxia (SaO_2 < 90%)	**(1600)**	❑1 Yes	❑0 No
22ki. If ***YES***, indicate the duration in minutes:	**(1610)**	__ __ __ minutes	
22l. Need for supplemental O_2 for ≥ 2 hours post procedure	**(1620)**	❑1 Yes	❑0 No
22m. Respiratory arrest	**(1630)**	❑1 Yes	❑0 No
22n. Seizure	**(1640)**	❑1 Yes	❑0 No
22o. Other	**(1650)**	❑1 Yes	❑0 No
22oi. If ***YES***, describe:	**(1650D)**	_____	

23. Was bronchoscopy completed as intended? **(1660)** ❑1 Yes ❑0 No

➔ ***If NO, describe below any aspect of the actual bronchoscopy that differed from planned procedure.***

Bronchoscopy Comments: **(6000)**

_____

_____

_____

POST-PROCEDURE (up until discharge)

24. Did the participant experience any of the following post-bronchoscopy?

24a. Cough	**(1670)**	❑$_1$ Yes	❑$_0$ No
24b. Chest Pain	**(1680)**	❑$_1$ Yes	❑$_0$ No
24c. Shortness of breath	**(1690)**	❑$_1$ Yes	❑$_0$ No
24d. Nausea or vomiting	**(1700)**	❑$_1$ Yes	❑$_0$ No
24e. More than trace hemoptysis	**(1710)**	❑$_1$ Yes	❑$_0$ No

If an adverse event occurred (i.e. including any of the above, if more severe than is customary following bronchoscopy), please complete the Clinical Adverse Events (AECLIN) form.

25. Was albuterol given? **(1720)** ❑$_1$ Yes ❑$_0$ No

25a. If ***YES***, dose administered? **(1730-1735)** __ __ ❑$_1$ nebulizations ❑$_2$ puffs

26. Time of first Spirometry Measurement after bronchoscopy *(based on 24-hour clock)* **(1740)** __ __ __ __

27. Time of final Spirometry Measurement after bronchoscopy *(based on 24-hour clock)* **(1750)** __ __ __ __

28. Was final $FEV_1 \geq 90\%$ of prebronchodilator FEV_1? **(1760)** ❑$_1$ Yes ❑$_0$ No

28a. If ***NO***, name of physician notified about the participant prior to discharge: **(1760D)** _____

29. Valid contact information reviewed? **(1770)** ❑$_1$ Yes ❑$_0$ No

Phone Contact By:	**Date (mm/dd/yyyy)** / **Time (based on 24-hour clock)**	**Albuterol puffs since discharge? +**	**Participant progressing satisfactorily?**	**Any adverse events since bronchoscopy?**	**Initials of Person Making Contact**
❑ MD ❑ RN ❑ Coordinator	__ __ /__ __ / 20 __ __ __ __ __ __	__ __ puffs	❑ Yes ❑ No	❑ Yes ❑ No	__ __ __

***If an adverse event occurred, please complete the Clinical Adverse Events (AECLIN) form*.**

POST-PROCEDURE (day after discharge)

30. Did the participant experience any of the following after discharge?

30a. Cough **(1780)** ❑$_1$ Yes ❑$_0$ No

30ai. If ***YES***, indicate how many hours **(1790)** __ __ hours

30b. Chest Pain **(1800)** ❑$_1$ Yes ❑$_0$ No

30bi. If ***YES***, indicate how many hours **(1810)** __ __ hours

30c. Shortness of breath **(1820)** ❑$_1$ Yes ❑$_0$ No

30ci. If ***YES***, indicate how many hours **(1830)** __ __ hours

30d. Nausea or vomiting **(1840)** ❑$_1$ Yes ❑$_0$ No

30di. If ***YES***, indicate how many hours **(1850)** __ __ hours

30e. More than trace hemoptysis **(1860)** ❑$_1$ Yes ❑$_0$ No

30ei. If ***YES***, indicate how many hours **(1870)** __ __ hours

If an adverse event occurred (i.e. including any of the above, if more severe than is customary following bronchoscopy), please complete the Clinical Adverse Events (AECLIN) form.

31. Has the participant required any of the following since bronchoscopy?

31a. Tyleonol, ibuprofen	**(1880)**	❑$_1$ Yes	❑$_0$ No
31b. Antibiotics	**(1890)**	❑$_1$ Yes	❑$_0$ No
31c. Prednisone	**(1900)**	❑$_1$ Yes	❑$_0$ No
31d. Increased bronchodilators	**(1910)**	❑$_1$ Yes	❑$_0$ No
31e. Change in asthma medications	**(1920)**	❑$_1$ Yes	❑$_0$ No

➔ ***If <u>YES</u>, please record on Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.***

32. Did the participant notice a loss of asthma control after discharge?	**(1930)**	❑$_1$ Yes ❑$_0$ No
32a. If ***YES***, for how many hours after bronchoscopy?	**(1940)**	__ __ hours
33. Did the participant experience a fever since the bronchoscopy?	**(1950)**	❑$_1$ Yes ❑$_0$ No
33a. If ***YES*** and measured by a thermometer, how high was the fever?	**(1960)**	__ __ __ . __ °Fahrenheit
33b. If ***YES***, how long did it last?	**(1970)**	__ __ hours
34. Did the participant experience more than trace hemoptysis > 4 hours after bronchoscopy?	**(1980)**	❑$_1$ Yes ❑$_0$ No
34a. If ***YES***, was its quantity:	**(1990)**	❑$_1$ < 1 teaspoon ❑$_2$ ≥ 1 teaspoon and ≤ 1 Tablespoon ❑$_3$ > 1 Tablespoon

AsthmaNet	MICROBIOME BRONCHOSCOPY CHECKLIST ASTHMATIC	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Technician ID: __ __ __ __

(Coordinator Completed)

The Bronchoscopy procedure and its related risks must be reviewed again at this visit. The participant must initial and date the appropriate consent to confirm that the bronchoscopy procedure has been reviewed one more time and that he/she is willing to undergo the procedure.

1.	Has the participant initialed and dated the appropriate consent form to confirm that the bronchoscopy procedure and its related risks have been reviewed again at this visit?	**(1000)**	❑1 Yes ❑0 No
2.	Is the participant's postbronchodilator $FEV_1 \geq 70\%$ predicted after 4 puffs of albuterol?	**(1010)**	❑1 Yes ❑0 No
3.	Is the participant's pulse oximetry demonstrating oxygen saturation of < 90% on room air?	**(1020)**	❑1 Yes ❑0 No
4.	Pregnancy test results *(Check N/A if the participant is male, or is female and is post-menopausal, had a hysterectomy or tubal ligation.)*	**(1030)**	❑1 Positive ❑0 Negative ❑9 N/A
5.	Within the past 6 months, has the participant experienced more than 2 asthma exacerbations requiring systemic corticosteroid treatment?	**(1040)**	❑1 Yes ❑0 No
6.	***(Visit 5 only)*** Did the participant receive systemic corticosteroid treatment for a significant asthma exacerbation since Visit 2?	**(1050)**	❑1 Yes ❑0 No
7.	Since Visit 1, has the participant had an ED visit or hospitalization for asthma?	**(1060)**	❑1 Yes ❑0 No
8.	Within the last 48 hours, did the participant use an average of > 8 puffs per 24 hours from his/her rescue inhaler?	**(1070)**	❑1 Yes ❑0 No
9.	Is the participant's Asthma Control Questionnaire Score, as calculated on the ACQ_SCORE form, ≤ 1.5?	**(1080)**	❑1 Yes ❑0 No
10.	Has a responsible adult, to whom the participant will be discharged, been identified?	**(1090)**	❑1 Yes ❑0 No
11.	Is there any other reason the participant should not proceed with bronchoscopy?	**(1100)**	❑1 Yes ❑0 No
	11a. If ***YES***, explain:	**(1100D)**	_____

12. Is the participant eligible to proceed with the bronchoscopy procedure? **(1110)** ❑1 Yes ❑0 No

If any of the shaded boxes are filled in, the participant is ineligible for the bronchoscopy procedure.

- ➔ ***If YES, continue with the remaining visit procedures.***
- ➔ ***Visit 2: If NO, complete the Microbiome Termination of Study Participation (P3_TERM_A) form.***
- ➔ ***Visit 5: If NO, and the participant is not eligible due to Q2 or Q3 only, STOP HERE. DO NOT send this form to the DCC and reschedule visit.***

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

MICROBIOME BRONCHOSCOPY CHECKLIST CONTROL

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

(Coordinator Completed)

The Bronchoscopy procedure and its related risks must be reviewed again at this visit. The participant must initial and date the appropriate consent to confirm that the bronchoscopy procedure has been reviewed one more time and that he/she is willing to undergo the procedure.

1. Has the participant initialed and dated the appropriate consent form to confirm that the bronchoscopy procedure and its related risks have been reviewed again at this visit? **(1000)** ☐1 Yes ☐0 No

2. Is the participant's prebronchodilator $FEV_1 \geq 80\%$ predicted? **(1010)** ☐1 Yes ☐0 No

3. Is the participant's pulse oximetry demonstrating oxygen saturation of < 90% on room air? **(1020)** ☐1 Yes ☐0 No

4. Pregnancy test results *(Check N/A if the participant is male, or is female and is post-menopausal, had a hysterectomy or tubal ligation.)* **(1030)** ☐1 Positive ☐0 Negative ☐9 N/A

5. Has a responsible adult, to whom the participant will be discharged, been identified? **(1090)** ☐1 Yes ☐0 No

6. Is there any other reason the participant should not proceed with bronchoscopy? **(1100)** ☐1 Yes ☐0 No

   6a. If ***YES***, explain: **(1100D)** _____

7. Is the participant eligible to proceed with the bronchoscopy procedure? **(1110)** ☐1 Yes ☐0 No

   If any of the shaded boxes are filled in, the participant is ineligible for the bronchoscopy procedure.

   ➔ ***If YES, continue with the remaining visit procedures.***

   ➔ ***If NO, complete the Microbiome Termination of Study Participation (P3_TERM_C) form.***

COMMENTS: **(6000)**

_____

_____

_____

P3 BRONCHCHK C

AsthmaNet

MICROBIOME COMPLIANCE CHECKLIST

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

(Coordinator Completed)

Check the following compliance criteria at Visits 3-5.

At Visit 3, if participant demonstrates ≥ 75% compliance with study medication, continue with visit. If not, re-emphasize the importance of maintaining daily dosing schedule and reschedule Visit 3 in 10-14 days.

1. Scheduled Diskus® Compliance

   1a. Number of scheduled puffs since the last visit **(1000)** __ __ __ puffs

   1b. Number of remaining puffs reflected on scheduled Diskus® counter* **(1010)** __ __ __ puffs

   1c. Number of puffs taken = 60* – Q1b **(1020)** __ __ __ puffs

   ➔ ***Note: If Visit 3, and Visit 3 was rescheduled due to compliance being less than 75%, calculate number of puffs taken using Q1b on previous Visit 3 P3_COMPLY form: Number of puffs taken = Q1b (previous Visit 3 P3_COMPLY) – Q1b (current Visit 3 P3_COMPLY)***

   ****<u>If more than one Diskus® is returned to you</u>, please record remaining puffs on Diskus® 1 + remaining puffs on Diskus® 2 for Q1b, and record 120-Q1b for Q1c.***

   1d. Percent compliance = $\frac{\text{Q1c}}{\text{Q1a}}$ X 100 **(1030)** __ __ __ . __ %

   ➔ ***If the participant took less than 75% of the scheduled Diskus® puffs, re-emphasize the importance of maintaining the daily dosing schedule.***

COMMENTS: (6000)

_____

_____

_____

P3 COMPLY

AsthmaNet

MICROBIOME COORDINATOR STUDY TREATMENT QUESTIONNAIRE

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

(Coordinator Completed)

This questionnaire is to be completed at Visit 5 by the AsthmaNet coordinator who was primarily responsible for the participant's Microbiome visits during the preceding 8 weeks. If a randomized participant terminates prior to Visit 5, this form should be completed at the time of the termination visit.

1. **Blinded Scheduled Diskus**

   Participants in the Microbiome study were randomized to receive either fluticasone Diskus or placebo Diskus. You were blinded to the actual treatment assignment. Please check the box that most closely represents your feelings about the treatment the participant received **during the randomized treatment period (Visit 2 through Visit 5)**.

(1000)

- ❑1 I am certain the Diskus contained placebo.
- ❑2 I think the Diskus probably contained placebo.
- ❑3 I have no idea which type of Diskus the participant received, but my guess would be:

(1010)

- ❑1 Placebo
- ❑2 Fluticasone

- ❑4 I think the Diskus probably contained fluticasone.
- ❑5 I am certain the Diskus contained fluticasone.

2. Please comment with respect to any other observations you made that helped you make your choice in Q1. **(1015D)**

_____

_____

_____

_____

Coordinator Source Documentation

Coordinator's Initials: __ __ __ **(1020)**

Date: __ __ / __ __ / 20 __ __ **(1030)**
MM DD YYYY

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 0 ASTHMATIC

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

(Coordinator Completed)

1. Did the participant sign the Microbiome Informed Consent document? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, record the date the consent form was signed. **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Is the participant between 18 and 60 years of age, inclusive? **(1020)** ❑1 Yes ❑0 No

3. Is the participant willing to undergo fiberoptic bronchoscopy with endobronchial brushings and bronchial lavage? **(1030)** ❑1 Yes ❑0 No

4. Is the participant willing to give blood for safety variable measurements? **(1040)** ❑1 Yes ❑0 No

5. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for Microbiome (P3_EXCLMED) reference card, or any chronic diseases (other than asthma) that would prevent participation in the trial or put the participant at risk by participation? **(1050)** ❑1 Yes ❑0 No

   5a. If ***YES***, describe: **(1050D)** _____

6. Does the participant have a history of atrial or ventricular tachyarrhythmia? **(1060)** ❑1 Yes ❑0 No

7. Does the participant have a history of a bleeding disorder? **(1070)** ❑1 Yes ❑0 No

8. Has the participant had an upper respiratory infection (cold) within the past 6 weeks? **(1080)** ❑1 Yes ❑0 No

9. Has the participant had sinusitis or bronchitis with purulent nasal discharge or sputum (i.e., thick, yellow mucus) within the past 3 months? **(1090)** ❑1 Yes ❑0 No

10. On more than 7 days during the past 6 weeks, has the participant had thick or discolored post-nasal drip or nasal discharge associated with facial pain, facial pressure, or maxillary tooth pain, causing moderate or severe discomfort? **(1100)** ❑1 Yes ❑0 No

11. At times other than after a viral respiratory infection, does the participant commonly have a cough productive of mucus? **(1110)** ❑1 Yes ❑0 No

12. When the participant has a cold, how often does it cause a cough productive of mucus? **(1120)**
    - ❑0 Never
    - ❑1 Rarely
    - ❑2 Sometimes
    - ❑3 Usually
    - ❑4 Always

13. Has the participant experienced a change in bowel function (e.g., diarrheal illness) in the past 4 weeks? **(1125)** ❑1 Yes ❑0 No

14. Is the participant currently taking any medications listed on the Exclusionary Drugs for Microbiome (P3_EXCLDRUG) reference card? **(1130)** ❑1 Yes ❑0 No

    14a. If ***YES***, list: **(1130D)** _____

    14b. If ***YES***, is the participant able to go off these medications for the required washout period prior to Visit 1 and for the duration of the study? **(1140)** ❑1 Yes ❑0 No
    ➔ Seek investigator input, as needed.

15. Has the participant taken any antibiotic (except for topical) within the past 3 months? **(1150)** ❑1 Yes ❑0 No

16. Has the participant used 10 or more doses of a nasal corticosteroid in the past 3 months? **(1160)** ❑1 Yes ❑0 No

17. Has the participant used any smokeless tobacco products (e.g., chew, snuff) in the past year? **(1170)** ❑1 Yes ❑0 No

18. Has the participant smoked cigarettes, a pipe, cigar, marijuana, or any other substance in the past year? **(1180)** ❑1 Yes ❑0 No

19. Does the participant have a smoking history of 5 or more pack-years? **(1190)** ❑1 Yes ❑0 No

    ➔ Note: Pack-year history will be recorded on the Adult Asthma and Allergy History (ASTHMA_HX_ADULT) form at Visit 1 if the participant is eligible to continue.

20. Has the participant received a physician diagnosis of asthma at least 12 months ago? **(1200)** ❑1 Yes ❑0 No

21. Does the participant plan to move away from the clinical site in the upcoming 3 months such that his/her ability to complete the study will be jeopardized? **(1210)** ❑1 Yes ❑0 No

22. Has the participant had an ED visit or hospitalization for asthma within the past 6 months? **(1220)** ❑1 Yes ❑0 No

23. Has the participant had an asthma exacerbation requiring systemic corticosteroid treatment in the past 5 years? **(1230)** ❑1 Yes ❑0 No

➔ If ***NO***, skip to Q24.

23a. How many exacerbations required oral corticosteroids? **(1240)** __ __

23b. Has the participant had more than 2 asthma exacerbations requiring systemic corticosteroids within the past 6 months? **(1250)** ❑1 Yes ❑0 No

23c. Has the participant experienced an asthma exacerbation requiring systemic corticosteroid treatment in the past 3 months? **(1260)** ❑1 Yes ❑0 No

24. Has the participant used a long-term asthma controller medication (inhaled or oral corticosteroid, leukotriene modifier, cromolyn or theophylline) within the past 6 months? **(1270)** ❑1 Yes ❑0 No

25. Is the participant potentially able to bear children? (*If participant is male, check N/A and go to Q26.)* **(1310)** ❑1 Yes ❑0 No ❑9 N/A

25a. If ***YES***, is the participant currently pregnant or lactating? **(1320)** ❑1 Yes ❑0 No

25b. If ***YES***, does the participant agree to use one of the approved methods indicated on the Birth Control Methods (BIRTH_CTRL) reference card for the duration of the study? **(1330)** ❑1 Yes ❑0 No

26. Is the participant's Asthma Control Questionnaire Score, as calculated on the ACQ_SCORE form, ≤ 1.5? **(1340)** ❑1 Yes ❑0 No

27. Is the participant eligible to proceed? **(1350)** ❑1 Yes ❑0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES,*** **proceed with remaining Visit 0 procedures.**

Participant Source Documentation

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

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

COMMENTS: (6000)

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 0 CONTROL

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

(Coordinator Completed)

1. Did the participant sign the Microbiome Informed Consent document? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, record the date the consent form was signed. **(1010)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

2. Is the participant between 18 and 60 years of age, inclusive? **(1020)** ❑1 Yes ❑0 No

3. Is the participant willing to undergo fiberoptic bronchoscopy with endobronchial brushings and bronchial lavage? **(1030)** ❑1 Yes ❑0 No

4. Is the participant willing to give blood for safety variable measurements? **(1040)** ❑1 Yes ❑0 No

5. Does the participant have current evidence of any of the conditions listed on the Exclusionary Medical Conditions for Microbiome (P3_EXCLMED) reference card, or any chronic diseases (including asthma) that would prevent participation in the trial or put the participant at risk by participation? **(1050)** ❑1 Yes ❑0 No

   5a. If ***YES***, describe: **(1050D)** _____

6. Does the participant have a history of atrial or ventricular tachyarrhythmia? **(1060)** ❑1 Yes ❑0 No

7. Does the participant have a history of a bleeding disorder? **(1070)** ❑1 Yes ❑0 No

8. Has the participant had an upper respiratory infection (cold) within the past 6 weeks? **(1080)** ❑1 Yes ❑0 No

9. Has the participant had sinusitis or bronchitis with purulent nasal discharge or sputum (i.e., thick, yellow mucus) within the past 3 months? **(1090)** ❑1 Yes ❑0 No

10. On more than 7 days during the past 6 weeks, has the participant had thick or discolored post-nasal drip or nasal discharge associated with facial pain, facial pressure, or maxillary tooth pain, causing moderate or severe discomfort? **(1100)** ❑1 Yes ❑0 No

11. At times other than after a viral respiratory infection, does the participant commonly have a cough productive of mucus? **(1110)** ❑1 Yes ❑0 No

P3 ELIGOC

12. When the participant has a cold, how often does it cause a cough productive of mucus? **(1120)**
- ❑0 Never
- ❑1 Rarely
- ❑2 Sometimes
- ❑3 Usually
- ❑4 Always

13. Has the participant experienced a change in bowel function (e.g., diarrheal illness) in the past 4 weeks? **(1125)** ❑1 Yes ❑0 No

14. Is the participant currently taking any medications listed on the Exclusionary Drugs for Microbiome (P3_EXCLDRUG) reference card? **(1130)** ❑1 Yes ❑0 No

14a. If ***YES***, list: **(1130D)** _____

14b. If ***YES***, is the participant able to go off these medications for the required washout period prior to Visit 1 and for the duration of the study? **(1140)** ❑1 Yes ❑0 No
➔ Seek investigator input, as needed.

15. Has the participant taken any antibiotic (except for topical) within the past 3 months? **(1150)** ❑1 Yes ❑0 No

16. Has the participant used 10 or more doses of a nasal corticosteroid in the past 3 months? **(1160)** ❑1 Yes ❑0 No

17. Has the participant used any smokeless tobacco products (e.g., chew, snuff) in the past year? **(1170)** ❑1 Yes ❑0 No

18. Has the participant smoked cigarettes, a pipe, cigar, marijuana, or any other substance in the past year? **(1180)** ❑1 Yes ❑0 No

19. Does the participant have a smoking history of 5 or more pack-years? **(1190)** ❑1 Yes ❑0 No

20. Has the participant received a physician diagnosis of asthma? **(1200)** ❑1 Yes ❑0 No

21. Was the participant ever a smoker? **(1290)** ❑1 Yes ❑0 No

➔ If ***NO***, skip to Q22.

21a. Record smoking history in pack-years* **(1300)** __ __ . __ pack-years

*Pack-years = # packs per day X # years smoked at that quantity (1 pack contains 20 cigarettes)

22. Is the participant potentially able to bear children? (*If participant is male, check N/A and go to Q23.)* **(1310)** ❑1 Yes ❑0 No ❑9 N/A

22a. If ***YES***, is the participant currently pregnant or lactating? **(1320)** ❑1 Yes ❑0 No

23. Is the participant eligible to proceed? **(1350)** ❑1 Yes ❑0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES,*** **proceed with remaining Visit 0 procedures.**

Participant Source Documentation

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

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

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 1 ASTHMATIC

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

(Coordinator Completed)

1. Is the participant atopic, as indicated by a positive Phadiatop result? **(1000)** ☐1 Yes ☐0 No

2. Since Visit 0, has the participant been treated with any corticosteroid (except for topical)? **(1010)** ☐1 Yes ☐0 No

3. Since Visit 0, has the participant experienced a respiratory infection? **(1020)** ☐1 Yes ☐0 No

4. Since Visit 0, has the participant been treated with any antibiotic (except for topical)? **(1030)** ☐1 Yes ☐0 No

5. Has the participant taken any medications listed on the Exclusionary Drugs for Microbiome (P3_EXCLDRUG) reference card within the specified time periods? **(1040)** ☐1 Yes ☐0 No

   5a. If ***YES***, list: **(1040D)** _____

6. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications (P3_MEDALLOW) reference card? **(1050)** ☐1 Yes ☐0 No

   6a. If ***YES***, list: **(1050D)** _____

7. Since Visit 0, has the participant experienced a significant asthma exacerbation? **(1060)** ☐1 Yes ☐0 No

8. Is the participant eligible to proceed? **(1070)** ☐1 Yes ☐0 No

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If NO, complete a Termination of Study Participation (P3_TERM_A) form.***

Participant Source Documentation
Participant Initials: __ __ __ **(1080)**
Date: __ __ / __ __ / 20 __ __ **(1090)**
MM DD YYYY

COMMENTS: **(6000)**

_____

P3 ELIG1A

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 1 CONTROL

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

(Coordinator Completed)

1. Is the participant atopic, as indicated by a positive Phadiatop result? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***NO***, does the participant have a history of any of the following:

   1a. Allergic rhinitis (i.e. seasonal runny nose, nasal congestion)? **(1001)** ❑1 Yes ❑0 No

   1b. Allergic conjunctivitis (i.e. seasonal itchy eyes)? **(1002)** ❑1 Yes ❑0 No

   1c. Eczema (i.e. rash in crook of elbow or bend of knee)? **(1003)** ❑1 Yes ❑0 No

   1d. Anaphylaxis to food or stinging insects? **(1005)** ❑1 Yes ❑0 No

   1e. Hives/urticaria to food or stinging insects? **(1008)** ❑1 Yes ❑0 No

2. Since Visit 0, has the participant been treated with any corticosteroid (except for topical)? **(1010)** ❑1 Yes ❑0 No

3. Since Visit 0, has the participant experienced a respiratory infection? **(1020)** ❑1 Yes ❑0 No

4. Since Visit 0, has the participant been treated with any antibiotic (except for topical)? **(1030)** ❑1 Yes ❑0 No

5. Has the participant taken any medications listed on the Exclusionary Drugs for Microbiome (P3_EXCLDRUG) reference card within the specified time periods? **(1040)** ❑1 Yes ❑0 No

   5a. If ***YES***, list: **(1040D)** _____

6. Is the participant currently taking prescription or OTC medication(s) other than those listed on the Allowed Medications (P3_MEDALLOW) reference card? **(1050)** ❑1 Yes ❑0 No

   6a. If ***YES***, list: **(1050D)** _____

7. Is the participant eligible to proceed? **(1070)** ❑1 Yes ❑0 No

If any of the shaded boxes are completed, the participant is ineligible to continue.

➔ ***If NO, complete a Termination of Study Participation (P3_TERM_C) form.***

Participant Source Documentation

Participant Initials: __ __ __ **(1080)**

Date: __ __ / __ __ / 20 __ __ **(1090)**
MM DD YYYY

COMMENTS: (6000)

_____

P3 ELIG1C

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 2 ASTHMATIC

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

(Coordinator Completed)

1. Based on physical exam and medical history taken at this visit, does the participant have evidence of any of the conditions listed on the Exclusionary Medical Conditions for Microbiome (P3_EXCLMED) reference card, including morbid obesity? **(1000)** ❑1 Yes ❑0 No

   1a. If ***YES***, describe: **(1000D)** _____

2. During physical examination, did the participant have thick strands of draining purulent discharge visible in pharynx? **(1005)** ❑1 Yes ❑0 No

3. Does the participant's ECG show evidence of cardiac arrhythmia or ischemia that precludes him/her from undergoing bronchoscopy? **(1010)** ❑1 Yes ❑0 No ❑9 N/A
   (Check N/A if the participant is ≤45 years of age.)

Physician Source Documentation
Physician Signature: _____ **(1014)**
Date: __ __ / __ __ / 20 __ __ **(1017)**
MM DD YYYY

4. Was the participant's methacholine $PC_{20} \leq 8$ mg/ml? **(1020)** ❑1 Yes ❑0 No

   4a. If ***NO***, did the participant's FEV_1 improve ≥ 12% in response to four puffs of albuterol? **(1030)** ❑1 Yes ❑0 No

5. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1070)** ❑1 Yes ❑0 No

   If ***YES***, describe: **(1070D)** _____

6. Is the participant eligible to proceed? **(1080)** ❑1 Yes ❑0 No

   If any of the shaded boxes are completed, the participant is ineligible.

   ➔ ***If YES,*** **proceed with remaining Visit 1 procedures.**

Participant Source Documentation
Participant Initials: __ __ __ **(1090)**
Date: __ __ / __ __ / 20 __ __ **(1100)**
MM DD YYYY

COMMENTS: **(6000)**

_____

P3 ELIG2A

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 2 CONTROL

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

(Coordinator Completed)

1. Based on physical exam and medical history taken at this visit, does the participant have evidence of any of the conditions listed on the Exclusionary Medical Conditions for Microbiome (P3_EXCLMED) reference card, including morbid obesity? **(1000)** ☐1 Yes ☐0 No

   1a. If ***YES***, describe: **(1000D)** _____

2. During physical examination, did the participant have thick strands of draining purulent discharge visible in pharynx? **(1005)** ☐1 Yes ☐0 No

3. Does the participant's ECG show evidence of cardiac arrhythmia or ischemia that precludes him/her from undergoing bronchoscopy? **(1010)** ☐1 Yes ☐0 No ☐9 N/A
   (Check N/A if the participant is ≤45 years of age.)

Physician Source Documentation
Physician Signature: _____ **(1014)**
Date: __ __ / __ __ / 20 __ __ **(1017)**
MM DD YYYY

4. Was the participant's prebronchodilator (baseline) FEV_1 < 80% of predicted? **(1040)** ☐1 Yes ☐0 No

5. Was the participant's prebronchodilator (baseline) FVC < 80% of predicted? **(1050)** ☐1 Yes ☐0 No

6. Was the participant's methacholine $PC_{20} \leq 16$ mg/ml? **(1060)** ☐1 Yes ☐0 No

7. Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation? **(1070)** ☐1 Yes ☐0 No

   If ***YES***, describe: **(1070D)** _____

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

If any of the shaded boxes are completed, the participant is ineligible.

➔ ***If YES,*** **proceed with remaining Visit 1 procedures.**

Participant Source Documentation
Participant Initials: __ __ __ **(1090)**
Date: __ __ / __ __ / 20 __ __ **(1100)**
MM DD YYYY

COMMENTS: **(6000)**

_____

P3 ELIG2C

AsthmaNet	MICROBIOME ELIGIBILITY CHECKLIST 3 ASTHMATIC	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Section 1

1.	Is the participant's blood creatinine elevated (≥ 1.30 mg/dL)?	**(1000)**	❑1 Yes	❑0 No
2.	Since Visit 1, has the participant been treated with any corticosteroid (except for topical)?	**(1010)**	❑1 Yes	❑0 No
3.	Since Visit 1, has the participant experienced a respiratory infection?	**(1020)**	❑1 Yes	❑0 No
4.	Since Visit 1, has the participant been treated with any antibiotic (except for topical)?	**(1030)**	❑1 Yes	❑0 No
5.	Since Visit 1, has the participant received treatment with any excluded medications (P3_EXCLDRUG)?	**(1040)**	❑1 Yes	❑0 No
6.	Since Visit 1, has the participant experienced a significant asthma exacerbation?	**(1050)**	❑1 Yes	❑0 No

Section 2

7.	Has bronchoscopy induced an immediate asthma exacerbation requiring systemic corticosteroid treatment?	**(1055)**	❑1 Yes	❑0 No
8.	Is the participant able to use the Diskus properly, as evidenced by achieving a score of 10 on two consecutive, separate inhalations using the Diskus Inhalation Technique Checklist (TECH_DISKUS)?	**(1060)**	❑1 Yes	❑0 No
9.	Does the participant have any condition or issue which, in the opinion of the investigator, might interfere with study participation?	**(1070)**	❑1 Yes	❑0 No
10.	Does the participant wish to withdraw consent?	**(1090)**	❑1 Yes	❑0 No
11.	Is there any new information that makes the participant ineligible according to the eligibility criteria?	**(1100)**	❑1 Yes	❑0 No

If ***YES***, describe: **(1100D)** _____

P3 ELIG3A

12. Is the participant eligible to proceed? **(1110)** ❑1 Yes ❑0 No

If any of the shaded boxes are completed, the participant is ineligible to be randomized.

➔ ***If NO, complete a Termination of Study Participation (P3_TERM_A) form.***

Participant Source Documentation

Participant Initials: __ __ __ **(1120)**

Date: __ __ / __ __ / 20 __ __ **(1130)**
MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

MICROBIOME ELIGIBILITY CHECKLIST 3 CONTROL

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

(Coordinator Completed)

1. Is the participant's blood creatinine elevated (≥ 1.30 mg/dL)? **(1000)** ☐1 Yes ☐0 No
2. Since Visit 1, has the participant been treated with any corticosteroid (except for topical)? **(1010)** ☐1 Yes ☐0 No
3. Since Visit 1, has the participant experienced a respiratory infection? **(1020)** ☐1 Yes ☐0 No
4. Since Visit 1, has the participant been treated with any antibiotic (except for topical)? **(1030)** ☐1 Yes ☐0 No
5. Since Visit 1, has the participant received treatment with any excluded medications (P3_EXCLDRUG)? **(1040)** ☐1 Yes ☐0 No
6. Did the participant's FEV_1 improve ≥ 12% in response to four puffs of albuterol? **(1080)** ☐1 Yes ☐0 No
7. Does the participant wish to withdraw consent? **(1090)** ☐1 Yes ☐0 No
8. Is there any new information that makes the subject ineligible according to the eligibility criteria? **(1100)** ☐1 Yes ☐0 No

   If ***YES***, describe: **(1100D)** _____

9. Is the participant eligible to proceed? **(1110)** ☐1 Yes ☐0 No

If any of the shaded boxes are completed, the participant is ineligible to continue.

➔ ***If NO, complete a Termination of Study Participation (P3_TERM_C) form.***

Participant Source Documentation
Participant Initials: __ __ __ **(1120)**
Date: __ __ / __ __ / 20 __ __ **(1130)**
MM DD YYYY

COMMENTS: (6000)

_____

_____

_____

P3 ELIG3C

AsthmaNet

MICROBIOME LABORATORY RESULTS

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

(Coordinator Completed)

(Visit 1 and 2)

1. CBC with differential cell count

1a. Eosinophils (absolute count)	**(1000)**	__ __ __ __ /mm^3
1b. WBC	**(1010)**	__ __ __ . __ K/uL
1c. HCT	**(1020)**	__ __ . __ %
1d. HGB	**(1030)**	__ __ . __ g/dL
1e. Platelet count	**(1040)**	__ __ __ K/uL
1f. Differential		
1fi. Lymphocytes	**(1050)**	__ __ . __ %
1fii. Monocytes	**(1060)**	__ __ . __ %
1fiii. Basophils	**(1070)**	__ __ . __ %
1fiv. Neutrophils	**(1080)**	__ __ . __ %
1fv. Eosinophils	**(1090)**	__ __ . __ %

(Visit 1 only)

2. BUN + Creatinine

2a. BUN	**(1100)**	__ __ __ mg/dL
2b. Creatinine	**(1110)**	__ __ . __ __ mg/dL

COMMENTS: (6000)

_____

_____

_____

AsthmaNet

MICROBIOME BAL LABORATORY RESULTS

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

(Coordinator Completed)

1. BAL white blood cell count with differential

1a.	Total cell count (excluding RBC's, squamous cells and epithelial cells)	**(1000)**	__ __ __ __ /mm^3
1b.	Eosinophils (absolute count)	**(1010)**	__ __ __ __ /mm^3
1c.	Differential		
	1ci. Lymphocytes	**(1020)**	__ __ . __ %
	1cii. Monocytes/Macrophages	**(1030)**	__ __ . __ %
	1ciii. Neutrophils	**(1040)**	__ __ . __ %
	1civ. Eosinophils	**(1050)**	__ __ . __ %

COMMENTS: (6000)

_____

_____

_____

P3 LAB BAL

AsthmaNet

MICROBIOME MICROBIAL EXPOSURE QUESTIONNAIRE

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

(Coordinator Completed by Interview)

To the Participant: The purpose of this questionnaire is to collect information on exposures that may affect the microbiome, or microscopic environment, of your lungs.

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

   7a. 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%

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

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):_____

_____

_____

RESPONDENT ID NUMBER

TODAY'S DATE

	DAY	YEAR		
Jan				
Feb				
Mar	00	2000		
Apr	11	2001		
May	22	2002		
Jun	33	2003		
Jul	4	2004		
Aug	5	2005	2010	2015
Sep	6	2006	2011	2016
Oct	7	2007	2012	2017
Nov	8	2008	2013	2018
Dec	9	2009	2014	2019

BRIEF FOOD QUESTIONNAIRE

This form is about the foods you usually eat.
It will take about 15 - 25 minutes to complete.

- **Please answer each question as best you can. Estimate if you aren't sure.**
- **Use only a No. 2 pencil.**
- **Fill in the circles completely, and erase completely if you make any changes.**

SEX
- Male
- Female

If female, are you pregnant or breast feeding?
- No
- Yes
- Not female

AGE

WEIGHT pounds

HEIGHT ft. in.

Please print your name in this box.

This form is about your usual eating habits in the past year or so. This includes all meals or snacks, at home or in a restaurant or carry-out. There are two kinds of questions for each food.

HOW OFTEN, on average, did you eat the food during the past year?
*Please DO NOT SKIP any foods. Mark "Never" if you didn't eat it.

HOW MUCH did you usually eat of the food?
*Sometimes we ask how many you eat, such as 1 egg, 2 eggs, etc., ON THE DAYS YOU EAT IT.
*Sometimes we ask "how much" as A, B, C or D. LOOK AT THE ENCLOSED PICTURES. For each food, pick the picture (bowls or plates) that looks the most like the serving size you usually eat. (If you don't have pictures: A=1/4 cup, B=1/2 cup, C=1 cup, D= 2 cups.)

EXAMPLE: This person drank apple juice twice a week, and had one glass each time. Once a week he ate a "C"-sized serving of rice (about 1 cup).

TYPE OF FOOD	HOW OFTEN IN THE PAST YEAR: NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME (SEE PORTION SIZE PICTURES FOR A-B-C-D)				
Apple juice	○	○	○	○	○	●	○	○	○	How many glasses each time	1 ●	2 ○	3 ○	4 ○
Rice	○	○	○	○	●	○	○	○	○	How much each time	A ○	B ○	C ●	D ○

PLEASE DO NOT WRITE IN THIS AREA

SERIAL #

TYPE OF FOOD	HOW OFTEN IN THE PAST YEAR									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you eat each of the following foods all year round?														
Eggs, including egg biscuits or Egg McMuffins (Not egg substitutes)	○	○	○	○	○	○	○	○	○	How many eggs each time	○ 1	○ 2	○ 3	○ 4
Bacon or breakfast sausage, including sausage biscuit	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Cooked cereals like oatmeal, cream of wheat or grits	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Cold cereals like Corn Flakes, Cheerios, Special K, fiber cereals	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D
Which cereal do you eat most often? **MARK ONLY ONE:** ○ Product 19, Just Right, Total ○ Bran Buds, Raisin Bran, Fruit-n-Fiber, other fiber cereals ○ Other cold cereal, like Corn Flakes, Cheerios, Special K														
Cheese, sliced cheese or cheese spread, including on sandwiches.	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Yogurt (not frozen yogurt)	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
How often do you eat each of the following fruits?														
Bananas	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
Apples or pears	○	○	○	○	○	○	○	○	○	How many	○ 1/2	○ 1	○ 2	○ 3
Oranges, tangerines, not including juice	○	○	○	○	○	○	○	○	○	How many	○ 1/2	○ 1	○ 2	○ 3
Applesauce, fruit cocktail, or any canned fruit	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Any other fruit, like grapes, melon, strawberries, peaches	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D

TYPE OF FOOD	HOW OFTEN IN THE PAST YEAR									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you eat each of the following vegetables, including fresh, frozen, canned or in stir fry, at home or in a restaurant?														
French fries, fried potatoes or hash browns	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
White potatoes not fried, incl. boiled, baked, mashed & potato salad	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Sweet potatoes, yams, or sweet potato pie	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Rice, or dishes made with rice	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Baked beans, chili with beans, pintos, any other dried beans	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Refried beans	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green beans or green peas	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Broccoli	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Carrots, or stews or mixed vegetables containing carrots	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Spinach, or greens like collards	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cole slaw, cabbage	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Green salad	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Raw tomatoes, including in salad	○	○	○	○	○	○	○	○	○	How much	○ 1/4	○ 1/2	○ 1	○ 2
Catsup, salsa or chile peppers	○	○	○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Salad dressing or mayonnaise (Not lowfat)	○	○	○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Any other vegetable, like corn, squash, okra, cooked green peppers, cooked onions	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Vegetable soup, vegetable beef, chicken vegetable, or tomato soup	○	○	○	○	○	○	○	○	○	Which bowl		○ B	○ C	○ D

PLEASE DO NOT WRITE IN THIS AREA

SERIAL # ○○○○○○○○○○○○○○○○○○○○○○

TYPE OF FOOD	HOW OFTEN IN THE PAST YEAR: NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME (SEE PORTION SIZE PICTURES FOR A-B-C-D)				
MEATS														
Do you ever eat chicken, meat or fish? ○ Yes ○ No IF NO, SKIP TO NEXT PAGE														
Hamburgers, cheeseburgers, meat loaf, at home or in a restaurant	○	○	○	○	○	○	○	○	○	How much meat	○ 1/8 lb.	○ 1/4 lb.	○ 1/2 lb.	○ 3/4 lb.
Tacos, burritos, enchiladas, tamales	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Beef steaks, roasts, pot roast, or in frozen dinners or sandwiches	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Pork, including chops, roasts, or dinner ham	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat beef or pork, do you ○ Avoid eating the fat ○ Sometimes eat the fat ○ Often eat the fat ○ I don't eat meat														
Mixed dishes with meat or chicken, like stew, corned beef hash, chicken & dumplings, or in frozen meals	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Fried chicken, at home or in a restaurant	○	○	○	○	○	○	○	○	○	# medium pieces	○ 1	○ 2	○ 3	○ 4
Chicken or turkey not fried, such as baked, grilled, or on sandwiches	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat chicken, do you ○ Avoid eating the skin ○ Sometimes eat the skin ○ Often eat the skin ○ N/A														
Fried fish or fish sandwich, at home or in a restaurant	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Any other fish or shellfish not fried, including tuna	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Hot dogs, or sausage like Polish, Italian or Chorizo	○	○	○	○	○	○	○	○	○	How many	○ 1	○ 2	○ 3	○ 4
Boloney, sliced ham, turkey lunch meat, other lunch meat	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
When you eat lunch meats, are they ○ Usually low-fat ○ Sometimes ○ Rarely low-fat ○ N/A														

SERIAL # PLEASE DO NOT WRITE IN THIS AREA

TYPE OF FOOD	HOW OFTEN IN THE PAST YEAR: NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY	HOW MUCH EACH TIME (SEE PORTION SIZE PICTURES FOR A-B-C-D)				
Pasta, breads, spreads, snacks														
Spaghetti, lasagna, or other pasta with tomato sauce	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Cheese dishes without tomato sauce, like macaroni and cheese	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Pizza, including carry-out	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Biscuits, muffins	○	○	○	○	○	○	○	○	○	How many each time	○ 1	○ 2	○ 3	○ 4
Rolls, hamburger buns, English muffins, bagels	○	○	○	○	○	○	○	○	○	How many each time	○ 1/2	○ 1	○ 2	○ 3
White bread or toast, including French, Italian, or in sandwiches	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Dark bread like rye or whole wheat, including in sandwiches	○	○	○	○	○	○	○	○	○	How many slices	○ 1	○ 2	○ 3	○ 4
Tortillas	○	○	○	○	○	○	○	○	○	How many each time	○ 1	○ 2	○ 3	○ 4
Margarine on bread, potatoes or vegetables	○	○	○	○	○	○	○	○	○	How many pats (Tsp.)	○ 1	○ 2	○ 3	○ 4
Butter on bread, potatoes or vegetables	○	○	○	○	○	○	○	○	○	How many pats (Tsp.)	○ 1	○ 2	○ 3	○ 4
Peanuts or peanut butter	○	○	○	○	○	○	○	○	○	How many TBSP.	○ 1	○ 2	○ 3	○ 4
Snacks like potato chips, corn chips, popcorn (Not pretzels)	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
Doughnuts, cake, pastry, pie	○	○	○	○	○	○	○	○	○	How many pieces	○ 1	○ 2	○ 3	○ 4
Cookies (Not lowfat)	○	○	○	○	○	○	○	○	○	How many	○ 1-2	○ 3-5	○ 6-7	○ 8+
Ice cream, frozen yogurt, ice cream bars	○	○	○	○	○	○	○	○	○	How much	○ A	○ B	○ C	○ D
When you eat ice cream or frozen yogurt, is it	○ Usually low-fat	○ Sometimes	○ Rarely low-fat	○ N/A										
Chocolate candy, candy bars	○	○	○	○	○	○	○	○	○	How many bars	○ 1 small	○ 1 medium	○ 1 large	○ 2 large

TYPE OF BEVERAGE	HOW OFTEN IN THE PAST YEAR									HOW MUCH EACH TIME SEE PORTION SIZE PICTURES FOR A-B-C-D				
	NEVER	A FEW TIMES per YEAR	ONCE per MONTH	2-3 TIMES per MONTH	ONCE per WEEK	TWICE per WEEK	3-4 TIMES per WEEK	5-6 TIMES per WEEK	EVERY DAY					
How often do you drink the following beverages?														
Real orange or grapefruit juice, Welch's grape juice, Minutemaid juices, Juicy Juice	○	○	○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Hawaiian Punch, Sunny Delight, Hi-C, Tang, or Ocean Spray juices	○	○	○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Kool Aid, Capri Sun or Knudsen juices	○	○	○	○	○	○	○	○	○	How many glasses each time	○ 1	○ 2	○ 3	○ 4
Instant breakfast milkshakes like Carnation, diet shakes like Slimfast, or liquid supplements like Ensure	○	○	○	○	○	○	○	○	○	How many glasses or cans	○ 1	○ 2	○ 3	○ 4
Glasses of milk (any kind)	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3	○ 4
When you drink glasses of milk what kind do you <u>usually</u> drink? **MARK ONLY ONE:**	○ Whole milk ○ Reduced fat 2% milk ○ Low-fat 1% milk				○ Non-fat milk ○ Rice milk ○ Soy milk				○ I don't drink milk or soy milk					
Cream, Half-and-Half or non-dairy creamer in coffee or tea	○	○	○	○	○	○	○	○	○	Total TBSP. on those days	○ 1	○ 2	○ 3-4	○ 5+
Regular soft drinks, or bottled drinks like Snapple (<u>Not</u> diet drinks)	○	○	○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+
Beer	○	○	○	○	○	○	○	○	○	How many bottles or cans	○ 1	○ 2	○ 3-4	○ 5+
Wine or wine coolers	○	○	○	○	○	○	○	○	○	How many glasses	○ 1	○ 2	○ 3-4	○ 5+
Liquor or mixed drinks	○	○	○	○	○	○	○	○	○	How many drinks	○ 1	○ 2	○ 3-4	○ 5+

During the past year, have you taken any vitamins or minerals regularly, at least once a month?

○ No, not regularly ○ Yes, fairly regularly →

(IF YES) WHAT DID YOU TAKE FAIRLY REGULARLY?

VITAMIN TYPE	HOW OFTEN					FOR HOW MANY YEARS?					
	DIDN'T TAKE	A FEW DAYS per MONTH	1-3 DAYS per WEEK	4-6 DAYS per WEEK	EVERY DAY	LESS THAN 1 YR.	1 YEAR	2 YEARS	3-4 YEARS	5-9 YEARS	10+ YEARS
Multiple Vitamins. Did you take…											
Regular Once-A-Day, Centrum, or Thera type	○	○	○	○	○	○	○	○	○	○	○
Stress-tabs or B-Complex type	○	○	○	○	○	○	○	○	○	○	○
Antioxidant combination type	○	○	○	○	○	○	○	○	○	○	○
Single Vitamins (not part of multiple vitamins)											
Vitamin A (not beta-carotene)	○	○	○	○	○	○	○	○	○	○	○
Beta-carotene	○	○	○	○	○	○	○	○	○	○	○
Vitamin C	○	○	○	○	○	○	○	○	○	○	○
Vitamin E	○	○	○	○	○	○	○	○	○	○	○
Folic acid, folate	○	○	○	○	○	○	○	○	○	○	○
Calcium or Tums, alone or combined with vit. D or magnesium	○	○	○	○	○	○	○	○	○	○	○
Zinc	○	○	○	○	○	○	○	○	○	○	○
Iron	○	○	○	○	○	○	○	○	○	○	○
Selenium	○	○	○	○	○	○	○	○	○	○	○
Vitamin D, alone or combined with calcium	○	○	○	○	○	○	○	○	○	○	○

If you took vitamin C or vitamin E:

How many milligrams of **vitamin C** did you usually take on the days you took it?

○ 100 ○ 250 ○ 500 ○ 750 ○ 1000 ○ 1500 ○ 2000 ○ 3000+ ○ don't know

How many IUs of **vitamin E** did you usually take on the days you took it?

○ 100 ○ 200 ○ 300 ○ 400 ○ 600 ○ 800 ○ 1000 ○ 2000+ ○ don't know

How often do you use fat or oil in cooking?

○ Less than once per week ○ A few times per week ○ Once a day ○ Twice a day ○ 3+ per day

What kinds of fat or oil do you usually use in cooking? MARK ONLY ONE OR TWO

○ Don't know, or Pam ○ Butter/margarine blend ○ Lard, fatback, bacon fat
○ Stick margarine ○ Low-fat margarine ○ Crisco
○ Soft tub margarine ○ Corn oil, vegetable oil
○ Butter ○ Olive oil or canola oil

Did you ever drink more beer, wine or liquor than you do now? ○ Yes ○ No

Do you smoke cigarettes now? ○ Yes ○ No

IF YES, On the average about how many cigarettes a day do you smoke now?

○ 1-5 ○ 6-14 ○ 15-24 ○ 25-34 ○ 35 or more

What is your ethnic group? (MARK ONE OR MORE)

○ Hispanic or Latino ○ Black or African American ○ American Indian or Alaska Native
○ White, not Hispanic ○ Asian ○ Native Hawaiian or Other Pacific Islander

Thank you very much for filling out this questionnaire. Please take a minute to go back and fill in anything you may have skipped.

PLEASE DO NOT WRITE IN THIS AREA

AsthmaNet

MICROBIOME PARTICIPANT STUDY TREATMENT QUESTIONNAIRE

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

(Participant Completed)

This questionnaire is to be completed by the Microbiome participant at the end of Visit 5. If a randomized participant terminates prior to Visit 5, please ask him/her to complete this form during the termination visit.

1. **Scheduled Diskus**

   As a Microbiome study participant you were randomized to receive either a real (i.e., active) fluticasone Diskus or a look-alike placebo (i.e., inactive) Diskus. Please check the box that most closely represents your feelings about the scheduled Diskus you took **since randomization at Visit 2**.

(1000)
- ❑1 I am certain the Diskus contained placebo.
- ❑2 I think the Diskus probably contained placebo.
- ❑3 I have no idea which type of Diskus I received, but my guess would be:

(1010)
- ❑1 Placebo
- ❑2 Fluticasone

- ❑4 I think the Diskus probably contained fluticasone.
- ❑5 I am certain the Diskus contained fluticasone.

2. Please comment with respect to the **taste** of the medication you received from your scheduled Diskus **since randomization at Visit 2**.

(1020)
- ❑1 Tasted good
  (Describe) _____
- ❑2 No noticeable taste
- ❑3 Tasted bad
  (Describe) _____

3. Please comment with respect to the **smell** of the medication you received from your scheduled Diskus **since randomization at Visit 2**.

(1030)
- ❑1 Smelled good
  (Describe) _____
- ❑2 No noticeable smell
- ❑3 Smelled bad
  (Describe) _____

4. Please comment with respect to any **physical sensations** produced by the medication you received from your scheduled Diskus **since randomization at Visit 2**.

(1040)
- ❑1 Pleasant sensations
  (Describe) _____
- ❑2 No noticeable sensations
- ❑3 Unpleasant sensations
  (Describe) _____

5. Please comment with respect to any other observations you may have made regarding your scheduled Diskus.

(1050)
- ❑1 I have no further comments
- ❑2 I observed the following: *(Describe below)*

(1050D) _____

_____

_____

_____

Participant Source Documentation

Participant's Initials: __ __ __ **(1060)**

Date: __ __ / __ __ / 20 __ __ **(1070)**
MM DD YYYY

P3 PARTTXQX

AsthmaNet

MICROBIOME PULMONARY PROCEDURE CHECKLIST

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

(Participant Interview Completed)

Complete this form at all visits where baseline spirometry is required. If any medications other than study or rescue Ventolin® 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 **6** hours? **Examples:** Pepsi, Coke, Coffee, Mountain Dew, Tea, Rootbeer, Red Bull	**(1000)**	❑1 Yes	❑0 No
2.	Have you used medications with caffeine in the past **6** 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 **6** hours? **Examples:** bitter orange, Xenadrine, EFX, Thermorexin	**(1020)**	❑1 Yes	❑0 No
4.	Have you consumed any food containing alcohol or beverages containing alcohol in the past **6** hours?	**(1030)**	❑1 Yes	❑0 No
5.	Have you used any oral antihistamines in the past **48** hours? **Examples:** Allegra, Chlor-Trimeton, Claritin, Tylenol PM	**(1040)**	❑1 Yes	❑0 No
6.	Have you used any nasal antihistamines in the past **6** hours? **Examples:** Astelin, Livostin, Patanase	**(1050)**	❑1 Yes	❑0 No
7.	Have you used any ophthalmic antihistamines in the past **6** hours? **Examples:** Alaway, Elestat, Emadine, Opitvar, Pataday, Patanol, Zaditor	**(1060)**	❑1 Yes	❑0 No
8.	Have you used any oral decongestants or cold remedies in the past **48** hours? **Examples:** pseudoephedrine (Sudafed), Tylenol Allergy	**(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 a rescue intermediate-acting inhaled beta-agonist in the past **6** hours? **Examples:** albuterol (Proventil), study RESCUE (Ventolin®)	**(1090)**	❑1 Yes	❑0 No

11. Have you used any smokeless tobacco products today? **(1100)** ☐1 Yes ☐0 No
Examples: chewing tobacco, snuff

12. ***(Visits 4 and 5 only)*** Have you had a respiratory infection within the past 4 weeks? **(1110)** ☐1 Yes ☐0 No

12a. If ***YES***, have 4 or more weeks transpired since the onset of symptoms? **(1120)** ☐1 Yes ☐0 No

➔ If ***NO***, visit should be rescheduled 4 weeks from the onset of symptoms.

13. ***(Visits 4 and 5 only)*** Have you taken any antibiotic (except for topical) within the past 4 weeks? **(1130)** ☐1 Yes ☐0 No

➔ If ***YES***, visit should be rescheduled 4 weeks from the last day of antibiotic use.

14. At this time, is your asthma worse because of recent exposure to triggers? **(1140)** ☐1 Yes ☐0 No
Examples: cold air, smoke, allergens, recent exercise, a recent respiratory tract infection, or other pulmonary infection

15. Is there any other reason you should not proceed with spirometry testing? **(1150)** ☐1 Yes ☐0 No

If ***YES,*** explain: **(1150D)** _____

_____

16. Is the participant eligible to proceed with the spirometry testing? **(1160)** ☐1 Yes ☐0 No

If any of the shaded boxes are filled in, the participant is ineligible for spirometry.

➔ ***If YES, proceed to Q17 or the next form/procedure listed on the visit procedure checklist.***

If participant is less than 21 years old, complete Q17 at Visits 2-5.

At Visits 1 and 6, refer to height recorded on the Adult Body Measurements (BODYMEAS_ADULT) form; do not record on this form.

17. Height (without shoes) **(1170)** __ __ __ cm

COMMENTS: **(6000)**

_____

_____

AsthmaNet

MICROBIOME SIGNIFICANT ASTHMA EXACERBATION

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

(Coordinator Completed)

Complete this form each time a participant experiences an asthma exacerbation.

1. Did the participant experience an increase in cough, chest tightness and/or wheezing in association with any of the following:

   1a. An increase in rescue albuterol of ≥ 8 inhalations/day over baseline use for a period of 48 hours, with baseline defined as average daily use during the week prior to randomization? **(1000)** ❑1 Yes ❑0 No ❑9 N/A

   ➔ Check ***N/A*** if completing form prior to or at Visit 2.

   1b. Use ≥ 16 actuations of his/her rescue inhaler in a 24 hour period? **(1010)** ❑1 Yes ❑0 No ❑9 N/A

   ➔ Check ***N/A*** if completing prior to or at Visit 1.

   1c. A fall in prebronchodilator FEV_1 to < 80% of baseline (Visit 1)? **(1020)** ❑1 Yes ❑0 No ❑9 N/A

   1d. A fall in prebronchodilator FEV_1 to < 50% of predicted? **(1030)** ❑1 Yes ❑0 No ❑9 N/A

   1e. Treatment with systemic corticosteroids for his/her asthma exacerbation? **(1040)** ❑1 Yes ❑0 No

   ➔ If ***YES***, please record on Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

2. Did the participant experience a significant asthma exacerbation? If any of the shaded boxes in Q1-Q5 are filled in, the participant experienced an asthma exacerbation. **(1050)** ❑1 Yes ❑0 No

   ➔ **If *YES*, complete the rest of this form and record the exacerbation on the Clinical Adverse Events (AECLIN) form using ICD-9 code 493.92.**

   ➔ **If *NO*, STOP HERE and continue with remaining visit procedures. Do NOT submit this form to the DCC.**

3. Date exacerbation conditions were met **(1060)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

4. Did the participant seek care for the asthma exacerbation? **(1070)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Q7.

5. What type of care was sought?

5a. Study Investigator or Coordinator? **(1080)** ❑1 Yes ❑0 No

5ai. If ***YES***, indicate type of contact **(1090)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

5b. Primary Care or Other Physician? **(1100)** ❑1 Yes ❑0 No

5bi. If ***YES***, indicate the type of contact **(1110)** ❑1 Scheduled clinic visit
❑2 Unscheduled clinic visit
❑3 Phone contact

5c. Emergency Department visit? **(1120)** ❑1 Yes ❑0 No

6. Was the participant hospitalized? **(1130)** ❑1 Yes ❑0 No

➔ If ***YES***, complete the Serious Adverse Event Reporting Form (SERIOUS).

If ***YES***,

6a. Duration of hospital stay **(1140)** __ __ . __ days

6b. Was intubation or ventilation assistance required? **(1150)** ❑1 Yes ❑0 No

7. Was the asthma exacerbation resolved by increasing use of the rescue inhaler? **(1160)** ❑1 Yes ❑0 No

➔ If ***YES***, skip to Q9.

8. Did the participant take any of the following medications (excluding study medication) for treatment of the asthma exacerbation?

   ➔ If ***YES*** to any of Q8a-Q8f, complete the Concomitant Medications for Asthma/Allergy and Adverse Events (CMED) form.

8a.	Inhaled corticosteroids	**(1180)**	❑1 Yes ❑0 No
8b.	Nebulized bronchodilator	**(1190)**	❑1 Yes ❑0 No
8c.	Oral corticosteroids	**(1200)**	❑1 Yes ❑0 No
8d.	IM or IV steroids	**(1210)**	❑1 Yes ❑0 No
8e.	Antibiotics	**(1220)**	❑1 Yes ❑0 No
8f.	Other	**(1230)**	❑1 Yes ❑0 No
		(1230D)	_____

9. ***(Visits 2, 3, 5 and 6 only)*** Was the significant asthma exacerbation a result of the bronchoscopy procedure at Visits 2 or 5? **(1240)**

- ❑1 Definitely related
- ❑2 Probably related
- ❑3 Relationship undetermined
- ❑4 Probably not related
- ❑5 Definitely not related

COMMENTS: **(6000)**

_____

_____

_____

AsthmaNet

MICROBIOME TERMINATION OF STUDY PARTICIPATION ASTHMATICS

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

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 0.

1. Has the participant completed the study through Visit 6? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, skip to the SIGNATURES section.

2. Who initiated termination of the participant? **(1010)** ❑$_1$ Participant ❑$_2$ Clinical Staff
   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***
   ➔ ***If Clinical Staff, skip to Q4.***

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

   ❑$_1$ no longer interested in participating* **(1020)**
   ❑$_2$ 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: (1030D)**

   _____

   _____

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

4. Did clinical staff terminate the participant due to…

   4a. pregnancy? **(1040)** ❑$_1$ Yes ❑$_0$ No ❑$_9$ N/A
   (Check N/A if participant is male.)

   4b. loss to follow-up?* **(1050)** ❑$_1$ Yes ❑$_0$ No

   4bi. If ***YES***, date of last contact with participant **(1060)** __ __ / __ __ / 20 __ __
   MM DD YYYY

4bi. If ***YES***, type of contact **(1070)** ❑1 In-person visit ❑2 Phone call

4c. an asthma-related adverse event?* **(1080)** ❑1 Yes ❑0 No

4d. a medication-related adverse event?* **(1090)** ❑1 Yes ❑0 No

4e. an adverse event not related to asthma or medications?* **(1100)** ❑1 Yes ❑0 No

4f. ineligibility during the run-in period (Visits 0-2)?* **(1110)** ❑1 Yes ❑0 No

4g. non-compliance with medication dosing?* **(1120)** ❑1 Yes ❑0 No

4h. non-compliance with visit attendance?* **(1130)** ❑1 Yes ❑0 No

4i. significant asthma exacerbation during run-in period (Visits 0-2)?* **(1140)** ❑1 Yes ❑0 No

4j. other reason?* **(1150)** ❑1 Yes ❑0 No

***Additional explanation required: (1160D)**

_____

_____

_____

4k. Indicate the letter corresponding to the **primary** reason the participant was terminated. **(1170)** __

SIGNATURES

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

I verify that all information collected on the AsthmaNet Microbiome 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.

_____ **(1180)** __ __ / __ __ / 20 __ __ **(1190)**
Coordinator Signature MM DD YYYY

_____ **(1200)** __ __ / __ __ / 20 __ __ **(1210)**
Principal Investigator Signature MM DD YYYY

AsthmaNet	MICROBIOME TERMINATION OF STUDY PARTICIPATION CONTROL	Part. ID: __ __ - __ __ __ - __ __ __ Part. Initials: __ __ __ Visit: __ __ Visit Date: __ __ / __ __ / 20 __ __ Coordinator ID: __ __ __ __

(Coordinator Completed)

Complete this form only for participants who successfully completed Visit 0.

1. Has the participant completed the study through Visit 2? **(1000)** ❑$_1$ Yes ❑$_0$ No
   ➔ If ***YES***, skip to the SIGNATURES section.

2. Who initiated termination of the participant? **(1010)** ❑$_1$ Participant ❑$_2$ Clinical Staff
   ➔ ***If participant withdrew due to impending clinical staff termination, indicate termination by clinical staff.***
   ➔ ***If Clinical Staff, skip to Q4.***

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

   ❑$_1$ no longer interested in participating* **(1020)**
   ❑$_2$ 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*
   ❑$_{10}$ other*

   ***Additional explanation required: (1030D)**

   _____

   _____

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

4. Did clinical staff terminate the participant due to…

4a. pregnancy? *(Check N/A if participant is male.)* **(1040)** ❑1 Yes ❑0 No ❑9 N/A

4b. loss to follow-up?* **(1050)** ❑1 Yes ❑0 No

4bi. If ***YES***, date of last contact with participant **(1060)** __ __ / __ __ / 20 __ __ (MM / DD / YYYY)

4bi. If ***YES***, type of contact **(1070)** ❑1 In-person visit ❑2 Phone call

4c. an adverse event?* **(1100)** ❑1 Yes ❑0 No

4d. ineligibility during the run-in period (Visits 0-2)?* **(1110)** ❑1 Yes ❑0 No

4e. non-compliance with visit attendance?* **(1130)** ❑1 Yes ❑0 No

4f. other reason?* **(1150)** ❑1 Yes ❑0 No

***Additional explanation required:** **(1160D)**

_____

_____

_____

4g. Indicate the letter corresponding to the **primary** reason the participant was terminated. **(1170)** __

SIGNATURES

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

I verify that all information collected on the AsthmaNet Microbiome 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.

_____ **(1180)** Coordinator Signature

__ __ / __ __ / 20 __ __ **(1190)** (MM / DD / YYYY)

_____ **(1200)** Principal Investigator Signature

__ __ / __ __ / 20 __ __ **(1210)** (MM / DD / YYYY)

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Steroid Medications			
Oral or intravenous steroids for any reason		Medrol, Prednisone	6 months *
Inhaled steroids except study drug (Flovent®)	beclomethasone, budesonide, ciclesonide, flunisolide, fluticasone, mometasone, triamcinolone acetonide	Advair, Aerobid, Alvesco, Asmanex, Azmacort, Dulera, Flovent®, Pulmicort, QVAR, Symbicort	6 months
Nonsteroidal Antiinflammatory Medications			
Leukotriene modifiers	montelukast, zafirlukast, zileuton	Accolate, Singulair, Zyflo	6 months
Cromolyn/Nedocromil for asthma	cromolyn, nedocromil	Intal, Tilade	6 months
Bronchodilators			
Oral β-agonists	albuterol, metaproterenol, terbutaline	Alupent, Brethine, Bricanyl, Metaprel, Proventil, Repetabs, Ventolin, Volmax	1 week
Short-acting inhaled β-agonists	epinephrine	Bronkaid Mist, Duo-Medihaler, Medihaler-Epi, Primatene Mist	6 hours
Intermediate-acting inhaled β-agonists (except study RESCUE drug)	albuterol, bitolterol, levalbuterol, metaproterenol, pirbuterol, terbutaline	Alupent, Brethaire, Brethine, Bronkometer, Maxair, Metaprel, Proventil, Tornalate, Ventolin, Xopenex	6 hours
Long-acting inhaled β-agonists	formoterol, salmeterol	Foradil, Serevent	24 hours
Short-acting anticholinergics	atropine, ipratropium bromide, pirenzepine, scopolamine	Atrohist, Atrovent, Bellatal, Combivent, Donnatal, Scopoderm, Transderm-Scop	6 hours
Long-acting anticholinergics	tiotropium	Spiriva	72 hours

* Washout 6 months for use as a long-term asthma controller, 3 months for treatment of an asthma exacerbation

Drugs to be withheld throughout the study.

Excluded Drug	Generic Names (may not be inclusive)	Trade Names (may not be inclusive)	Washout Prior to Visit 1
Xanthine Derivatives			
Short-acting theophylline	theophylline	Aminophylline, Slo-Phyllin	6 months
Long-acting theophylline	theophylline	Slo-bid, Theo-Dur	6 months
Ultra long-acting theophylline	theophylline	Theo-24, Uniphyl	6 months
Anti-IgE Therapy			
	omalizumab	Xolair	6 months
Cardiac Drugs			
Alpha-beta blockers	labetalol	Normodyne	2 weeks
Beta blockers	acebutolol, atenolol, betaxolol, bisoprolol, carteolol, metoprolol, nadolol, penbutolol, pindolol, propranolol, timolol	Blocadren, Cartrol, Corgard, Inderal, Kerlone, Levatol, Lopressor, Sectral, Tenormin, Visken, Zebeta	2 weeks
Anticoagulants and Antiplatelets	warfarin, clopidogrel	Coumadin, Plavix	2 weeks
Psych or CNS-Related Drugs			
Monoamine oxidase (MAO) inhibitors	harmaline, iproclozide, iproniazid, isocarboxazid, nialamide, phenelzine, selegiline, toloxatone, tranylcypromine	Nardil, Parnate	4 weeks
Antibiotics			
Any antibiotic except for topical	azithromycin, clarithromycin, dirithromycin, erythromycin, roxithromycin, troleandomycin	Biaxin, Dynabac, Rulid, Surlid, TAO, Zithromax, Zitromax	3 months

Drugs/substances to be withheld prior to Visits 1-6*.

Drug/Substance	Trade Names (may not be inclusive)	Washout Prior to Visits
Albuterol (study RESCUE inhaler)	Ventolin	6 hours
Oral Antihistamines (chlorpheniramine, desloratadine, diphenhydramine, fexofenadine, loratadine and others)	Allegra, Allegra-D, Benadryl, Chlor-Trimeton, Clarinex, Claritin and others	48 hours
Nasal Antihistamines (azelastine nasal, olopatadine, levocabastine)	Astelin, Astepro, Patanase, Livostin	6 hours
Ophthalmic Antihistamines (azelastine ophthalmic, emedastine difumarate, epinastine ophthalmic, ketotifen fumarate, olopatadine ophthalmic)	Alaway, Elestat, Emadine, Opitvar, Pataday, Patanol, Zaditor	6 hours
Oral Decongestants (pseudoephedrine and others)	Sudafed and others	48 hours
Nasal Decongestants (oxymetazoline and others)	Afrin and others	6 hours
Methylxanthine-containing food or beverages (caffeinated colas, coffee, tea)	Coke, Barq's Rootbeer, Mello-Yellow, Mountain Dew, Pepsi, Red Bull	6 hours
Methylxanthine-containing medications	Anacin, Darvon, Esgic, Excedrin, No-Doz, Norgesic, Vivarin	6 hours
Alcohol-containing foods or beverages		6 hours

*These drugs/substances are allowed between visits, but not prior to pulmonary function testing.

Drugs/substances to be withheld prior to Visits 2 and 5 (in addition to above).

Drug/Substance	Trade Names (may not be inclusive)	Washout Prior to Visits 2, 5
Nonsteroidal anti-inflammatory drugs or NSAIDs (aspirin, ibuprofen and others)	Advil, Bayer, Ecotrin, Motrin	1 week

Exclusionary Medical Conditions for Microbiome (may not be inclusive)

- Addison's disease
- AIDS
- Bleeding disorder (history of)
- Cardiac arrhythmias (clinically significant)
- Cardiac ischemia
- Congenital anomaly, including growth abnormalities (clinically significant)
- Congestive heart failure
- Coronary artery disease (unstable or severe)
- Cushing's disease
- Diabetes mellitus (poorly controlled)
- Dyspnea by any cause other than asthma
- Eating disorder (e.g. anorexia or bulimia (active disease))
- Hematologic disease (unstable, e.g. severe anemia)
- Hepatic disease
- Hypertension (poorly controlled)
- Hyperthyroidism
- Immunologic compromise
- Chronic kidney disease (glomerulonephritis, polycystic kidney disease, etc.)
- Lactation
- Lidocaine allergy
- Lung disease other than asthma (COPD, emphysema, chronic bronchitis, pulmonary embolism, malignancy, cystic fibrosis, among others)
- Lupus (active disease requiring immunosuppressant)
- Any malignancy other than basal cell skin cancers
- Mental illness (uncontrolled)
- Mental retardation
- Morbid obesity (BMI ≥ 35)
- Neurologic disease (including epilepsy requiring treatment)
- Peptic ulcer disease (active)
- Pregnancy
- Renal insufficiency (creatinine > 1.2 mg/dl)
- Schizophrenia
- Skeletal disorders, including osteoporosis and rheumatoid arthritis (excludes degenerative disc disease, scoliosis, and spinal stenosis)
- Sleep apnea (untreated)
- Sleep disorder (history of)
- Substance abuse (including active drug or alcohol abuse)
- Tachyarrhythmia (atrial or ventricular, history of)
- Tuberculosis (history of positive skin test with negative chest x-ray allowed)
- Urinary retention (active symptoms within last 6 months)
- Vocal cord dysfunction (diagnosis of)

P3 EXCLMED

- acetaminophen
- analgesics for acute/chronic pain management (with MD discretion)
- antianxiety agents/anxiolytics (e.g., diazepam, chlordiazepoxide, alprazolam, lorazepam, gabapentin, buspirone) at a stable dose
- antibiotics (topical only)
- anti-cholesterol medications (e.g., Lopid, statin medications), except cholestipol and cholestyramine
- specific antidepressants at a stable dose
    - Selective Serotonin Reuptake Inhibitors (SSRI) (e.g., alaproclate, etoperidone, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, zimelidine)
    - Selective Serotonin Norepinephrine Reuptake Inhibitors (SSNRI) (e.g. desvenlafaxine, duloxetine, venlafaxine)
    - Non-SSRI/SSNRI antidepressants (except MAOI class drugs) (e.g. amitriptyline, amoxapine, bupropion, mirtazapine, nefazodone, trazodone and others)
- antihistamines (e.g. chlorpheniramine (Chlor-Trimeton), desloratadine (Clarinex), diphenhydramine (Benadryl), fexofenadine (Allegra, Allegra-D), loratadine (Claritin), and others)
- specific antihypertensive medications
    - alpha blockers (e.g. doxazosin, prazosin, terazosin)
    - angiotensin converting enzyme (ACE) inhibitors (e.g. benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril)
    - angiotensin receptor blockers (Sartans) (e.g. candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan)
    - calcium channel blockers (e.g. amlodipine, diltiazem, felodipine, isradipine, nicardipine, nifedipine, verapamil)
    - diuretics (e.g. amiloride, bumetanide, chlorothiazide, chlorthalidone, furosemide, hydrochlorothiazide, indapamide, methyclothiazide, metolazone, spironolactone, triameterene)
    - mineralocorticoid receptor antagonists (e.g. eplerenone)
    - sympathetic nerve inhibitors (e.g. clonidine, guanabenz, guanfacine, methyldopa)
- antitussives (OTC only) (e.g. dextromethorphan)
- bisphosphonates (e.g. alendronate (Fosamax), ibandronate (Boniva), zoledronic acid (Zometa))
- calcium-based antacids (e.g. TUMS®)
- calcium supplements
- CNS stimulants/appetite suppressants (e.g. lisdexamfetamine, methylphenidate, hydrochloride, amphetamine preps, sibutramine)
- Cox-2 drugs (e.g. celecoxib (Celebrex), rofecoxib (Vioxx) and valdecoxib (Bextra))
- decongestants (e.g. pseudoephedrine (Sudafed), oxymetazoline (Afrin), and others)
- Depo-Provera®
- oral diabetes medications (for treatment of stable, controlled diabetes)
- erectile dysfunction medications (e.g. sildenafil, tadalafil, vardenafil)
- estrogen/progesterone replacement therapy for postmenopausal women
- expectorants (OTC only) (e.g. guaifenesin)
- eye preparations for allergic eye symptoms (topical) (e.g. antihistamines, NSAIDS, antiallergic compounds, mast cell stabilizers)
- H_2 blockers (e.g. ranitidine, cimetidine, famotidine, nizatidine) for GERD
- hair growth preparations (e.g. finasteride (Propecia®))
- hemorrhoid treatments
- herpes medications (e.g. acyclovir (Zovirax), valacyclovir (Valtrex))
- insulin (for treatment of stable, controlled diabetes)

- laxatives
- Librax
- lithium
- migraine analgesics/preventatives (e.g. butalbital, Midrin, sumatriptan, topiramate)
- nasal antiallergic spray (Cromolyn/Atrovent)
- nasal saline spray
- non-steroidal anti-inflammatory medications (e.g. aspirin, ibuprofen, naproxen, ketoprofen)
- Norplant®
- oral contraceptives
- proton pump inhibitors (e.g. omeprazole (Prilosec), lansoprazole (Prevacid), esomeprazole (Nexium)) for GERD
- psyllium
- sleep aids used PRN
- stool softeners
- study medications
- thyroid replacement medication (e.g. Levothroid, Levoxyl, Synthroid)
- tretinoin (Retin-A) for acne
- vitamins, minerals
- Low potency topical corticosteroids (BID)

  aciometasone dipropionate
  desonide
  dexamethasone
  dexamethasone sodium phosphate
  fluocinolone acetonide
  hydrocortisone
  hydrocortisone acetate

- Medium potency topical corticosteroids (BID)

betamethasone benzoate	fluocinonide .05%
betamethasone dipropionate	flurandrenolide
betamethasone valerate	fluticasone propionate
clocortolone pivalate	hydrocortisone butyrate
desoximetasone	hydrocortisone valerate
diflorasone .05%	mometasone furoate
fluocinolone acetonide	triamcinolone acetonide

Record the number of the most recent type of inhaled steroid taken in Q12a on the PRIOR_TRT form.

100 beclomethasone MDI (1 puff = 40 mcg) (**e.g., QVAR**)
101 beclomethasone MDI (1 puff = 80 mcg) (**e.g., QVAR**)
102 beclomethasone MDI (1 puff = 100 mcg) (**e.g., QVAR—Canadian**)
200 budesonide DPI (1 puff = 90 mcg) (**e.g., Pulmicort Flexhaler**)
201 budesonide DPI (1 puff = 180 mcg) (**e.g., Pulmicort Flexhaler**)
300 ciclesonide MDI (1 puff = 80 mcg) (**e.g., Alvesco**)
301 ciclesonide MDI (1 puff = 160 mcg) (**e.g., Alvesco**)
400 flunisolide MDI (1 puff = 80 mcg) (**e.g., Aerospan**)
501 fluticasone propionate MDI (1 puff = 44 mcg) (**e.g., Flovent**)
502 fluticasone propionate MDI (1 puff = 110 mcg) (**e.g., Flovent**)
503 fluticasone propionate MDI (1 puff = 220 mcg) (**e.g., Flovent**)
600 fluticasone propionate DPI (1 puff = 50 mcg) (**e.g., Flovent Diskus**)
601 fluticasone propionate DPI (1 puff = 100 mcg) (**e.g., Flovent Diskus**)
602 fluticasone propionate DPI (1 puff = 250 mcg) (**e.g., Flovent Diskus**)
610 fluticasone furoate (1 puff = 100 mcg) (**e.g., Arnuity Ellipta DPI**)
611 fluticasone furoate (1 puff = 200 mcg) (**e.g., Arnuity Ellipta DPI**)
700 mometasone DPI (1 puff = 110 mcg) (**e.g., Asmanex Twisthaler**)
701 mometasone DPI (1 puff = 220 mcg) (**e.g., Asmanex Twisthaler**)
702 mometasone furoate (1 puff = 100 mcg) (**e.g., Asmanex HFA**)
999 Other

Record the number of the most recent type of nebulized steroid taken in Q13a on the PRIOR_TRT form.

10 budesonide (1 neb = 0.25 mg) (**e.g., Pulmicort Respules**)
11 budesonide (1 neb = 0.5 mg) (**e.g., Pulmicort Respules**)
12 budesonide (1 neb = 1.0 mg) (**e.g., Pulmicort Respules**)
99 Other

Record the number of the most recent type of inhaled steroid/long-acting beta-agonist taken in Q14a on the PRIOR_TRT form.

1000 budesonide (1 puff = 80 mcg) / formoterol (1 puff = 4.5 mcg) (**e.g., Symbicort MDI**)
1001 budesonide (1 puff = 160 mcg) / formoterol (1 puff = 4.5 mcg) (**e.g., Symbicort MDI**)
1100 fluticasone propionate (1 puff = 100 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1101 fluticasone propionate (1 puff = 250 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1102 fluticasone propionate (1 puff = 500 mcg) / salmeterol (1 puff = 50 mcg) (**e.g., Advair Diskus**)
1103 fluticasone propionate (1 puff = 45 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1104 fluticasone propionate (1 puff = 115 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1105 fluticasone propionate (1 puff = 230 mcg) / salmeterol (1 puff = 21 mcg) (**e.g., Advair MDI**)
1110 fluticasone furoate (1 puff = 100 mcg) / vilanterol (1 puff = 25 mcg) (**e.g., Breo Ellipta DPI**)
1111 fluticasone furoate (1 puff = 200 mcg) / vilanterol (1 puff = 25 mcg) (**e.g., Breo Ellipta DPI**)
1200 mometasone (1 puff = 100 mcg) / formoterol (1 puff = 5 mcg) (**e.g., Dulera MDI**)
1201 mometasone (1 puff = 200 mcg) / formoterol (1 puff = 5 mcg) (**e.g., Dulera MDI**)
9999 Other

UNITS, FREQUENCY, AND ROUTE CODES FOR USE ON THE CONCOMITANT MEDICATIONS FOR ASTHMA/ALLERGY AND ADVERSE EVENTS FORM (CMED)

AsthmaNet

Codes for Units (Q1040)	
Code	Units
1	mg
2	mcg (µg)
3	ml
4	mg/ml
5	mEq
6	g
7	U
8	teaspoon
9	tablespoon
10	patch
11	puffs (oral inhalation)
12	nasal spray
13	packet
14	1 drop
15	mm
16	percent
98	no units
99	other

Codes for Frequency (Q1050)		
Code	Frequency	
1	QD	1 time a day
2	BID	2 times a day
3	TID	3 times a day
4	QID	4 times a day
5	q4h	every 4 hours
6	q5h	every 5 hours
7	q6h	every 6 hours
8	q8h	every 8 hours
9	q12h	every 12 hours
10	q24h	every 24 hours
11	hs	every night at bedtime
12	PRN	as required
13	qod	every other day
14	qw	once a week
15	biw	2 times per week
16	tiw	3 times per week
17	5 times per week	
18	every 5 days	
19	once a month	
20	taper dose	
99	other	

Codes for Route (Q1055)	
Route	Route Desc
1	Epidural Injection
2	External/Topical
3	Inhalation
4	Intraarterial Injection
5	Intraarticular/Intracapsular Injection
6	Intramuscular Injection – IM
7	Intrathecal Injection
8	Intravenous Injection – IV
9	Medicated Gums
10	Misc. Injection
11	Nasal
12	Nebulization
13	Ophthalmic
14	Oral
15	Otic
16	Patch
17	Rectal
18	Subcutaneous Injection – SQ
19	Sublingual
20	Swallowed
21	Urological
22	Vaginal

FREQUENTLY USED ASTHMA & ALLERGY DRUG CODES

AsthmaNet

Class Name	Generic Drug Name	UN Code
Anticholinergic Agents	Atropine	384024
	Ipratropium	395021
	Tiotropium	304004
Antihistamines	Acrivastine	394040
	Brompheniramine	382545
	Carbinoxamine	382883
	Cetirizine	398026
	Chlorpheniramine	382543
	Cimetidine	382256
	Clemastine	382542
	Cyproheptadine	382541
	Desloratadine	302004
	Dimenhydrinate	382140
	Diphenhydramine	382539
	Doxylamine	382537
	Emedastine	399007
	Famotidine	387011
	Fexofenadine	397035
	Hydroxyzine	382866
	Ketotifen	399018
	Levocetirizine	307015
	Lodoxamide	394014
	Loratadine	397038
	Meclizine	382548
	Nizatidine	394030
	Olopatadine	399006
	Promethazine	382752
	Ranitidine	384046
	Triprolidine	382533
Beta-2 Adrenergic Agonists	Albuterol/Levalbuterol	382145
	Arformoterol	307016
	Formoterol	301023
	Metaproterenol	382084
	Salmeterol	395001
	Terbutaline	382144
Corticosteroids	Beclomethasone	381047
	Budesonide	303008
	Ciclesonide	308032
	Dexamethasone	382869
	Difluprednate	308031
	Flunisolide	381048

Class Name	Generic Drug Name	UN Code
Corticosteroids	Fluocinolone	305019
	Fluorometholone	382870
	Fluticasone	395002
	Hydrocortisone	382871
	Loteprednol	399008
	Mometasone	301021
	Prednisolone	382873
	Prednisone	382796
	Rimexolone	396035
	Triamcinolone	301019
Leukotriene Modifiers	Montelukast	300014
	Zafirlukast	397007
	Zileuton	397013
Xanthine Derivatives	Theophyllines	381006