Childhood Asthma Research & Education
NIH / NHLBI

CLINICAL ADVERSE EVENTS 2

Subject ID: ___ ___- ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

(Clinic Coordinator completed)

Complete this log if the participant experienced any clinical adverse events (including intercurrent events). Since this is a cumulative form, the table should be updated at each visit. Check "None" only if the child has not experienced any clinical adverse events at the time of data entry. If "None", sign and date in the gray box.

CC's Signature: _____ (1000)
Date: __ __ / __ __ / __ __ __ __ (1010)

❑0 None

(1020) DESCRIPTION OF ADVERSE EVENT	(1030) 1. ICD9 CODE	(1040) 2. DATE STARTED (Top Line) / 3. DATE STOPPED (Bottom Line) (1050) MONTH / DAY / YEAR	(1060) 4. ONGOING at data entry	(1070) 5. DURATION Complete ONLY if duration is less than 24 hours. HOUR(S)	(1080) 6. TYPE 1 - INTERMITTENT 2 - CONTINUOUS	(1090) 7. SEVERITY 1 - MILD 2 - MODERATE 3 - SEVERE	(1100) 8. SERIOUS * 1-YES 0 - NO	(1110) 9. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE 5 - HIGHLY PROBABLE	(1120) 10. CHANGE IN STUDY MEDICATIONS 1 - DISCONTINUED 2 - REDUCED 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE 4 - UNCHANGED 5 - INCREASED	(1130) 11. OUTCOME *(Skip if #3 is missing.)* 1 - COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *	(1140) 12. TREATMENT REQUIRED 1 - NONE 2 - MEDICATION ** 3 - HOSPITALIZATION * 4 - OTHER
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							

* Please complete a Serious Adverse Event Reporting Form (SERIOUS).

** Please complete the appropriate Concomitant Medications Log (CMED).

❑ Data Entered?

Childhood Asthma Research & Education
NIH / NHLBI

LABORATORY ADVERSE EVENTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

If an abnormal laboratory value is deemed clinically adverse, complete this form. Complete one form for each lab-related adverse event.

1. Test date — ___ ___ / ___ ___ / ___ ___ ___ ___ (1000) (month / day / year)

2. Laboratory test
   - ❑ 1 EKG (1010)
   - ❑ 2 Chemistry
   - ❑ 3 CBC
   - ❑ 4 UA
   - ❑ 5 Other _____

3. Abnormality observed
   - ❑ 1 EKG disturbances (1020)
     Specify: _____
   - ❑ 2 BUN
   - ❑ 3 Creatinine
   - ❑ 4 Other _____

4. Was this Laboratory Adverse Event considered serious (i.e., resulting in hospitalization, extension of hospital stay, or death)?
   ➜ ***If YES, please complete the Serious Adverse Event Reporting Form (SERIOUS).***
   - ❑ 1 Yes
   - ❑ 0 No (1030)

5. Likelihood of relationship to study drug
   - ❑ 1 None (1040)
   - ❑ 2 Unlikely (Remote)
   - ❑ 3 Possible
   - ❑ 4 Probable
   - ❑ 5 Highly Probable

6. Did the subject require treatment with medication other than study drugs for this Laboratory Adverse Event?

   ➔ ***If YES, please complete the appropriate Concomitant Medications form.***

❑1 Yes ❑0 No (1050)

7. Did the subject require any other type of treatment for this Laboratory Adverse Event?

   If ***YES,*** describe: _____

❑1 Yes ❑0 No (1060)

8. Adverse Event status

❑1 Ongoing (1070)
❑2 Completely Recovered
❑3 Recovered, but with lasting effects
❑4 Death

9. Date Adverse Event resolved

___ ___ / ___ ___ / ___ ___ ___ ___ (1080)
month *day* *year*

Childhood Asthma Research & Education
NIH / NHLBI

BASELINE ASTHMA AND ALLERGY HISTORY

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Subject Interview completed)

PARENT/GUARDIAN IDENTIFICATION

1. What is your relationship to the child? (*Check one box only*)
   - ❑1 Parent (1000)
   - ❑2 Stepparent
   - ❑3 Grandparent
   - ❑4 Legal guardian (but not parent)
   - ❑5 Other _____

ASTHMA HISTORY

2. How old was the child when chest symptoms suggesting asthma first began? ___ ___ years (1010) ___ ___ months (1020)
3. How old was the child when a doctor first said he or she had asthma? ___ ___ years (1030) ___ ___ months (1040)

ASTHMA TREATMENT

4. Has the child ever been hospitalized overnight for asthma? ❑1 Yes ❑0 No (1050)
   - 4a. If ***YES***, during the past 12 months, how many times has the child been hospitalized overnight for asthma? ___ ___ times (1060)
5. Has the child ever been admitted to an intensive care unit for asthma? ❑1 Yes ❑0 No (1070)
   - 5a. If ***YES***, during the past 12 months, how many times has the child been admitted to an intensive care unit for asthma? ___ ___ times (1080)
6. During the past 12 months, how many: (*Enter '00' if none*)
   - 6a. Times has the child been seen in an emergency department for asthma? ___ ___ times (1090)
   - 6b. Times has the child been seen at a doctor's office for asthma? *(Include both routine visits and visits for acute problems)* ___ ___ times (1100)
   - 6c. Days of work or school did the child miss because of asthma? ___ ___ days (1110)
   - 6d. Days of work did you miss because of the child's asthma? ___ ___ days (1120)

SENSITIVITIES

(Check only one response for each question below)

Is the child's asthma provoked on:

		Never causes asthma	Occasionally causes asthma	Frequently causes asthma	Always or almost always causes asthma	Don't know	
7.	Exposure to house dust?	❑1	❑2	❑3	❑4	❑5	(1130)
8.	Exposure to animals?	❑1	❑2	❑3	❑4	❑5	(1140)
9.	Emotional factors? (e.g., stress)	❑1	❑2	❑3	❑4	❑5	(1150)
10.	Exercise/play?	❑1	❑2	❑3	❑4	❑5	(1160)
11.	Exposure to damp, musty area? (e.g., damp basement)	❑1	❑2	❑3	❑4	❑5	(1170)
12.	Exposure to tobacco smoke?	❑1	❑2	❑3	❑4	❑5	(1180)
13.	Exposure to a change in the weather?	❑1	❑2	❑3	❑4	❑5	(1190)
14.	Respiratory infections?	❑1	❑2	❑3	❑4	❑5	(1200)
15.	Exposure to chemicals? (e.g., perfume, household cleaners)	❑1	❑2	❑3	❑4	❑5	(1210)
16.	Food?	❑1	❑2	❑3	❑4	❑5	(1220)
17.	Exposure to cold air?	❑1	❑2	❑3	❑4	❑5	(1230)
18.	Aspirin?	❑1	❑2	❑3	❑4	❑5	(1240)
19.	Exposure to spring and fall pollens?	❑1	❑2	❑3	❑4	❑5	(1250)

ALLERGY HISTORY

20. Has the child ever had hay fever? (i.e., itchy eyes, runny nose, or sneezing recurring over several weeks in a particular season) ❑1 Yes ❑0 No (1260)
    ➜ ***If NO, skip to Question #21.***

    20a. At what age did the child FIRST have hay fever? ___ ___ years (1270) ___ ___ months (1280)

    20b. During the past 12 months, did the child have hay fever? ❑1 Yes ❑0 No (1290)

    20c. Has the child ever seen a doctor or other health practitioner because of hay fever? ❑1 Yes ❑0 No (1300)

21. Has the child ever had atopic dermatitis (eczema)? ☐1 Yes ☐0 No (1310)

➜ ***If NO, skip to Question #22.***

21a. At what age did the child FIRST have atopic dermatitis (eczema)? ____ ____ years (1320) ____ ____ months (1330)

21b. During the past 12 months, did the child have atopic dermatitis? ☐1 Yes ☐0 No (1340)

21c. Has the child ever seen a doctor or other health practitioner because of atopic dermatitis? ☐1 Yes ☐0 No (1350)

22. Has a doctor or other health practitioner ever said that the child has allergies? ☐1 Yes ☐0 No (1360)

➜ ***If NO, skip to Question #24.***

23. To which of the following did a doctor or other health practitioner say the child was allergic:

23a. Medicines ☐1 Yes ☐0 No (1370)

23b. Foods ☐1 Yes ☐0 No (1380)

23c. Things you breathe in or inhale (e.g., dust, pollens, molds, animal fur, or dander) ☐1 Yes ☐0 No (1390)

23d. Stinging insects such as bees or wasps ☐1 Yes ☐0 No (1400)

23e. Other _____ ☐1 Yes ☐0 No (1410)

ASTHMA SYMPTOMS

24. On average, during the past MONTH, how often has the child had a cough, wheeze, shortness of breath, or chest tightness?

☐1 2 times or less per week (1420)
☐2 3 - 6 times per week
☐3 Daily
☐4 More than once a day

25. On average, during the past MONTH, how often was the child awakened from sleep because of coughing, wheezing, shortness of breath, or chest tightness?

☐1 2 times or less per month (1430)
☐2 3 - 4 times per month
☐3 5 - 9 times per month
☐4 10 or more times per month

26. On average, during the past MONTH, how often has the child had cough, wheeze, shortness of breath, or chest tightness while exercising or playing? (1440)

- ☐ 1 2 times or less per month
- ☐ 2 3 - 4 times per month
- ☐ 3 5 - 9 times per month
- ☐ 4 10 or more times per month

27. On average, during the past MONTH, how often does asthma keep the child from doing what the child wants? (1450)

- ☐ 1 2 times or less per month
- ☐ 2 3 - 4 times per month
- ☐ 3 5 - 9 times per month
- ☐ 4 10 or more times per month

28. In general, during the past MONTH, how bothered was the child by his/her asthma? (1460)

- ☐ 1 Not bothered at all
- ☐ 2 Hardly bothered at all
- ☐ 3 Somewhat bothered
- ☐ 4 Bothered
- ☐ 5 Quite bothered
- ☐ 6 Very bothered
- ☐ 7 Extremely bothered

Childhood Asthma Research & Education
NIH / NHLBI

CAP/FEIA RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1.	Mite Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1000)
2.	Roach Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1010)
3.	Cat CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1020)
4.	Dog CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1030)
5.	Mold Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1040)
6.	Grass Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1050)
7.	Tree Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1060)
8.	Weed Mix CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1070)
9.	Milk CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1080)
10.	Egg CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1090)
11.	Peanut CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1100)
12.	Other _____CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1110)
13.	Other _____CAP/FEIA test results	___ ___ ___ . ___ ___ Au/L	(1120)

Childhood Asthma Research & Education
NIH / NHLBI

CONCOMITANT MEDICATIONS for ASTHMA/ALLERGY-RELATED DRUGS and ADVERSE EVENTS

Subject ID: ___ ___- ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___/ ___ ___/ ___ ___ ___ ___
Month Day Year

(Coordinator completed)

Instructions: Please list all concomitant medications used to treat asthma/allergies or taken for adverse events. Since this is a cumulative form, the table should be updated at each visit. If the concomitant medication was used for an adverse event, record the corresponding AECLIN2 event number. If the concomitant medication was taken to treat asthma/allergies and was unrelated to an adverse event, please check the 'NA' box. Check the 'None' box only if the participant has **not** taken any concomitant medications used to treat asthma/allergies or adverse events at the time of data entry.

❑0 None

NAME OF MEDICATION (1010)	CODE (1000)	RELATED EVENT (1020) (1030)	DOSE/ UNITS	FREQUENCY (1040)	ROUTE	START DATE (MM/DD/YYYY) (1060) (1070) (1080)	STOP DATE (MM/DD/YYYY) (1090)	ONGOING AT DATA ENTRY (1100)
__ __		Event __ __ ❑1 NA				___/___/____	___/___/____	❑1
__ __		Event __ __ ❑1 NA				___/___/____	___/___/____	❑1
__ __		Event __ __ ❑1 NA				___/___/____	___/___/____	❑1
__ __		Event __ __ ❑1 NA				___/___/____	___/___/____	❑1
__ __		Event __ __ ❑1 NA				___/___/____	___/___/____	❑1

❑ Data Entered?

Childhood Asthma Research & Education
NIH / NHLBI

AIMS COMPLIANCE CHECKLIST

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following adherence criteria at Visits 3 through 9.

1. How many RTI's (or illnesses) has your child had since the last visit? ___ ___ (1000)

2. Were the study drug kits returned to the clinic at this visit? ❑ 1 Yes ❑ 0 No (1005)

   If No, please remind the parents of the importance of bringing the drug kits to every study visit.

   ➔ ***If NO, STOP HERE.***

3. **"Respule" count**

   2a. Number of respules dispensed ___ ___ ___ respules (1010)

   2b. Number of respules returned ___ ___ ___ respules (1020)

   2c. Number of respules scheduled (Question #1 x 28 respules) ___ ___ ___ respules (1030)

   2d. Actual number of respules used (Question #2a - Question #2b) ___ ___ ___ respules (1040)

   2e. Percent adherence = $\frac{\textit{Question \#2d}}{\textit{Question \#2c}}$ x *100* ___ ___ ___ . ___ % (1050)

3. **"Tablet/Granule Packet" count**

   3a. Number of tablets/granule packets dispensed ___ ___ ___ tablets/granule packets (1060)

   3b. Number of tablets/granule packets returned ___ ___ ___ tablets/granule packets (1070)

   3c. Number of scheduled doses (Question #1 x 7 tablets/granule packets) ___ ___ ___ doses (1080)

   3d. Actual number of tablets/granule packets used (Question #3a - Question #3b) ___ ___ ___ tablets/granule packets (1090)

   3e. Percent adherence = $\frac{\textit{Question \#3d}}{\textit{Question \#3c}}$ x *100* ___ ___ ___ . ___ % (1100)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS COMPLIANCE CHECKLIST

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following adherence criteria at Visits 3 through 9 for used study drug kits. For each unused study drug kit returned, please count to be sure the correct number of respules and tablets/granules packets are present.

1. How many RTI's (or respiratory illnesses) has your child *completed* since the last scheduled clinical visit? ___ ___ illnesses (1000)

   ➔ ***If 0, skip to Question #3.***

2. Were study drug kits used for all the above illnesses? ❑1 Yes ❑0 No (1003)

   2a. If ***NO***, please explain: _____

   _____

   2b. If ***NO***, for how many illnesses were study drug kits used? ____ ____ illnesses (1004)

3. How many *used* study drug kits were returned at this study visit for *any* AIMS illnesses? ___ ___ kits (1008)

   ➔ ***If 0, STOP HERE. Please remind the parents of the importance of bringing the drug kits to every study visit.***

4. **"Respule" count**

   4a. Number of respules dispensed ___ ___ ___ respules (1010)

   4b. Number of respules returned ___ ___ ___ respules (1020)

   4c. Number of respules scheduled (Question #3 x 28 respules) ___ ___ ___ respules (1030)

   4d. Actual number of respules used (Question #4a - Question #4b) ___ ___ ___ respules (1040)

   4e. Percent adherence = $\frac{\textit{Question \#4d}}{\textit{Question \#4c}}$ x *100* ___ ___ ___ . ___ % (1050)

5. **"Tablet/Granule Packet" count**

   5a. Number of tablets/granule packets dispensed ___ ___ ___ tablets/granule packets (1060)

   5b. Number of tablets/granule packets returned ___ ___ ___ tablets/granule packets (1070)

   5c. Number of scheduled doses (Question #3 x 7 tablets/granule packets) ___ ___ ___ doses (1080)

   5d. Actual number of tablets/granule packets used (Question #5a - Question #5b) ___ ___ ___ tablets/granule packets (1090)

   5e. Percent adherence = $\frac{\textit{Question \#5d}}{\textit{Question \#5c}}$ x *100* ___ ___ ___ . ___ % (1100)

Childhood Asthma Research & Education
NIH / NHLBI

(Parent/Guardian completed)

AIMS DIARY CARD

Initials: ___ ___ ___ (1000)

Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (1010)

Subject ID: 0 4 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Return Visit Number: ___ ___

Return Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Date (month/day) (dmonth/dday)							
Day of the week (Mon, Tie, etc...)							
Complete each morning: Covers period of time from when your child went to bed for the night to when he/she awoke this morning							
1. How much did your child cough last night after going to bed until he/she awoke this morning? (1020) 0 = Not at all 1 = Very little 2 = Several times 3 = Frequently 4 = Almost all night 5 = I do not know	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
2. How many times did you give your child albuterol since he/she went to bed last night? (If your child did not wake up last night due to asthma, then you fill in "0".) Number of times: (1030)	____	____	____	____	____	____	____
3. How many puffs or nebulizer treatments of albuterol did your child use since he/she was put to bed for the night until he/she awoke this morning? (If your child did not wake up last night due to asthma, then you should fill in "0".) Albuterol Inhaler: number of puffs (1040) Albuterol by nebulizer: number of treatments (1050)	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____
Complete each night after child goes to bed: Covers period of time since your child awoke this morning for the day.							
4. How severe was your child's cough today? (1060) 0 = No cough 1 = Very mild cough 2 = Mild cough 3 = Moderate cough 4 = Severe cough 5 = Very severe cough	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
5. How severe was your child's wheezing today? (1070) 0 = No wheezing 1 = Very mild wheezing 2 = Mild wheezing 3 = Moderate wheezing 4 = Severe wheezing 5 = Very severe wheezing	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
6. How severe was your child's trouble breathing today? (1080) 0 = No trouble breathing 1 = Very mild trouble breathing 2 = Mild trouble breathing 3 = Moderate trouble breathing 4 = Severe trouble breathing 5 = Very severe trouble breathing	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5

*****REMEMBER TO COMPLETE THE BACK OF THE DIARY CARD EACH DAY*****

Date (month/day) (dmonth/dday)							
Day of the week (Mon, Tue, etc...)							
7. How much did your child's asthma symptoms interfere with your child's activities today? (1090) 0 = Did not interfere 1 = Very mildly interfered 2 = Mildly interfered 3 = Moderately interfered 4 = Severly interfered 5 = Very severely interfered	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5	0 1 2 3 4 5
8. Did your child visit a doctor, emergency room , or hospital for asthma symptoms (other than a scheduled visit to a doctor), or was your child treated with oral prednisone during the previous 24 hours? (1100) ***If Question 8 is answered Yes, complete Questions #8a - 8d:***	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
8a. Visited a doctor (1110)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
8b. Visited an Emergency Room (1120)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
8c. Admitted to the Hospital Overnight (1130)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
8d. Treated with Prednisone (1140)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
9. How many times did you give your child albuterol since he/she awoke this morning? (If your child did not use any albuterol since waking up this morning, fill in "0".) Number of times: (1150)	____	____	____	____	____	____	____
10. How many puffs or nebulizer treatments of albuterol did your child use since he/she woke up this morning? (If your child did not use any albuterol since waking up this morning, then you should fill in "0".) Albuterol Inhaler: number of puffs (1160) Albuterol by nebulizer: number of treatments (1170)	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____	 ____ ____
Additional Medications/Symptoms Today							
11. Did your child take the nebulizer study medication this morning? (1180)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
12. Did your child take the nebulizer study medication tonight? (1190)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
13. Did your child take the study granules/tablet today? (1200)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
If your child starts study medication (granules/tablets and/or nebulized study medication other than albuterol), follow your Action Plan and contact study personnel within 72 hours.							
14. Was your child absent from school or daycare today due to breathing problems? (1210)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
15. Was a parent unable to go to work or school today due to your child's breathing problems? (1220)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0

You will be asked at the next study visit about any medications taken and any medical problems that occurred since the last study visit. Keeping notes below between study visits will be helpful in answering these questions.

MEDICAL OR BREATHING PROBLEMS

Please indicate any medical or breathing problems your child has had during the week.

Date/Time	Problem Description	Date/Time	Problem Description

NON-STUDY MEDICATIONS

Please indicate any non-study medications (both prescription and over-the-counter) your child used during the week.

Medication	Dosage/Frequency	Dates Taken	Reason

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
ELIGIBILITY CHECKLIST 1
Screening Visit (S1)

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Informed Consent

1. Has a parent/legal guardian appropriately signed and dated the informed consent? ☐ 1 Yes ☐ 0 No (1000)

2. If **YES**, record the date the form was signed. ___ ___ / ___ ___ / ___ ___ ___ ___ (1010) (month / day / year)

Medical History Criteria

3. Is the participant 12 to 59 months old? ☐ 1 Yes ☐ 0 No (1020)

4. Was the participant born before 36 weeks gestation? ☐ 1 Yes ☐ 0 No (1030)

5. Is the participant up-to-date with immunizations? ☐ 1 Yes ☐ 0 No (1040)

6. Has the participant ever had chicken pox or received the chicken pox vaccine? *(Refer to MOP for discussion on immunization records)* ☐ 1 Yes ☐ 0 No (1050)

7. Does the participant have any immunodeficiency disorders? ☐ 1 Yes ☐ 0 No (1060)

8. Does the participant have a chronic or active lung disease other than asthma? ☐ 1 Yes ☐ 0 No (1070)

9. Does the participant have a significant medical illness other than asthma (e.g. heart disease, thyroid disease, diabetes mellitus, Cushing's, Addison's, or hepatic disease)? ☐ 1 Yes ☐ 0 No (1080)

10. Does the participant have a history of cataracts, glaucoma, or other medical disorders (such as thrush that is difficult to treat) associated with an adverse effect to glucocorticoids? ☐ 1 Yes ☐ 0 No (1090)

11. Does the participant have concurrent medical problems other than asthma that are likely to require oral or injectable corticosteriods during the study? ☐ 1 Yes ☐ 0 No (1100)

12. Is the participant being treated with antibiotics for sinus disease? ☐ 1 Yes ☐ 0 No (1110)

13. Is the participant being treated with medication for gastroesophageal reflux? ☐ 1 Yes ☐ 0 No (1120)

14. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1130)

➜ ***If NO, please STOP HERE and complete the source documentation box on the last page, and complete the Termination of Study Participation (P4_TERM) form.***

Wheezing/Asthma Criteria

15. During the past year, has the participant had 2 or more episodes of wheezing during a respiratory tract illness or cold? ☐ 1 Yes ☐ 0 No (1140)

16. During the past year, was at least one wheezing episode during a respiratory tract illness or cold documented by a health care provider? (Parental Report) ☐ 1 Yes ☐ 0 No (1150)

17. During the past year, did at least one wheezing episode during a respiratory tract illness or cold occur within the preceding 6 months? ☐ 1 Yes ☐ 0 No (1160)

18. How many wheezing episodes, during a respiratory tract illness or cold, has your child had in the past year which required treatment with **at least** a bronchodilator **and** resulted in a visit to a health care provider, urgent care area, emergency room, or hospital? (Enter '00' if none) ___ ___ (1170)

19. How many courses of oral corticosteroid (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone) for wheezing episodes, during a respiratory tract illness or cold, did your child receive **without** a visit to any health care provider, urgent care area, room, or hospital visits? (Enter '00' if none) ___ ___ (1180)

20. Is the sum of Question #18 and Question #19 ≥ 2? ☐ 1 Yes ☐ 0 No (1190)

21. Has your child been hospitalized overnight for a wheezing illness 3 or more times in the past year? ☐ 1 Yes ☐ 0 No (1200)

22. Has the participant ever had a seizure (during an asthma episode) that the physician thought was due to asthma? ☐ 1 Yes ☐ 0 No (1210)

23. Has the participant ever had respiratory failure resulting in mechanical ventilation? ☐ 1 Yes ☐ 0 No (1220)

24. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1230)

➜ ***If NO, please STOP HERE and complete the source documentation box on the last page, and complete the Termination of Study Participation (P4_TERM) form.***

Medication Criteria

25. During the past year, has the participant had more than 6 oral or injectable corticosteroid courses? ☐ 1 Yes ☐ 0 No (1240)

26. During the past year, has the participant used controller medications (ICS, LTRA, cromolyn/nedocromil or theophylline) for a total of 4 or more months? ☐ 1 Yes ☐ 0 No (1250)

27. Within the past 2 weeks, has the participant used any controller medications (ICS, LTRA, cromolyn/nedocromil or theophylline)? ☐ 1 Yes ☐ 0 No (1260)

28. Has the participant ever had an adverse reaction to budesonide (Pulmicort), montelukast (Singulair), or any of their ingredients? ☐ 1 Yes ☐ 0 No (1270)

29. Has the participant tolerated oral corticosteroids (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone)? ☐ 1 Yes ☐ 0 No ☐ 9 N/A (1280)

30. Has the participant tolerated albuterol? ☐ 1 Yes ☐ 0 No ☐ 9 N/A (1290)

31. Has the participant used any systemic corticosteroid treatments (oral or injectable) within the past 2 weeks? ☐ 1 Yes ☐ 0 No (1300)

32. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P4_EXCLDRUG) during the designated washout periods? ☐ 1 Yes ☐ 0 No (1310)

Other Criteria

33. Does the parent/legal guardian feel they will be able to coordinate the use of the study nebulizer? ☐ 1 Yes ☐ 0 No (1320)

34. Does the parent/legal guardian feel they will be able to coordinate the use of the study granules/tablets? ☐ 1 Yes ☐ 0 No (1330)

35. Currently or within the past month, has the participant been involved in an investigational drug trial? ☐ 1 Yes ☐ 0 No (1340)

36. Does the participant's family have plans to move out of the area before the end of the study? ☐ 1 Yes ☐ 0 No (1350)

37. Is there any other reason for which this participant should not be included in this study? ☐ 1 Yes ☐ 0 No (1360)

If ***YES***, describe: _____
_____

38. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1370)

➜ ***If NO, please STOP HERE and complete the source documentation box, and complete the Termination of Study Participation (P4_TERM) form.***

Physician/CC signature: _____ (1380)
Date: __ __ / __ __ / __ __ __ __ (1390)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
ELIGIBILITY CHECKLIST 2
Randomization Visit (RZ)

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Medication Use Symptom Criteria

1. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P4_EXCLDRUG) during the designated washout periods? ☐ 1 Yes ☐ 0 No (1010)

Compliance

For Questions #2 - #5, please refer to the participant's Diary Cards (P4_DIARY), collected at Visit 2.

2. Number of days between Visit 1 and Visit 2 (excluding today and the participant's Visit 1 date) ___ ___ days (1020)

3. Diary compliance

   3a. Number of days diary card is completed ___ ___ days (1030)

   3b. Percent adherence = $\frac{\textit{Question \#3a}}{\textit{(Question \#2)}}$ x *100* ___ ___ ___ . ___ % (1040)

   3c. Is Question #3b ≥ 80%? ☐ 1 Yes ☐ 0 No (1050)

Symptom Criteria

4. Number of days with symptoms and/or albuterol use. Do not count any day more than once. (If P4_DIARY Q 1, 2, 5, 6, 7, or 9 = anything other than '0', count that day, if P4_DIARY Q 4 = anything greater than '2', count that day) (Total days should not exceed the answer for Q 2.) ___ ___ days (1060)

5. Average number of days per week with symptoms and/or albuterol use for breathing problems.

   $$\textit{Average} = \frac{\textit{Question \#4}}{\textit{Question \#2}} \times 7$$ ___ . ___ days (1070)

   5a. Is Question #5 < 4.0? ☐ 1 Yes ☐ 0 No (1080)

6. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1090)

   ➜ ***If NO, please STOP HERE and complete the source documentation box on the last page, and complete the Termination of Study Participation (P4_TERM) form.***

Asthma Predictive Index

7. Has the participant had 4 or more exacerbations of wheezing during the previous 12 months with at least one of these documented by a health care provider? ☐ 1 Yes ☐ 0 No (1100)

   ➜ **If Question 7 is NO, then Question 11 is also NO.**

8. Have either of the participant's parents been diagnosed with asthma by a health care provider? ☐ 1 Yes ☐ 0 No (1110)

9. Has the participant ever been diagnosed with atopic dermatitis by a health care provider? ☐ 1 Yes ☐ 0 No (1120)

Please complete the Allergy Skin Test Results (SKIN) form and use the results to complete Question #10.

10. Does the participant have a positive allergy test to at least one aeroallergen? ☐ 1 Yes ☐ 0 No (1130)

11. Is the participant's API positive? ☐ 1 Yes ☐ 0 No (1140)
    (API+ if Q 7 is 'yes' and at least one of Q 8, 9, or 10 is 'yes'.)

Other Criteria

12. Does the parent/legal guardian believe that they will be able to comply with the study schedule and study requirements? ☐ 1 Yes ☐ 0 No (1150)

13. Is there any other reason for which this participant should not be included in this study? ☐ 1 Yes ☐ 0 No (1160)

    If ***YES***, describe: _____
    _____

14. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1170)

    ➜ ***If NO, please STOP HERE and complete the source documentation box, and complete the Termination of Study Participation (P4_TERM) form.***

    ➜ ***If YES, the participant can be randomized.***

15. Drug Packet Number (record on P4_LOG) ___ (1180) - ___ (1190) - ___ (1200)

Physician/CC signature: _____ (1210)
Date: __ __ / __ __ / __ __ __ __ (1220)

Childhood Asthma Research & Education
NIH / NHLBI

eNO Study
In Young Children Aged 12-59 Months

Supervisor ID: ___ ___ ___ ___ ___
(Do not data enter Supervisor ID)

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___

(Technician completed)

Please note the number of breaths, the child's condition and mouth opening pressure in the boxes, while obtaining 5 exhaled breaths into each bag.

EXCLUSIONS

1. Is the child currently stable without an acute wheezing exacerbation? ❑ 1 Yes ❑ 0 No (1000)

2. Does the child have respiratory distress or a respiratory rate over 40 breaths per minute? ❑ 1 Yes ❑ 0 No (1010)

3. Did the child take an oral steroid within the past month? ❑ 1 Yes ❑ 0 No (1020)

4. Has the child ever used an AIMS study drug kit for an illness? ❑ 1 Yes ❑ 0 No (1025)
If YES, the child is NOT eligible for ENO testing at any time during the AIMS study.

5. Is the child eligible to proceed with the ENO testing? ❑ 1 Yes ❑ 0 No (1030)
If any of the shaded boxes are filled in, the child is NOT eligible for ENO testing.
➜ ***If NO, STOP HERE.***

CONFOUNDERS

6. Was the ENO procedure performed? ❑ 1 Yes ❑ 0 No (1035)
   6a. If **NO**, indicate the primary reason
   ❑ 1 Child/Parent refused (1036)
   ❑ 2 Equipment failure
   ❑ 3 Child uncooperative
   ❑ 4 Other _____

If Question #6 is answered NO, STOP HERE and attempt to complete this form at the next visit.

7. During the past 4 hours, has the child used a short-acting bronchodilator or albuterol? ❑ 1 Yes ❑ 0 No ❑ 9 Unknown (1040)

8. During the past 12 hours, has the child used a long-acting bronchodilator or sameterol? ❑ 1 Yes ❑ 0 No ❑ 9 Unknown (1050)

9. Has the child been exposed to a smoker in the past 24 hours? ❑ 1 Yes ❑ 0 No ❑ 9 Unknown (1060)

10. Did the child eat or drink in the past hour? ❑ 1 Yes ❑ 0 No ❑ 9 Unknown (1070)

11. ENO Measurement Bag #1 ___ ___ ___ . ___ ___ ppb (1080)

11a. Number of Breaths ___ ___ ___ ___ (1090)

11b. Was the child fussy? ❑1 Yes ❑0 No (1100)

12. ENO Measurement Bag #2 ___ ___ ___ . ___ ___ ppb (1120)

12a. Number of Breaths ___ ___ ___ ___ (1130)

12b. Was the child fussy? ❑1 Yes ❑0 No (1140)

13. ENO Measurement Bag #3 ___ ___ ___ . ___ ___ ppb (1160)

13a. Number of Breaths ___ ___ ___ ___ (1170)

13b. Was the child fussy? ❑1 Yes ❑0 No (1180)

Childhood Asthma Research & Education
NIH / NHLBI

eNO Study
In Young Children Aged 12-59 Months
Visit 9

Supervisor ID: ___ ___ ___ ___ ___
(Do not data enter Supervisor ID)

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Technician ID: ___ ___ ___ ___ ___
Offline Reader ID: ___ ___ ___ ___ ___
(Do not data enter Reader ID)

(Technician completed)

MASK OFFLINE : *(for all children) Please note the number of breaths, the child's condition and mouth opening pressure in the boxes, while obtaining 5 exhaled breaths into each bag.*

MOUTHPIECE ONLINE : *(for children ages 3 and older)*

EXCLUSIONS

1. Is the child currently stable without an acute wheezing exacerbation? ☐1 Yes ☐0 No (1000)

2. Does the child have respiratory distress or a respiratory rate over 40 breaths per minute? ☐1 Yes ☐0 No (1010)

3. Did the child take any anti-inflammatory medications (including corticosteroids and leukotriene modifiers) within the past 4 weeks? ☐1 Yes ☐0 No (1020)

4. Has the child used an AIMS study drug kit for an illness within the past 4 weeks? ☐1 Yes ☐0 No (1025)

5. Is the child eligible to proceed with the ENO testing? ☐1 Yes ☐0 No (1030)
If any of the shaded boxes are filled in, the child is NOT eligible for ENO testing.
➜ ***If NO, STOP HERE.***

CONFOUNDERS

6. Was the ENO procedure performed? ☐1 Yes ☐0 No (1035)
   6a. If **NO**, indicate the primary reason
   ☐1 Child/Parent refused (1036)
   ☐2 Equipment failure
   ☐3 Child uncooperative
   ☐4 Other _____

If Question #6 is answered NO, STOP HERE

7. During the past 4 hours, has the child used a short-acting bronchodilator or albuterol? ☐1 Yes ☐0 No ☐9 Unknown (1040)

8. During the past 12 hours, has the child used a long-acting bronchodilator or sameterol? ☐1 Yes ☐0 No ☐9 Unknown (1050)

9. Has the child been exposed to secondhand smoke in the past 24 hours? ❑1 Yes ❑0 No ❑9 Unknown (1060)

10. Did the child eat or drink in the past hour? ❑1 Yes ❑0 No ❑9 Unknown (1070)

MASK OFFLINE *(for all children)*

11. Was the eNO performed using the mask? ❑1 Yes ❑0 No (1080)

➜If NO, Skip to Question #15.

12. ENO Measurement Bag #1 ___ ___ ___ . ___ ___ ppb (1090)

12a. Number of Breaths ___ ___ ___ ___ (1100)

12b. Was the child fussy? ❑1 Yes ❑0 No (1110)

13. ENO Measurement Bag #2 ___ ___ ___ . ___ ___ ppb (1120)

13a. Number of Breaths ___ ___ ___ ___ (1130)

13b. Was the child fussy? ❑1 Yes ❑0 No (1140)

14. ENO Measurement Bag #3 ___ ___ ___ . ___ ___ ppb (1150)

14a. Number of Breaths ___ ___ ___ ___ (1160)

14b. Was the child fussy? ❑1 Yes ❑0 No (1170)

MOUTHPIECE ONLINE *(for children age 3 and older)*

15. Was the eNO performed using the mouthpiece? ❑1 Yes ❑0 No (1180)

➜If NO, STOP HERE.

16. ENO Measurement #1 ___ ___ ___ . ___ ___ ppb (1190)

17. ENO Measurement #2 ___ ___ ___ . ___ ___ ppb (1200)

18. ENO Measurement #3 ___ ___ ___ . ___ ___ ppb (1210)

19. Average FE_{NO} ___ ___ ___ . ___ ___ ppb (1220)

20. Average V_{NO} ___ ___ ___ . ___ ___ nl/min (1230)

21. Test Profile

- ❑ 1 10 sec ATS (1240)
- ❑ 2 6 sec ATS
- ❑ 3 6 sec Non-ATS
- ❑ 4 Modified by user - Only 2 ATS acceptable
- ❑ 5 Modified by user - Other

21a. If Question #21 is answered 'Modified by user - Other', please explain in the comment section below:

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH / NHLBI

HOME ENVIRONMENT QUESTIONNAIRE 2

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Parent/Legal Guardian completed)

PARENT/GUARDIAN INFORMATION

1. What is your relationship to the child? (*Check one box only*)

- ❑1 Parent (1000)
- ❑2 Stepparent
- ❑3 Grandparent
- ❑4 Legal guardian (but not parent)
- ❑5 Other _____

GENERAL HOME CHARACTERISTICS

2. Has the child lived in his/her current home since birth?

❑1 Yes ❑0 No (1010)

➜ ***If YES, skip to Question #4.***

3. How long has your child lived in the current home?

___ ___ (1015) years ___ ___ (1016) months

4. Which best describes the child's current home? (*Check one box only*)

- ❑1 A one-family house detached from any other house (1080)
- ❑2 A one-family house attached to one or more houses
- ❑3 A building for 2 families
- ❑4 A building for 3 or 4 families
- ❑5 A building for 5 or more families
- ❑6 A mobile home or trailer
- ❑7 A boat, tent, or van
- ❑8 Other _____

5. How old is the child's current home? *(Estimate if uncertain)*

___ ___ ___ years (1090)

6. Does the child's home use a portable heater?

❑1 Yes ❑0 No (1100)

7. Does the child's home use a wood burning stove as a primary source of heat?

❑1 Yes ❑0 No (1110)

8. Does the child's home use a cooling system? ❑1 Yes ❑0 No (1120)

   ➜ ***If NO, skip to Question #11.***

9. Which type of cooling system is used in the child's home? *(Check one box only)*

   ➜ ***If NOT Window units (options 2, 4, 5, 7, and 8), skip to Question #11.***

   ❑1 Window unit(s) (1130)
   ❑2 Central air
   ❑3 Central air and window unit(s)
   ❑4 Evaporative cooling
   ❑5 Evaporative cooling and central air
   ❑6 Evaporative cooling and window units
   ❑7 Other _____
   ❑8 Don't know

10. Which rooms use a window unit?

    10a. Child's bedroom ❑1 Yes ❑0 No (1140)

    10b. Other bedrooms ❑1 Yes ❑0 No (1150)

    10c. Living or family room ❑1 Yes ❑0 No (1160)

    10d. Kitchen ❑1 Yes ❑0 No (1170)

    10e. Other _____ ❑1 Yes ❑0 No (1180)

11. Does the child's home use a humidifier? *(Include humidifier built into the heating system of the child's home)* ❑1 Yes ❑0 No ❑9 Don't know (1190)

    ➜ ***If NO or DON'T KNOW, skip to Question #13.***

12. Which rooms use a humidifier?

    12a. Child's bedroom ❑1 Yes ❑0 No (1200)

    12b. Other bedrooms ❑1 Yes ❑0 No (1210)

    12c. Living or family room ❑1 Yes ❑0 No (1220)

    12d. Kitchen ❑1 Yes ❑0 No (1230)

    12e. Other _____ ❑1 Yes ❑0 No (1240)

13. Does the child's home use a de-humidifier? *(Include de-humidifier built into the cooling system of the child's home)* ❑1 Yes ❑0 No ❑9 Don't know (1250)

14. Has there been water damage to the child's home, basement, or its contents during the past 12 months? ❑1 Yes ❑0 No ❑9 Don't know (1260)

15. Has there been any mold or mildew, on any surfaces, inside the child's home in the past 12 months? ❑1 Yes ❑0 No ❑9 Don't know (1270)

    ➜ ***If NO or Don't know, skip to Question #17.***

16. Which room(s) have or have had mold or mildew?

16a.	Bathroom(s)	❑1 Yes	❑0 No (1280)
16b.	Child's bedroom	❑1 Yes	❑0 No (1290)
16c.	Other bedrooms	❑1 Yes	❑0 No (1300)
16d.	Living or family room	❑1 Yes	❑0 No (1310)
16e.	Kitchen	❑1 Yes	❑0 No (1320)
16f.	Basement or attic	❑1 Yes	❑0 No (1330)
16g.	Other _____	❑1 Yes	❑0 No (1340)

17. Do you ever see cockroaches in the child's home? ❑1 Yes ❑0 No (1350)

➜ ***If NO, skip to Question #19.***

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

18a.	Bathroom(s)	❑1 Yes	❑0 No (1360)
18b.	Child's bedroom	❑1 Yes	❑0 No (1370)
18c.	Other bedrooms	❑1 Yes	❑0 No (1380)
18d.	Living or family room	❑1 Yes	❑0 No (1390)
18e.	Kitchen	❑1 Yes	❑0 No (1400)
18f.	Basement or attic	❑1 Yes	❑0 No (1410)
18g.	Other _____	❑1 Yes	❑0 No (1420)

CHARACTERISTICS OF CHILD'S BEDROOM

(If child does not have a bedroom, answer in terms of the room where the child sleeps)

19. Does the child share his/her bedroom with another person? ❑1 Yes ❑0 No (1430)

19a. If ***YES***, how many others? ___ ___ (1440)

20. What is the floor covering in the child's bedroom? *(Check one box only)*

❑1 Rug/carpet (1450)
❑2 Vinyl tile or linoleum
❑3 Wood
❑4 Ceramic tile
❑5 Other _____
❑6 Don't know

20a. If ***carpeted***, what type of padding is under the carpet in the child's bedroom? *(Check one box only)*

- ❑ 1 None (1460)
- ❑ 2 Foam
- ❑ 3 Other _____
- ❑ 4 Don't know

21. What type of mattress is on the child's bed? *(Check one box only)*
➜ If NONE or DON'T KNOW, skip to Question #24.

- ❑ 1 None (1470)
- ❑ 2 Inner spring mattress
- ❑ 3 Foam mattress
- ❑ 4 Waterbed
- ❑ 5 Air mattress
- ❑ 6 Other _____
- ❑ 7 Don't know

22. How old is the mattress used on the child's bed? *(Estimate if uncertain)*

____ ____ years (1480)

23. Is the mattress completely enclosed in an allergy-proof, encasing cover?

❑ 1 Yes ❑ 0 No (1490)

24. Does the child's bed have a box spring?
➜ If NO, skip to Question #26.

❑ 1 Yes ❑ 0 No (1500)

25. Is the box spring completely enclosed in an allergy-proof, encasing cover?

❑ 1 Yes ❑ 0 No (1510)

26. What type of pillow is used on the child's bed? *(Check one box only)*
➜ If NONE or DON'T KNOW, skip to Question #29.

- ❑ 1 None (1520)
- ❑ 2 Feather/down
- ❑ 3 Foam
- ❑ 4 Dacron/synthetic
- ❑ 5 Other _____
- ❑ 6 Don't know

27. How old is the pillow used on the child's bed? *(Estimate if uncertain)*

____ ____ years (1530)

28. Is the pillow completely enclosed in an allergy-proof, encasing cover?

❑ 1 Yes ❑ 0 No (1540)

29. Are the child's bed covers or sheets washed in hot water at least 1 time per week?

❑ 1 Yes ❑ 0 No (1550)

30. Are any of the following located on your property?

30a.	Barns	❑1 Yes	❑0 No	(1020)
30b.	Hay	❑1 Yes	❑0 No	(1030)
30c.	Woodsheds	❑1 Yes	❑0 No	(1040)
30d.	Firewood	❑1 Yes	❑0 No	(1050)
30e.	Chicken coops	❑1 Yes	❑0 No	(1060)
30f.	Horses	❑1 Yes	❑0 No	(1070)

ANIMALS

31. Does your family have any animals? ❑1 Yes ❑0 No (1560)

➜ If NO, skip to Question #33.

32. Enter the number of animals that the family has. *(Enter '00' if none)*

32a.	Cat	___ ___	(1570)
32b.	Dog	___ ___	(1580)
32c.	Rabbit, guinea pig, hamster, gerbil, or mouse	___ ___	(1590)
32d.	Bird	___ ___	(1600)
32e.	Other _____	___ ___	(1610)

33. Are there any animals in the child's home? ❑1 Yes ❑0 No (1620)

➜ If NO, skip to Question #36.

34. Which animals are in the child's home?

34a.	Cat	❑1 Yes	❑0 No	❑9 N/A	(1630)
34b.	Dog	❑1 Yes	❑0 No	❑9 N/A	(1640)
34c.	Rabbit, guinea pig, hamster, gerbil, or mouse	❑1 Yes	❑0 No	❑9 N/A	(1650)
34d.	Bird	❑1 Yes	❑0 No	❑9 N/A	(1660)
34e.	Other _____	❑1 Yes	❑0 No	❑9 N/A	(1670)

35. Which animals are in the child's bedroom?

35a.	Cat	❑1 Yes	❑0 No	❑9 N/A	(1680)
35b.	Dog	❑1 Yes	❑0 No	❑9 N/A	(1690)
35c.	Rabbit, guinea pig, hamster, gerbil, or mouse	❑1 Yes	❑0 No	❑9 N/A	(1700)
35d.	Bird	❑1 Yes	❑0 No	❑9 N/A	(1710)
35e.	Other _____	❑1 Yes	❑0 No	❑9 N/A	(1720)

36. In general and on a regular basis, is the child exposed to any of the following animals for more than one hour each day?

36a.	Cat	❑ 1 Yes	❑ 0 No	❑ 9 N/A (1730)
36b.	Dog	❑ 1 Yes	❑ 0 No	❑ 9 N/A (1740)
36c.	Rabbit, guinea pig, hamster, gerbil, or mouse	❑ 1 Yes	❑ 0 No	❑ 9 N/A (1750)
36d.	Bird	❑ 1 Yes	❑ 0 No	❑ 9 N/A (1760)
36e.	Other _____	❑ 1 Yes	❑ 0 No	❑ 9 N/A (1770)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
SERUM IgE
(Visit 2)

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

1. IgE ___ ___ ___ ___ ___ . ___ kU/L (1000)

Complete the exact value, or check the box if the value is < 2 kU/L.

❑1 <2 kU/L (1010)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS JUNIPER ASTHMA CONTROL QUESTIONNAIRE

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator or Parent/Guardian completed)

Check the number of the response that best describes how your child has been during the past week?

1. Who is the respondent?
   - ❑1 Mother (1000)
   - ❑2 Father
   - ❑3 Stepparent
   - ❑4 Grandparent
   - ❑5 Legal Guardian
   - ❑6 Other _____

2. On average, during the past week, how often was your child awakened by breathing problems during the night?
   - ❑0 Never (1010)
   - ❑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

3. On average, during the past week, how bad were your child's breathing problems when he/she woke up in the morning?
   - ❑0 No symptoms (1020)
   - ❑1 Very mild symptoms
   - ❑2 Mild symptoms
   - ❑3 Moderate symptoms
   - ❑4 Quite severe symptoms
   - ❑5 Severe symptoms
   - ❑6 Very severe symptoms

4. In general, during the past week, how limited were your child's activities because of breathing problems?
   - ❑0 Not limited at all (1030)
   - ❑1 Very slightly limited
   - ❑2 Slightly limited
   - ❑3 Moderately limited
   - ❑4 Very limited
   - ❑5 Extremely limited
   - ❑6 Totally limited

5. In general, during the past week, how much shortness of breath did your child experience because of breathing problems?
   - ❑0 None (1040)
   - ❑1 A very little
   - ❑2 A little
   - ❑3 A moderate amount
   - ❑4 Quite a lot
   - ❑5 A great deal
   - ❑6 A very great deal

6. In general, during the past week, how much of the time did your child wheeze?

- ❑0 Not at all (1050)
- ❑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

7. On average, during the past week, how many puffs of albuterol has your child used each day?

- ❑0 <1 puff most days (1060)
- ❑1 1 - 2 puffs most days
- ❑2 3 - 4 puffs most days
- ❑3 5 - 8 puffs most days
- ❑4 9 - 12 puffs most days
- ❑5 13 - 16 puffs most days
- ❑6 More than 16 puffs most days

8. On average, during the past week, how many nebulizer treatments of albuterol has your child used each day?

- ❑0 <1 dose most days (1070)
- ❑1 1 - 2 doses most days
- ❑2 3 - 4 doses most days
- ❑3 5 - 8 doses most days
- ❑4 9 - 12 doses most days
- ❑5 13 - 16 doses most days
- ❑6 More than 16 doses most days

9. Since the last visit, did the child take any oral steroids for breathing problems (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol)?

❑1Yes ❑0No (1080)

If ***YES***, on how many days?

____ ____ days (1090)

➜***If YES and the child is not a treatment failure, make sure the Coordinator was notified and a Prednisolone Medication Form (P4_PRED) was completed.***

Skip Question #10 if Visit 10 or 10a-10g.

10. Since the last visit, did the child take the study medication?

❑1Yes ❑0No (1100)

If ***YES***, on how many days?

____ ____ days (1110)

AIMS
LABORATORY TESTS

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

BLOOD TESTS

1. Total WBC ___ ___ ___ ___ ___ cu. mm (1000)

2. Eosinophils ___ ___ . ___ % (1010)

3. Is the child's eosinophil count greater than 4% in circulation? ❑1 Yes ❑0 No (1030)

NASAL WASHING

4. Were you able to collect a nasal washing sample on the participant today? ❑1 Yes ❑0 No (1040)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS SCHEDULED MEDICATIONS

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. What type of visit is this?

❑ 1 Scheduled visit (1000)
❑ 2 Unscheduled visit

MEDICATION LABEL

Affix the new drug label below:

Copy the drug label number below:

4 - ___ ___ ___ - ___ ___ ___
(1010) (1020) (1030)

Coordinator Signature: _____ (1040)
Date: __ __/ __ __/ __ __ __ __ (1050)

By signing in the source documentation box you are:

1) Confirming that the label on the scheduled medications matches the number on the outside of the packet and the outside of the kit.
2) Confirming that the ID number written on the outside of the kit corresponds to the person receiving this medication.
3) Confirming that this is the correct medication to be distributed at this visit.

Childhood Asthma Research & Education
NIH / NHLBI

AIMS BASELINE MEDICAL AND FAMILY HISTORY

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Guardian completed)

PARENT/GUARDIAN IDENTIFICATION

1. What is your relationship to the child? (*Check one box only*)

- ❑ 1 Parent (1000)
- ❑ 2 Stepparent
- ❑ 3 Grandparent
- ❑ 4 Legal guardian (but not parent)
- ❑ 5 Other _____

CHILD'S DEMOGRAPHIC DATA

2. What is the child's date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___ (*month / day / year*) (1010)

3. Race and Ethnicity

3a. What is the child's ethnic background? *(Check one box only)*

- ❑ 1 Hispanic or Latino (1015)
- ❑ 2 Not Hispanic or Latino

3b. What is the child's racial background? *(Check at least one 'Yes')*

3bi.	American Indian or Alaskan Native	❑ 1 Yes	❑ 0 No (1016)
3bii.	Asian	❑ 1 Yes	❑ 0 No (1017)
3biii.	Black or African American	❑ 1 Yes	❑ 0 No (1018)
3biv.	Native Hawaiian or Other Pacific Islander	❑ 1 Yes	❑ 0 No (1019)
3bv.	White	❑ 1 Yes	❑ 0 No (1020)

4. What is the child's gender? *(Do not ask child)*

- ❑ 1 Male (1030)
- ❑ 2 Female

CHILD'S MEDICAL HISTORY

5. During the past 12 months, did the child have any illnesses other than asthma (do not count minor colds or allergies)? ❑ 1 Yes ❑ 0 No (1050)

5a. If ***YES***, list the child's illnesses:

_____
_____
_____

SYMPTOM HISTORY

6. During the past 12 months, has the child had any asthma symptoms? ❑1 Yes ❑0 No (1060)

   6a. If ***YES***, what were the child's symptoms:

   6ai. Wheezing ❑1 Yes ❑0 No (1061)

   6aii. Coughing ❑1 Yes ❑0 No (1062)

   6aiii. Shortness of breath ❑1 Yes ❑0 No (1063)

   6aiv. Chest tightness ❑1 Yes ❑0 No (1064)

   6av. Other _____ ❑1 Yes ❑0 No (1065)

7. Has your child experienced any wheezing not associated with colds? ❑1 Yes ❑0 No (1066)

8. During the past 12 months, has the child had:

   8a. Pneumonia ❑1 Yes ❑0 No (1070)

   8b. Sinusitis ❑1 Yes ❑0 No (1080)

NOSE/EYE/SINUS SYMPTOMS

9. During the past 12 months has the child had any chronic symptoms that affected his/her nose, eyes, or sinuses? ❑1 Yes ❑0 No (1160)

   ➔ ***If NO, skip to Question #15.***

10. During the past 12 months, how frequently has the child used antihistamines and/or decongestants to treat nose, eye, and sinus symptoms (prescription or over the counter)? *(Check one box only)*

- ❑1 Almost every day (1180)
- ❑2 At least once a week, but not daily
- ❑3 At least once a month, but not weekly
- ❑4 At least once, but not monthly
- ❑5 Never

11. During the past 12 months, how frequently has the child used nasal steroids to treat nose, and sinus symptoms? *(Check one box only)*

- ❑1 Almost every day (1190)
- ❑2 At least once a week, but not daily
- ❑3 At least once a month, but not weekly
- ❑4 At least once, but not monthly
- ❑5 Never

12. During the past 12 months, how many times have you contacted or visited a doctor because of problems with the child's nose, eyes, or sinuses? *(Enter '00' if none)* ____ ____ (1200)

13. During the past 12 months, how many times has the child had a sinus infection that required treatment with antibiotics? *(Enter '00' if none)* ____ ____ (1210)

14. During the past 12 months, how many times has the child had a sinus infection that required treatment with an oral steroid? *(Enter '00' if none)* ____ ____ (1220)

15. Has the child ever had sinus surgery? ❑1 Yes ❑0 No (1230)

FAMILY HISTORY

16. Has a doctor ever said that the [BIOLOGICAL] father of the child had:

16a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1300)

16b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1310)

16c. Chronic bronchitis, emphysema, chronic obstructive lung disease,or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1320)

17. Has a doctor ever said that the [BIOLOGICAL] mother of the child had:

17a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1330)

17b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1340)

17c. Chronic bronchitis, emphysema, chronic obstructive lung disease,or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1350)

18. Does the child have a [BIOLOGICAL] sibling? *(Include half siblings)* ❑1 Yes ❑0 No (1360)

➜ ***If NO, skip to Question #20.***

19. Has a doctor ever said that a [BIOLOGICAL] sibling of the child had: *(Include half siblings)*

19a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1370)

19b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1380)

19c. Chronic bronchitis, emphysema, chronic obstructive lung disease,or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1390)

SMOKING EXPOSURE

20. Did the child's mother smoke while she was pregnant with this child? ❑1 Yes ❑0 No ❑9 Don't know (1400)

➜ ***If NO or DON'T KNOW, skip to Question #23.***

21. During pregnancy, approximately how many cigarettes per day did the child's mother smoke?

- ☐ 1 < 10 per day (1405)
- ☐ 2 10 - 20 per day
- ☐ 3 20 - 30 per day
- ☐ 4 30 - 40 per day
- ☐ 5 > 40 per day

22. During which part(s) of the pregnancy did the child's mother smoke?

22a.	First 3 months	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1410)
22b.	Middle 3 months	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1420)
22c.	Last 3 months	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1430)

23. Between the time the child was born and he/she turned two years old:

23a.	Did the child's mother (or stepmother or female guardian) smoke in the child's home?	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1440)
23b.	Did the child's father (or stepfather or male guardian) smoke in the child's home?	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1450)
23c.	Were there any other smokers in the household? *(Include visitors, such as grandparents or babysitters, who visited at least weekly)*	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1460)

24. Since the child turned two years old and until the present time OR until the start of first grade:

➜ ***If the child is under 2 years of age, do not complete Question #24a - #24c.***

24a.	Did the child's mother (or stepmother or female guardian) smoke in the child's home?	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1470)
24b.	Did the child's father (or stepfather or male guardian) smoke in the child's home?	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1480)
24c.	Were there any other smokers in the household? *(Include visitors, such as grandparents or babysitters, who visited at least weekly)*	☐ 1 Yes	☐ 0 No	☐ 9 Don't know (1490)

25. How many people who live in the child's home smoke? [Including respondent] ___ ___ (1500)

26. Is your child exposed to smoke (cigarette, pipe, cigar) while in your home? ☐ 1 Yes ☐ 0 No (1510)

27. Is your child exposed to smoke (cigarette, pipe, cigar) while at day care? ☐ 1 Yes ☐ 0 No ☐ 9 N/A (1520)

INFANT FEEDING

28. Was your child ever breastfed? ☐ 1 Yes ☐ 0 No (1530)

➜ ***If NO, skip to Question #31.***

29. How many months did your child receive ONLY breast milk? ___ ___ months (1540)

30. How many months did your child receive ANY breast milk? ___ ___ months (1550)

31. At what age were foods other than breast milk or formula introduced to your child? ___ ___ months (1560)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
NASAL WASHING

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Complete this form using the Nasal Washing Directions form (P4_HTNASL) when the nasal washing samples are received at the clinic.

NASAL WASHING AT START OF STUDY DRUG

1. Was the Day 1 nasal washing completed and a sample collected? ❑1 Yes ❑0 No (1010)

   ➜ ***If YES, what was the time and date of the nasal washing?*** *(based on a 24 hour clock)* ___ ___ : ___ ___ (1020)

   ___ ___ / ___ ___ / ___ ___ ___ ___ (1030)
   Month Day Year

2. What time and date were the study medications started? *(based on a 24 hour clock)* ___ ___ : ___ ___ (1050)

   ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
   Month Day Year

NASAL WASHING AT DAY 4 OF STUDY DRUG

3. Was the Day 4 nasal washing completed and a sample collected? ❑1 Yes ❑0 No (1110)

   ➜ ***If YES, what was the time and date of the nasal washing?*** *(based on a 24 hour clock)* ___ ___ : ___ ___ (1120)

   ___ ___ / ___ ___ / ___ ___ ___ ___ (1130)
   Month Day Year

Childhood Asthma Research & Education
NIH / NHLBI

AIMS BREATHING ILLNESS FOLLOW-UP PHONE CONTACT

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

Check the response that best describes how the participant has been during time since he/she started the illness?

1. Who is the respondent?
   - ❑1 Mother (1000)
   - ❑2 Father
   - ❑3 Stepparent
   - ❑4 Grandparent
   - ❑5 Legal Guardian
   - ❑6 Other _____

2. When was the start of the illness?
   Date: __ __ / __ __ / __ __ __ __ (1005)

3. On average, since the start of the illness, how often was your child awakened by breathing problems during the night?
   - ❑0 Never (1010)
   - ❑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

4. On average, since the start of the illness, how bad were your child's breathing problems when he/she woke up in the morning?
   - ❑0 No symptoms (1020)
   - ❑1 Very mild symptoms
   - ❑2 Mild symptoms
   - ❑3 Moderate symptoms
   - ❑4 Quite severe symptoms
   - ❑5 Severe symptoms
   - ❑6 Very severe symptoms

5. In general, since the start of the illness, how limited were your child's activities because of breathing problems?
   - ❑0 Not limited at all (1030)
   - ❑1 Very slightly limited
   - ❑2 Slightly limited
   - ❑3 Moderately limited
   - ❑4 Very limited
   - ❑5 Extremely limited
   - ❑6 Totally limited

6. In general, since the start of the illness, how much shortness of breath did your child experience because of breathing problems?

- ❑0 None (1040)
- ❑1 A very little
- ❑2 A little
- ❑3 A moderate amount
- ❑4 Quite a lot
- ❑5 A great deal
- ❑6 A very great deal

7. In general, since the start of the illness, how much of the time did your child wheeze?

- ❑0 Not at all (1050)
- ❑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

8. Have you started the study drugs? ❑1 Yes ❑0 No (1060)

8a. ***If YES,*** when were the drugs started?

Date: __ __ / __ __ / __ __ __ __ (1070)

Time: ____ ____ ____ ____ (1080)

9. Have you been giving your child the study granules or tablets? ❑1 Yes ❑0 No (1090)

10. Have you been giving your child the study nebulizer? ❑1 Yes ❑0 No (1100)

11. Have you been giving your child the albuterol? (4 times a day for the first 48 hours, then PRN) ❑1 Yes ❑0 No (1110)

12. Since the start of the illness, has your child needed to take any systemic or oral steroids by mouth (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone)? ❑1 Yes ❑0 No (1120)

If ***YES***, on how many days? ____ ____ days (1130)

➜ ***If YES, make sure the Coordinator was notified and a Prednisolone Medication Form (P4_PRED) was completed.***

Childhood Asthma Research & Education
NIH / NHLBI

AIMS PREDNISOLONE MEDICATION FORM

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

Complete this form each time an AIMS subject receives oral/systemic corticosteroids (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol) for treatment of a breathing illness.

1. Start date of oral/systemic corticosteroid. ___ ___ / ___ ___ / ___ ___ ___ ___ (1000) (Month / Day / Year)

Prior to starting the oral/systemic corticosteroid:

2. Did your child have more than 6 nebulized treatments or 12 puffs of albuterol for more than 24 hours? ❑1 Yes ❑0 No (1010)

3. Did your child continue to have symptoms after 3 albuterol treatments that were given every 15 minutes? ❑1 Yes ❑0 No (1020)

4. In the past week, on how many days has your child had moderate to severe coughing and/or moderate to severe wheezing? ____ ____ days (1030)

   4a. Is the number of days ≥ 5? ❑1 Yes ❑0 No (1040)

Question #5 should be completed by the Coordinator. Do not ask the parent Question #5.

5. Was the child given oral/systemic corticosteroid due to physician discretion? ❑1 Yes ❑0 No (1050)
   Reason: _____

Prednisolone Checklist

____6. Since enrolling in the AIMS study, including the course prescribed in #1 above, how many corticosteroid courses have been given?

- ❑1 One course (1060)
- ❑2 Two courses
- ❑3 Three courses
- ❑4 Four courses
- ❑9 N/A (Steroid given for croup alone)

➜ ***If this is the participant's 4th corticosteroid course since enrolling in the AIMS study, the child should be assigned to treatment failure status. Please STOP HERE and complete the Treatment Failure (P4_TRTFAIL) Form and the Treatment Failure Follow Up Visit (P4_TRTFAIL_VISIT) Form. See the AIMS Manual of Operations for further details.***

➜ ***Schedule Treatment Failure Visit*** ___ ___ / ___ ___ / ___ ___ ___ ___ (1070) (Month / Day / Year)

____7. Schedule a telephone call to review the Two Week Prednisolone Call Section on the Prednisolone Medication Follow Up Form (P4_PRED_F/U).

   7a. Date of scheduled telephone call. ___ ___ / ___ ___ / ___ ___ ___ ___ (1080) (Month / Day / Year)

____8. Instruct the parents to call if the child's condition does not improve.

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
PREDNISOLONE MEDICATION FOLLOW UP FORM

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

Two Week Prednisolone Call Section

1. Since the last course of oral/systemic corticosteroid recorded on the Prednisolone Medication (P4_PRED) form, has your child received an additional corticosteroid course? ❑1 Yes ❑0 No (1000)
   ➜***If* YES**, ***STOP HERE and complete another Prednisolone Medication Form (P4_PRED).***

2. In the past 2 weeks, has your child been hospitalized for breathing problems? ❑1 Yes ❑0 No (1010)
   ➜***If* YES**, ***STOP HERE and go to Treatment Failure (P4_TRTFAIL) Form.***

3. In the past 24 hours, did your child have more than 6 nebulized treatments or 12 puffs of albuterol? ❑1 Yes ❑0 No (1020)

4. During the past 24 hours, did your child continue to have symptoms after 3 albuterol treatments that were given every 15 minutes? ❑1 Yes ❑0 No (1030)

5. In the past week, on how many days has your child had moderate to severe coughing and/or moderate to severe wheezing? ____ days (1040)

   5a. Is the number of days ≥ 5? ❑1 Yes ❑0 No (1050)

   ➜ ***If Questions #3, 4, or 5a are answered YES, complete a new Prednisolone Medication Form (P4_PRED).***

   ➜ ***If Questions #3, 4, and 5a are all answered NO, instruct parents to continue to follow their action plan.***

Childhood Asthma Research & Education
NIH / NHLBI

PRIOR ASTHMA MEDICATION HISTORY

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Who is the respondent?

- ❑ 1 Participant (1100)
- ❑ 2 Mother
- ❑ 3 Father
- ❑ 4 Stepparent
- ❑ 5 Grandparent
- ❑ 6 Legal Guardian
- ❑ 7 Other _____

2. In the ***past 12 months***, has the participant used any asthma medication(s) other than albuterol (Proventil, Ventolin)?
   ➜ ***If NO, please STOP HERE.***

❑ 1 Yes ❑ 0 No (1000)

3. In the ***past 12 months***, for how many months has the participant used the following medications:
   (Enter '00' if none)

3a.	Salmeterol (Serevent) or formoterol (Foradil)	___ ___ months (1010)
3b.	Inhaled or nebulized corticosteroids [beclomethasone (Beclovent, Vanceril, QVAR), budesonide (Pulmicort), flunisolide (Aerobid), fluticasone (Flovent), triamcinolone (Azmacort)]	___ ___ months (1020)
3c.	Montelukast (Singulair)	___ ___ months (1030)
3d.	Zafirlukast (Accolate)	___ ___ months (1040)
3e.	Theophylline (Slo-bid, Theo-dur, Slo-Phyllin)	___ ___ months (1050)
3f.	Advair	___ ___ months (1060)
3g.	Cromolyn/Nedocromil	___ ___ months (1065)

3h. Other: _____ ___ ___ months (1070)

3i. Other: _____ ___ ___ months (1080)

4. In the ***past 12 months***, how many courses of prednisolone (Prelone) or prednisone has the participant taken?

- ❑ 0 0 courses (1090)
- ❑ 1 1 course
- ❑ 2 2 courses
- ❑ 3 3 courses
- ❑ 4 4 courses
- ❑ 5 5 courses
- ❑ 6 More than 5 courses

Childhood Asthma Research & Education
NIH / NHLBI

PEDIATRIC QUALITY OF LIFE
Ages 2-4

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Guardian completed)

*The following is a list of things that might be a problem for **the child**. Please tell us **how much of a problem** each one has been for **your child** during the past **ONE month.***

*In the past **ONE month,** how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Walking (1000)	0	1	2	3	4
2. Running (1010)	0	1	2	3	4
3. Participating in active play or exercise (1020)	0	1	2	3	4
4. Lifting something heavy (1030)	0	1	2	3	4
5. Bathing (1040)	0	1	2	3	4
6. Helping to pick up his or her toys (10	0	1	2	3	4
7. Having hurts or aches (1060)	0	1	2	3	4
8. Low energy level (1070)	0	1	2	3	4

EMOTIONAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
9. Feeling afraid or scare (1080)	0	1	2	3	4
10. Feeling sad or blue (1090)	0	1	2	3	4
11. Feeling angry (1100)	0	1	2	3	4
12. Trouble sleeping (1110)	0	1	2	3	4
13. Worrying (1120)	0	1	2	3	4

SOCIAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
14. Playing with other children (1130)	0	1	2	3	4
15. Other kids not wanting to play with him or her (1140)	0	1	2	3	4
16. Getting teased by other children (1150)	0	1	2	3	4

17. Not able to do things that other children his or her age can do (1160)	0	1	2	3	4
18. Keeping up when playing with other children (1170)	0	1	2	3	4

Please complete this section if your child attends school or daycare

SCHOOL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
19. Doing the same school activities as peers (1180)	0	1	2	3	4
20. Missing school/daycare because of not feeling well (1190)	0	1	2	3	4
21. Missing school/daycare to go to the doctor or hospital (1200)	0	1	2	3	4

Childhood Asthma Research & Education
NIH / NHLBI

PEDIATRIC CAREGIVER QUALITY OF LIFE JUNIPER

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Guardian completed)

RESPONDENT IDENTIFICATION

1. What is your relationship to the child? (*Check one box only*)

- ❑1 Parent (1000)
- ❑2 Stepparent
- ❑3 Grandparent
- ❑4 Guardian (but not parent)
- ❑5 Other _____

This questionnaire is designed to find out how you have been during the last week. We want to know about the ways in which your child's asthma has interfered with your normal daily activities and how this has made you feel. Please answer each question by placing a check mark in the appropriate box. You may only check one box per question.

DURING THE PAST WEEK, **HOW OFTEN**:

	All of the Time	Most of the Time	Quite Often	Some of the Time	Once in Awhile	Hardly Any of the Time	None of the Time	
2. Did you feel helpless or frightened when your child experienced cough, wheeze, or breathlessness?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1010)
3. Did your family need to change plans because of your child's asthma?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1020)
4. Did you feel frustrated or impatient because your child was irritable due to asthma?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1030)
5. Did your child's asthma interfere with your job or work around the house?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1040)
6. Did you feel upset because of your child's cough, wheeze, or breathlessness?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1050)

	All of the Time	Most of the Time	Quite Often	Some of the Time	Once in Awhile	Hardly Any of the Time	None of the Time	
7. Did you have sleepless nights because of your child's asthma?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1060)
8. Were you bothered because your child's asthma interfered with family relationships?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1070)
9. Were you awakened during the night because of your child's asthma?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1080)
10. Did you feel angry that your child has asthma?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1090)

DURING THE PAST WEEK, **HOW WORRIED OR CONCERNED** WERE YOU:

	Very, Very Worried/ Concerned	Very Worried/ Concerned	Fairly Worried/ Concerned	Somewhat Worried/ Concerned	A Little Worried/ Concerned	Hardly Worried/ Concerned	Not Worried/ Concerned	
11. About your child's performance of normal daily activities?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1100)
12. About your child's asthma medications and side effects?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1110)
13. About being over-protective of your child?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1120)
14. About your child being able to lead a normal life?	❑1	❑2	❑3	❑4	❑5	❑6	❑7	(1130)

Childhood Asthma Research & Education
NIH / NHLBI

SERIOUS ADVERSE EVENT REPORTING FORM

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

Please fax this form to the DCC at (717) 531-3922, within 72 hours after notification of a serious Adverse Event. Also, please fax the corresponding forms: Clinical Adverse Events Log (AECLIN, AECLIN2), Concomitant Medications Log (CMED_AS, CMED_ASAE), and any relevant source documents.

1. Date of Adverse Event — ___ ___ / ___ ___ / ___ ___ ___ ___ (1000) *(month / day / year)*

2. Description of Adverse Event (ICD9 Code) — ___ ___ ___ . ___ ___ (1010)

   Describe: _____

3. Time interval between the last administration of the study drug and the Adverse Event. — ___ ___ ___ (1020)

4. What was the unit of time for the above interval?
   - ☐ 1 second(s) (1030)
   - ☐ 2 minute(s)
   - ☐ 3 hour(s)
   - ☐ 4 day(s)

5. Why was the event serious?

5a.	Fatal event	☐ 1 Yes	☐ 0 No	(1040)
5b.	Life-threatening event	☐ 1 Yes	☐ 0 No	(1050)
5c.	Inpatient hospitalization required	☐ 1 Yes	☐ 0 No	(1060)

➜ ***If NO, skip to Question #5d.***

5c1. Admission date — ___ ___ / ___ ___ / ___ ___ ___ ___ (1070) *(month / day / year)*

5c2. Discharge date — ___ ___ / ___ ___ / ___ ___ ___ ___ (1080) *(month / day / year)*

5d.	Hospitalization prolonged	☐ 1 Yes	☐ 0 No	(1090)
5e.	Disabling or incapacitating	☐ 1 Yes	☐ 0 No	(1100)
5f.	Overdose	☐ 1 Yes	☐ 0 No	(1110)
5g.	Cancer	☐ 1 Yes	☐ 0 No	(1120)
5h.	Congenital anomaly	☐ 1 Yes	☐ 0 No	(1130)
5i.	Serious laboratory abnormality with clinical symptoms	☐ 1 Yes	☐ 0 No	(1140)
5j.	Height failure	☐ 1 Yes	☐ 0 No	(1145)
5k.	Pregnancy	☐ 1 Yes ☐ 0 No	☐ 9 N/A	(1147)
5l.	Other _____	☐ 1 Yes	☐ 0 No	(1150)

SERIOUS

6. What, in your opinion, caused the event?

6a.	Toxicity of study drug(s)	❑1 Yes	❑0 No	(1160)
6b.	Withdrawal of study drug(s)	❑1 Yes	❑0 No	(1170)
6c.	Concurrent medication If ***YES***, describe _____	❑1 Yes	❑0 No	(1180)
6d.	Concurrent disorder If ***YES***, describe _____	❑1 Yes	❑0 No	(1190)
6e.	Other event If ***YES***, describe _____	❑1 Yes	❑0 No	(1200)

DO NOT ENTER QUESTIONS #7 - 8: FOR REPORTING PURPOSES ONLY.

7. If subject died, cause of death: _____
_____

8. Was an autopsy performed? ❑1 Yes ❑0 No

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

REPORTING INVESTIGATOR:

9. Name: _____

Address: _____
_____
_____

Signature: _____

Date: __ __ / __ __ / __ __ __ __

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

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
SHORT PHYSICAL EXAM

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___/ ___ ___/ ___ ___ ___ ___
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

STADIOMETER CALIBRATION

1. Was the Harpenden stadiometer calibrated, per CARE MOP, immediately prior to the visit? ❑1 Yes ❑0 No (1000)

2. Was the Infantometer Baby Board calibrated, per CARE MOP, immediately prior to the visit? ❑1 Yes ❑0 No (1001)

MEASUREMENTS (Height/Length/Weight)

3. Is the child able to stand on his/her own? ❑1 Yes ❑0 No (1005)
   ➜ ***If NO, skip to Question #7***

4. Time height measurements started *(based on 24-hour clock)* ____ ____ ____ ____ (1010)

5. Standing height *(barefoot or thin socks)*

   5a. First measurement ____ ____ ____ . ____ cm (1020)

   5b. Second measurement ____ ____ ____ . ____ cm (1030)

   5c. Third measurement ____ ____ ____ . ____ cm (1040)

   5d. Average height measurement ____ ____ ____ . ____ cm (1041)

   ➜***Plot average height on sensitive growth chart. See study MOP for further details.***

   5e. Is the subject's height measurement acceptable? ❑1 Yes ❑0 No (1045)

   5ei. If **NO**, why is it unacceptable? _____
   _____

6. Is the child's height < 100 cms? ❑1 Yes ❑0 No (1310)
   ➜ ***If NO, skip to Question #9.***

7. Time length measurements started *(based on 24-hour clock)* ____ ____ ____ ____ (1320)

8. Length

   8a. First measurement ____ ____ ____ . ____ cm (1330)

   8b. Second measurement ____ ____ ____ . ____ cm (1340)

   8c. Third measurement ____ ____ ____ . ____ cm (1350)

   8d. Average length measurement ____ ____ ____ . ____ cm (1360)

   ➜ ***Plot average length on sensitive growth chart. See study MOP for further details.***

8e. Is the subject's length measurement acceptable? ❑1 Yes ❑0 No (1370)

8ei. If **NO**, why was it unacceptable? _____

_____

9. Weight (*shoes off, light clothing)* ___ ___ ___ . ___ kg (1050)

PHYSICAL EXAM

10. Is chest auscultation clear? ❑1 Yes ❑0 No (1060)

11. Does the subject have evidence of oral candidiasis? ❑1 Yes ❑0 No (1135)

➜ ***If YES, please complete the Clinical Adverse Events (AECLIN) form.***

12. Does the child currently have any signs of illness that affect his/her nose, eyes, or sinuses? ❑1 Yes ❑0 No (1140)

13. Does the child currently have any eczema? ❑1 Yes ❑0 No (1210)

Physician/CC signature: _____ (1380)

Date: __ __ / __ __ / __ __ __ __ (1390)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
SHORT PHYSICAL EXAM

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___/ ___ ___/ ___ ___ ___ ___
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

STADIOMETER CALIBRATION

1. Was the Harpenden stadiometer calibrated, per CARE MOP, immediately prior to the visit? ❑1 Yes ❑0 No (1000)

2. Was the Infantometer Baby Board calibrated, per CARE MOP, immediately prior to the visit? ❑1 Yes ❑0 No (1001)

MEASUREMENTS (Height/Length/Weight)

3. Is the subject less than 2 years old? ❑1 Yes ❑0 No (1005)
   ➜ ***If Yes, skip to Question #6***

4. Time height measurements started *(based on 24-hour clock)* ____ ____ ____ ____ (1010)

5. Standing height *(barefoot or thin socks)*

   5a. First measurement ____ ____ ____ . ____ cm (1020)

   5b. Second measurement ____ ____ ____ . ____ cm (1030)

   5c. Third measurement ____ ____ ____ . ____ cm (1040)

   5d. Average height measurement ____ ____ ____ . ____ cm (1041)

   ➜***Plot average height on sensitive growth chart. See study MOP for further details.***

   5e. Is the subject's height measurement acceptable? ❑1 Yes ❑0 No (1045)

   ➜ ***If YES, skip to Question #8***

   5ei. If **NO**, why is it unacceptable? _____
   _____

6. Time length measurements started *(based on 24-hour clock)* ____ ____ ____ ____ (1320)

7. Length

   7a. First measurement ____ ____ ____ . ____ cm (1330)

   7b. Second measurement ____ ____ ____ . ____ cm (1340)

   7c. Third measurement ____ ____ ____ . ____ cm (1350)

   7d. Average length measurement ____ ____ ____ . ____ cm (1360)

   ➜ ***Plot average length on sensitive growth chart. See study MOP for further details.***

7e. Is the subject's length measurement acceptable? ❑1 Yes ❑0 No (1370)

8ei. If **NO**, why was it unacceptable? _____

_____

8. Weight (*shoes off, light clothing)* ___ ___ ___ . ___ kg (1050)

PHYSICAL EXAM

9. Is chest auscultation clear? ❑1 Yes ❑0 No (1060)

10. Does the subject have evidence of oral candidiasis? ❑1 Yes ❑0 No (1135)
➜ ***If YES, please complete the Clinical Adverse Events (AECLIN) form.***

11. Does the child currently have any signs of illness that affect his/her nose, eyes, or sinuses? ❑1 Yes ❑0 No (1140)

12. Does the child currently have any eczema? ❑1 Yes ❑0 No (1210)

Physician/CC signature: _____ (1380)
Date: __ __ / __ __ / __ __ __ __ (1390)

Childhood Asthma Research & Education
NIH / NHLBI

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

1. Has the subject had a previous skin test using CARE procedures within the approved time limit? ☐ 1 Yes ☐ 0 No (2000)
   - ➜ ***(Protocol-specific time limits for reusing the SKIN form can be found in the Manual of Operations for each protocol.)***
   - ➜ ***If YES,***

   Date of previous skin test ___ ___ / ___ ___ / ___ ___ ___ ___ (2010) (Month / Day / Year)

   ID of coordinator who perfomed the skin test ___ ___ ___ ___ ___ (2020)

2. Has the child used any of the medications, listed in the skin test section of the CARE MOP, within the exclusionary periods? ☐ 1 Yes ☐ 0 No (1000)
   - ➜ ***If YES, STOP HERE, reschedule the skin testing procedure.***

3. Has the child ever had a severe systemic reaction to allergy skin testing? ☐ 1 Yes ☐ 0 No (1010)
   - ➜ ***If YES, STOP HERE. Complete CAP/FEIA tests for all allergens and record results on the CAP/FEIA form.***
4. Has the child ever had an anaphylactic reaction to egg? ☐ 1 Yes ☐ 0 No (1020)
5. Has the child ever had an anaphylactic reaction to peanut? ☐ 1 Yes ☐ 0 No (1030)
6. Has the child ever had an anaphylactic reaction to milk? ☐ 1 Yes ☐ 0 No (1040)
   - ➜ ***If Question #4, #5, or #6 is answered YES, do not administer that particular allergen. Perform a CAP/FEIA test in place of that allergen and record the results on the CAP/FEIA form.***

Time test sites **pricked** (based on 24-hour clock) ___ ___ ___ ___ (1050)

Time test sites **evaluated** (based on 24-hour clock) ___ ___ ___ ___ (1060)

➜ ***Test sites must be evaluated 15 minutes after pricking the test sites.***

If there was a positive result, transfer the tracing of each wheal and record the longest diameter and the diameter at the perpendicular midpoint in mm.

7. $\frac{(\text{Histamine: Largest Wheal}) + (\text{Histamine: Perpendicular Wheal})}{2}$ = ___ ___ ___ . ___ mm (1061)

7a. Is Q7 < 3mm? ☐ 1 Yes ☐ 0 No (1062)

➜ ***If YES, the test is not valid. The skin test should be repeated at a later date or a CAP/FEIA test can be performed.***

8. $\frac{(\text{Saline: Largest Wheal}) + (\text{Saline: Perpendicular Wheal})}{2}$ = ___ ___ ___ . ___ mm (1063)

8a. Q7 - Q8 = ___ ___ ___ . ___ mm (1064)

8b. Is Q8a < 3 mm? ☐ 1 Yes ☐ 0 No (1065)

➜ ***If YES, the test is not valid. The skin test should be repeated at a later date or a CAP/FEIA test can be performed.***

9. Q8 + 3 mm = ___ ___ ___ . ___ mm (1066)

For each allergen, calculate the wheal size:

Wheal Size = $\frac{\text{Largest Wheal + Perpendicular Wheal}}{2}$

Indicate whether there was a positive reaction. A positive reaction is defined as a wheal ≥ Q9.

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Interviewer ID: ___ ___ ___ ___ ___

1. Histamine (A1)	Was there a reaction? (1490) ❑0 No ❑1 Yes Largest Wheal (1500) Diameter ___ ___ ___ mm Perpendicular Wheal (1510) Diameter ___ ___ ___ mm	2. Mite Mix (A2)	Was there a reaction? (1100) ❑0 No ❑1 Yes Largest Wheal (1110) Diameter ___ ___ ___ mm Perpendicular Wheal (1120) Diameter ___ ___ ___ mm
3. Roach Mix (A3)	Was there a reaction? (1130) ❑0 No ❑1 Yes Largest Wheal (1140) Diameter ___ ___ ___ mm Perpendicular Wheal (1150) Diameter ___ ___ ___ mm	4. Cat (A4)	Was there a reaction? (1160) ❑0 No ❑1 Yes Largest Wheal (1170) Diameter ___ ___ ___ mm Perpendicular Wheal (1180) Diameter ___ ___ ___ mm
5. Dog (A5)	Was there a reaction? (1190) ❑0 No ❑1 Yes Largest Wheal (1200) Diameter ___ ___ ___ mm Perpendicular Wheal (1210) Diameter ___ ___ ___ mm	6. Mold Mix (A6)	Was there a reaction? (1220) ❑0 No ❑1 Yes Largest Wheal (1230) Diameter ___ ___ ___ mm Perpendicular Wheal (1240) Diameter ___ ___ ___ mm
7. Grass Mix (A7)	Was there a reaction? (1250) ❑0 No ❑1 Yes Largest Wheal (1260) Diameter ___ ___ ___ mm Perpendicular Wheal (1270) Diameter ___ ___ ___ mm	8. Saline (A8)	Was there a reaction? (1070) ❑0 No ❑1 Yes Largest Wheal (1080) Diameter ___ ___ ___ mm Perpendicular Wheal (1090) Diameter ___ ___ ___ mm

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

Interviewer ID: ___ ___ ___ ___ ___

9. Tree Mix (B1)	Was there a reaction? (1280) ❑0 No ❑1 Yes Largest Wheal (1290) Diameter ___ ___ ___ mm Perpendicular Wheal (1300) Diameter ___ ___ ___ mm	10. Weed Mix (B2)	Was there a reaction? (1310) ❑0 No ❑1 Yes Largest Wheal (1320) Diameter ___ ___ ___ mm Perpendicular Wheal (1330) Diameter ___ ___ ___ mm
11. Milk (B3)	Was there a reaction? (1340) ❑0 No ❑1 Yes Largest Wheal (1350) Diameter ___ ___ ___ mm Perpendicular Wheal (1360) Diameter ___ ___ ___ mm	12. Egg (B4)	Was there a reaction? (1370) ❑0 No ❑1 Yes Largest Wheal (1380) Diameter ___ ___ ___ mm Perpendicular Wheal (1390) Diameter ___ ___ ___ mm
13. Peanut (B5)	Was there a reaction? (1400) ❑0 No ❑1 Yes Largest Wheal (1410) Diameter ___ ___ ___ mm Perpendicular Wheal (1420) Diameter ___ ___ ___ mm	14. Other _____ (B6)	Was there a reaction? (1460) ❑0 No ❑1 Yes Largest Wheal (1470) Diameter ___ ___ ___ mm Perpendicular Wheal (1480) Diameter ___ ___ ___ mm
15. Other _____ (B7)	Was there a reaction? (1430) ❑0 No ❑1 Yes Largest Wheal (1440) Diameter ___ ___ ___ mm Perpendicular Wheal (1450) Diameter ___ ___ ___ mm	16. Other _____ (B8)	Was there a reaction? (1520) ❑0 No ❑1 Yes Largest Wheal (1530) Diameter ___ ___ ___ mm Perpendicular Wheal (1540) Diameter ___ ___ ___ mm

Childhood Asthma Research & Education
NIH / NHLBI

AIMS SYMPTOMS OF BREATHING ILLNESS SURVEY

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Coordinator completed)

Please answer the following questions about your child's typical breathing illness during a cold:

1. **What is usually the very first symptom you notice that leads you to believe your child is starting a breathing illness?** Please choose one of the categories from the general list provided. Then choose the symptom from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space.)

   General: _____ (1000)
   Specific: _____ (1010)
   Other: _____

2. **Is there usually a symptom you notice that makes you very certain that the illness will lead to significant breathing problems?**
   ➜ ***If NO, go to Question #3.***

   ❑1 Yes ❑0 No (1030)

   2a. **What is usually the most important symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the categories from the general list provided. Then choose the symptom from the specific list within that category. (If the symptom is not on the list, please indicate the symptom in the 'Other' space.)

   General: _____ (1040)
   Specific: _____ (1050)
   Other: _____

   2b. **Is there usually a second symptom you notice that makes you very certain that the illness will lead to significant breathing problems?**
   ➜ ***If NO, go to Question #3.***

   ❑1 Yes ❑0 No (1070)

   2c. **What is usually the second symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the categories from the general list provided. Then choose the symptom from the specific list within that category. (If the symptom is not on the list, please indicate the symptom in the 'Other' space.)

   General: _____ (1080)
   Specific: _____ (1090)
   Other: _____

3. **How long is it from the time you notice the very first symptom of illness (Responses 1000 & 1010) until the point you are very certain that the illness (Responses 1040 & 1050) will usually lead to significant breathing problems?** *(Check one box only)*

   ❑1 less than 2 hrs (1110)
   ❑2 2 - 6 hrs
   ❑3 7 - 12 hrs
   ❑4 12 - 23 hrs
   ❑5 1 day
   ❑6 2 or more days

AIMS SYMPTOMS OF BREATHING ILLNESS SURVEY

Subject ID: 0 4 - ___ - ___ ___ ___

Visit Number: ___ ___

4. **What <u>two</u> symptoms are <u>usually</u> present when you first give medications intended to lessen the symptoms of your child's breathing illness?** Please choose two of the categories from the <u>general</u> list provided. Then choose the symptom from each <u>specific</u> list within that category. (If the symptom is not on the list, please indicate the symptom in the 'Other' space.)

Number 1 symptom

General: _____ (1120)

Specific: _____ (1130)

Other: _____

Number 2 symptom

General: _____ (1150)

Specific: _____ (1160)

Other: _____

<u>Appearance Changes</u> (100)
dark circles under eyes (101)
glassy eyes (102)
watery eyes (103)
other _____ (099)

<u>Appetite Changes</u> (200)
eating less/won't eat (201)
spitting-up/vomitting (202)
other _____ (099)

<u>Behavior Problems</u> (300)
bedwetting (301)
fussy/cranky/irritable (302)
hyperactive (303)
less active (won't play) (304)
other _____ (099)

<u>Breathing Problems</u> (400)
breathing worse (401)
"can't breathe" (402)
flaring of the nose (403)
not breathing well/trouble breathing (404)
pulling in of ribs/neck (405)
rapid breathing (406)
short of breath (407)
breathing problems leading to color change (408)
turning blue (409)
other _____ (099)

<u>Changes in Sleep Patterns</u> (500)
awakening during sleep (501)
sleepy during the day/lethargic (502)
other _____ (099)

<u>Cough A</u> (600)
infrequent (601)
mild (602)
not concerning (603)
other _____ (099)

<u>Cough B</u> (700)
concerning (701)
constant (702)
interrupts activities (703)
interrupts sleep (704)
repetitive (705)
"THE asthma cough" (706)
other _____ (099)

<u>Fever</u> (800)
any fever (801)
high fever (802)
skin feels warm/hot to touch (803)
other _____ (099)

<u>Noisy Breathing</u> (900)
hoarse voice (901)
snoring (902)
other _____ (099)

<u>Noisy Chest</u> (1000)
gurgling (1001)
rattling (1002)
wheezing (1003)
other _____ (099)

<u>Nose Symptoms</u> (1100)
congested/stuffy (1101)
runny (1102)
sneezing (1103)
other _____ (099)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS SYMPTOMS OF BREATHING ILLNESS

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: - ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

This form is completed when the parent/guardian calls within 72 hours of begining the study medications. Instruct the parent/guardian to refer to the Symptoms of Breathing Illness (P4_SYMP_PARENT) form. Record their responses onto this form using the symptom codes. Each unbolded symptom corresponds to a general (bolded) symptom code and a specific (unbolded) symptom code. If the parent/guardian specified an other symptom, be sure to record the general code that the symptom was written under as well as the parent/guardian's description of the other symptom.

1. What was the very first symptom you noticed that led you to believe that your child was starting a breathing illness? General:_____ (1000) Specific:_____ (1010) Other:_____

2. What was the most important symptom you noticed that made you feel certain this illness would lead to significant breathing problems? General:_____ (1020) Specific:_____ (1030) Other:_____

3. What were the two most important symptoms present that led you to start the study medications?
   3a. Symptom: General:_____ (1040) Specific:_____ (1050) Other:_____
   3b. Symptom: General:_____ (1060) Specific:_____ (1070) Other:_____

Appearance Changes (100)
dark circles under eyes (101)
glassy eyes (102)
watery eyes (103)
other _____ (099)

Appetite Changes (200)
eating less/won't eat (201)
spitting-up/vomitting (202)
other _____ (099)

Behavior Problems (300)
bedwetting (301)
fussy/cranky/irritable (302)
hyperactive (303)
less active (won't play) (304)
other _____ (099)

Breathing Problems (400)
breathing worse (401)
"can't breathe" (402)
flaring of the nose (403)
not breathing well/trouble breathing (404)
pulling in of ribs/neck (405)
rapid breathing (406)
short of breath (407)
breathing problems leading to color change (408)
turning blue (409)
other _____ (099)

Changes in Sleep Patterns (500)
awakening during sleep (501)
sleepy during the day/lethargic (502)
other _____ (099)

Cough A (600)
infrequent (601)
mild (602)
not concerning (603)
other _____ (099)

Cough B (700)
concerning (701)
constant (702)
interrupts activities (703)
interrupts sleep (704)
repetitive (705)
"THE asthma cough" (706)
other _____ (099)

Fever (800)
any fever (801)
high fever (802)
skin feels warm/hot to touch (803)
other _____ (099)

Noisy Breathing (900)
hoarse voice (901)
snoring (902)
other _____ (099)

Noisy Chest (1000)
gurgling (1001)
rattling (1002)
wheezing (1003)
other _____ (099)

Nose Symptoms (1100)
congested/stuffy (1101)
runny (1102)
sneezing (1103)
other _____ (099)

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
TERMINATION OF STUDY PARTICIPATION

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation

1. Has the participant completed the study? ❑1 Yes ❑0 No (1000)

   ➜ ***If YES, skip to the SIGNATURES section.***

2. ***(Pre-randomization)***
   Has the participant been deemed ineligible? ❑1 Yes ❑0 No (1010)

3. Has the participant experienced a serious adverse event? ❑1 Yes ❑0 No (1020)

   ➜ ***If YES, complete the Serious Adverse Event Reporting (SERIOUS) form.***

4. Is there any other reason why the participant is being terminated from the study? ❑1 Yes ❑0 No (1030)

   If ***YES***, indicate the **primary** reason.

   ❑1 parent withdrew consent (1040)
   ❑2 no longer interested in participating
   ❑3 no longer willing to follow protocol
   ❑4 difficult access to clinic (location, transportation, parking)
   ❑5 unable to make visits during clinic hours
   ❑6 moving out of the area
   ❑7 unable to continue due to personal constraints
   ❑8 dissatisfied with asthma control
   ❑9 unable to continue due to medical condition unrelated to asthma
   ❑10 side effects of study medications
   ❑11 lost to follow up
   ❑12 physician initiated termination of study participation, reason _____
   ❑13 other _____

SIGNATURES

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

I verify that all information collected on the CARE AIMS 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 CARE AIMS Protocol.

_____ (1050) ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
Clinic Coordinator's Signature month day year

_____ (1070) ___ ___ / ___ ___ / ___ ___ ___ ___ (1080)
Principal Investigator's Signature month day year

Childhood Asthma Research & Education
NIH / NHLBI

AIMS
TREATMENT FAILURE

Subject ID: 0 4 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant been hospitalized for an acute exacerbation of wheezing? ☐ 1 Yes ☐ 0 No (1000)

2. Has the participant had a hypoxic seizure due to asthma? ☐ 1 Yes ☐ 0 No (1010)

3. Has the participant required intubation for asthma? ☐ 1 Yes ☐ 0 No (1020)

4. Has the participant received a fourth burst of prednisolone? ☐ 1 Yes ☐ 0 No (1030)

5. Has the participant been deemed a treatment failure due to physician discretion? ☐ 1 Yes ☐ 0 No (1035)

   ➜If ***YES,*** what is the reason?_____

   _____

6. Has the participant had a Serious Adverse Event related to use of a study medication? ☐ 1 Yes ☐ 0 No (1040)

   ➜***If YES, please complete the Serious Adverse Event Form (SERIOUS)***

7. Is the participant a treatment failure? ***If any of the shaded boxes are selected, the participant is a treatment failure.*** ☐ 1 Yes ☐ 0 No (1050)

8. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
   month day year

Physician/CC signature: _____ (1070)
Date: __ __ / __ __ / __ __ __ __ (1080)