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Childhood Asthma Research & Education
NIH / NHLBI

PEAK ACUTE EXACERBATION FORM

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

(Coordinator completed)

1. Has the child had cough and wheezing for more than 24 hours? ❑1 Yes ❑0 No (1000)
   ➜***If NO, STOP HERE and start albuterol nebulizations every 4-6 hours.***

   (Instruct parents to call if the child continues to cough and wheeze more than 24 hours, needs to be seen by a physician, or is having more problems breathing)

2. Has the child required albuterol for more than 24 hours or had an unscheduled visit for acute asthma care in a physician's office, urgent care, or emergency department? ❑1 Yes ❑0 No (1010)
   ➜***If NO, STOP HERE and start albuterol nebulizations every 4-6 hours.***

   (Instruct parents to call if more than 24 hours of albuterol is needed)

3. Has the cough and wheezing continued for more than 2 weeks? ❑1 Yes ❑0 No (1020)
   ➜***If YES, answer Question #3a only.***

   ➜***If NO, answer Question #3b only.***

   3a. If ***YES***, has the cough and wheezing continued for more than 4 weeks? ❑1 Yes ❑0 No (1030)

   ➜***If YES, STOP HERE and go to Persistent Symptoms Evaluation (P1_PS_EVAL) form.***

   ➜***If NO, Repeat prednisolone bursts (2mg/kg/day for 2 days and then 1mg/kg/day for 2 days) if cough and wheeze last more than 2 weeks but less than 4 week.***

   ➜***Complete the Prelone Medication Form (P1_PREL) if a prednisolone burst is administered.***

   3b. If ***NO***, start albuterol nebulizations every 4-6 hours if parent has not. [Consider prednisolone bursts (2mg/kg/day for 2 days *and then 1 mg/kg/day for 2 days) if: 1) Needs 6 albuterol nebulizations or 12 puffs per day for more than 24 hours OR 2) Experiences nocturnal awakening for 2 days OR 3) Has 48 hours or more of wheezing.]*

   ➜***Complete the Prelone Medication Form (P1_PREL) if a prednisolone burst is administered.***

Childhood Asthma Research & Education
NIH/NHLBI

CLINICAL ADVERSE EVENTS

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

(Clinic Coordinator completed)

Complete this log if the child experienced any clinical adverse events (including intercurrent events) since the last visit. Check "None" if the child has not experienced any clinical adverse events. 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) (1050) 3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR	(1060) 4. ONGOING at current visit	(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	__ __							
__ __	___.__	__/__/____ / __/__/____	❑1	__ __							

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

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

Childhood Asthma Research & Education
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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)?
   - ❑1 Yes ❑0 No (1030)

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

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

PEAK AFTER TREATMENT SYMPTOM EVALUATION & REDUCTION

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

(Coordinator completed)

1. During the past month, has the child had any unscheduled physician office, ER, or urgent care visits for asthma symptoms? ❑1 Yes ❑0 No (1000)
   ➜ ***If YES, STOP HERE. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

2. During the past month, has the child been hospitalized for asthma? ❑1 Yes ❑0 No (1010)
   ➜ ***If NO, skip to Question #3.***

   If **YES**, what was the hospitalization date? ___ ___ / ___ ___ / ___ ___ ___ ___ (1020) (month / day / year)

   2a. Was this the second hospitalization during the past 12 months? ❑1 Yes ❑0 No (1030)
   ➜ ***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form. Refer to MOP for follow up at Visit 8.***

   2b. Was the child already on fluticasone? ❑1 Yes ❑0 No (1040)
   ➜ ***If YES, STOP HERE and go to Physician Discretion Form (P1_PHYS).***

   2c. Was fluticasone started? ❑1 Yes ❑0 No (1050)
   ➜ ***If NO, STOP HERE and go to Fluticasone Medication Form (P1_FLUT)***

   2ci. ***If YES, STOP HERE.*** Enter date started and continue fluticasone for 2 months. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form. ___ ___ / ___ ___ / ___ ___ ___ ___ ***(1060)*** (month / day / year)

3. During the past month, has the child used oral or systemic corticosteroids? ❑1 Yes ❑0 No (1070)
   ➜ ***If YES, STOP HERE. Continue asthma medications for 2 months. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

4. During the past 2 weeks, has the child used rescue albuterol treatment averaging more than 4 days per week? ❑1 Yes ❑0 No (1080)
   ➜ ***If YES, STOP HERE and go to Persistent Symptoms Evaluation (P1_PS_EVAL) form.***

5. During the past 2 weeks, has the child had nighttime symptoms of asthma causing him/her to wake up averaging at least once per week? ❑1 Yes ❑0 No (1090)

➜ ***If YES, STOP HERE and go to Persistent Symptoms Evaluation (P1_PS_EVAL) form.***

6. Has the child been on the current cycle of asthma medication for less than 2 months? ❑1 Yes ❑0 No (1100)

➜ ***If YES, STOP HERE. Continue asthma medications for a total of at least 2 months. Schedule a telephone call at the end of this 2 month period to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

7. What is the child's current treatment? *(Check one box only)*

No asthma medication (with or without study medication) ❑1 (1110)

➜ ***Reduction is complete. Continue study medication if appropriate.***

Montelukast or other leukotriene antagonist (with or without study medication) ❑2

➜ ***If checked, go to Leukotriene Checklist (P1_AFTRT_EVAL).***

Fluticasone or other inhaled corticosteroid (with or without study medication) ❑3

➜ ***If checked, go to Inhaled Steroid Checklist (P1_AFTRT_EVAL).***

Half dose fluticasone or other half dose inhaled corticosteroid (with or without study medication) ❑4

➜ ***If checked, go to Leukotriene Checklist (P1_AFTRT_EVAL).***

Fluticasone or other inhaled corticosteroid AND other asthma medication (with or without study medication) ❑5

➜ ***If checked, go to Other Asthma Medication Checklist (P1_AFTRT_EVAL).***

Montelukast AND other asthma medication (with or without study medication) ❑6

➜ ***If checked, go to Other Asthma Medication Checklist (P1_AFTRT_EVAL).***

Fluticasone or other inhaled corticosteroid AND montelukast or other leukotriene antagonist (with or without study medication) ❑7

➜ ***If checked, go to Fluticasone and Montelukast Checklist (P1_AFTRT_EVAL).***

Fluticasone or other inhaled corticosteroid AND montelukast or other leukotriene antagonist AND other asthma medication (with or without study medication) ❑8

➜ ***If checked, go to Fluticasone and Montelukast and Other Asthma Medication Checklist (P1_AFTRT_EVAL).***

Leukotriene Checklist

____1. Discontinue current dose of asthma medication (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1120)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Inhaled Steroid Checklist

____1. Decrease fluticasone or other inhaled corticosteroid to half the original dose for 4 weeks.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1130)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Other Asthma Medication Checklist

____1. Discontinue other asthma medication (except study medication) without weaning.

____2. Continue montelukast or fluticasone.

____3. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

3a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1140)
month day year

____4. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Fluticasone and Montelukast Checklist

____1. Discontinue montelukast (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1150)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Fluticasone and Montelukast and Other Asthma Medication Checklist

____1. Discontinue other asthma medication (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1160)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education NIH/NHLBI	**CONCOMITANT MEDICATIONS for ASTHMA/ALLERGY-RELATED DRUGS**	Subject ID: ___ ___ - ___ - ___ ___ ___ Subject Initials: ___ ___ ___ Visit Number: ___ ___ Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

(Coordinator completed)

First visit: Please list all concomitant medications, used to treat **asthma** and **allergies,** that the child has taken since signing the informed consent. Indicate the name of the medication, code, dose/units, frequency, route, and start date. Refer to section 7.12 of the CARE General MOP for applicable drug codes (Q1000 and Q1040). Check the "None" box if the child has not taken any **asthma** or **allergy** concomitant medications since signing the informed consent.
Subsequent visits: Please list all concomitant medications, used to treat **asthma** and **allergies,** that the child has started taking since the last visit. Indicate the name of the medication, code, dose/units, frequency, route, start date, and stop date, if applicable. Refer to section 7.12 of the CARE General MOP for applicable drug codes (Q1000 and Q1040). Check the "None" box if the child has not started taking any **asthma** or **allergy** concomitant medications since the last visit.

❑0 None

NAME OF MEDICATION (1010)	CODE (1000)	DOSE/UNITS	FREQUENCY (1040)	ROUTE	START DATE (MM/DD/YYYY) (1060) (1070) (1080)	STOP DATE (MM/DD/YYYY) (1090)	ONGOING AT CURRENT VISIT (1100)
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1
__ __					___/___/_____	___/___/_____	❑1

Childhood Asthma Research & Education
NIH/NHLBI

Visit 1
Dosing Compliance Form

Subject ID: __ __ - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 1
Visit Date: __ __ / __ __ / __ __ __ __
Month Day Year
Interviewer ID: __ __ __ __ __

Directions: Subject compliance with the protocol dosing schedule must be assessed at visit 1. Complete the table below using the Doser™ history for all full days between the current and last visit. You may not need to complete all of the days that are included in the table. If the number of puffs taken is at least 4, the subject is considered to be compliant for the given day.

Doser™ Day (1000)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
# Scheduled puffs	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
# Puffs in Doser™ history (1010)																							
Compliant? (✓ if yes)																							

Doser™ Day (1000)	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
# Scheduled puffs	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
# Puffs in Doser™ history (1010)																							
Compliant? (✓ if yes)																							

1. Number of days between current and last visit ___ ___ days

2. Number of compliant days ___ ___ days

3. Compliance percent $\frac{\textit{Question \#2}}{\textit{Question \#1}}$ *x 100* ___ ___ ___ . ___ %

If the compliance percent is less than 80%, the subject is non-compliant. Therefore, the subject is NOT eligible for the study. Enter this information in Question #7 on the P1_ELIG3 form.

Childhood Asthma Research & Education
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Visits 2-8
Dosing Compliance
Form 2

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

Directions: Complete the table below using the Doser™ history for all full days between the current and last visit. You may not need to complete all of the days that are included in the table.

Doser™ Day (1000)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
# Puffs in Doser™ history (1010)																							

Doser™ Day (1000)	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	Total
# Puffs in Doser™ history (1010)																							

Childhood Asthma Research & Education
NIH / NHLBI

PEAK ASTHMA DIARY

Initials: __ __ __ (1000)
Date: __ __ / __ __ / __ __ __ __ (1010)

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

(Guardian completed)

Date (month/day) (dmonth/dday)	__/__	__/__	__/__	__/__	__/__	__/__	__/__
Day of the week (Mon, Tue, etc...)							
Each morning circle an answer for the following questions (Questions 1-2):							
1. Did your child use the study medication this morning? (1020)	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$_0$
2. Did your child wake up during the night because of his/her asthma? (1030)	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$_0$
Each night before you go to bed circle an answer for the following questions (Questions 3-7):							
3. Did your child use the study medication this evening? (1040)	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$_0$
4. Did your child have a cold or cold symptoms today? (1050)	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$_0$
5. How much was your child bothered by his/her asthma today? (1060) 0 = Not at all 2 = Quite a bit 1 = A little bit 3 = A lot	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
6. Circle **HOSP** if your child is spending tonight in the hospital due to asthma or breathing problems. Circle **ER** if your child went to the ER due to asthma or breathing problems. Circle **CLINIC** if your child went to the clinic due to asthma or breathing problems. Circle **NONE** if your child had no visits. (1070)	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$	Hosp$_1$ ER$_2$ Clinic$_3$ None$_4$
7. **Other Medicines:** For each medicine listed below, circle 'Yes' if your child used that medicine today. Circle 'No' if your child did not use that medicine today.							
7a. albuterol (1080)	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$_0$
7b.	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$_0$
7c.	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 7b and 7c are asthma/allergy related medications, please record these on the CMED_AS form)

Childhood Asthma Research & Education
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PEAK
ELIGIBILITY CHECKLIST 1

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

(Coordinator completed)

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)

3. Is the child between the ages of 24 - 48 months? ☐ 1 Yes ☐ 0 No (1020)

4. During the past 12 months, has the child had less than four exacerbations of wheezing? ☐ 1 Yes ☐ 0 No (1030)

5. During the past 12 months, has the child seen a physician for at least one asthma exacerbation? ☐ 1 Yes ☐ 0 No (1040)

6. Does the child have at least one parent/guardian who can communicate with the study staff to allow assessment of study outcomes? ☐ 1 Yes ☐ 0 No (1050)

7. Does at least one parent/guardian have reliable access to a contact telephone number? ☐ 1 Yes ☐ 0 No (1060)

8. Has the child ever had chicken pox or received the chicken pox vaccine? ☐ 1 Yes ☐ 0 No (1070)
   ➜ ***Refer to MOP for discussion on immunization records.***

9. Is the child eligible at this time? ***If any of the shaded boxes are selected, the child is ineligible.*** ☐ 1 Yes ☐ 0 No (1080)
   ➜ ***If NO, STOP HERE and please complete the Termination of Study Participation (P1_TERM) form.***

10. Have either of the child's parents been diagnosed with asthma by a physician? ☐ 1 Yes ☐ 0 No (1090)

11. Has the child ever been diagnosed with atopic dermatitis by a physician? ☐ 1 Yes ☐ 0 No (1100)

12. Does the child possess an allergic sensitization to at least one aeroallergen? ☐ 1 Yes ☐ 0 No (1110)

13. Is the child eligible at this time? ***If at least one of the questions is YES (Questions #10-12), the child is eligible to participate in the PEAK study. STOP HERE.*** ☐ 1 Yes ☐ 0 No (1120)
   ➜ ***If NO, please continue with form.***

14. Has the child experienced any wheezing not associated with colds? ☐ 1 Yes ☐ 0 No (1130)

15. Does the child possess an allergic sensitization to milk, egg, or peanuts? ☐ 1 Yes ☐ 0 No (1140)

16. Is the child's eosinophil count greater than 4% in circulation? ☐ 1 Yes ☐ 0 No (1150)

17. Is the child eligible? ***If at least two of the questions are YES (Questions #14-16), the child is eligible to participate in the PEAK study.*** ☐ 1 Yes ☐ 0 No (1160)

➜ ***If NO, please complete the Termination of Study Participation (P1_TERM) form.***

Physician/CC signature: _____ (1170)

Date: __ __ / __ __ / __ __ __ __ (1180)

Childhood Asthma Research & Education
NIH/NHLBI

PEAK
ELIGIBILITY CHECKLIST 2

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

(Coordinator completed)

1. Does the child have any of these systemic illnesses?

   1a. seizures — ☐ 1 Yes ☐ 0 No (1000)

   1b. gastroesophageal reflux requiring medication — ☐ 1 Yes ☐ 0 No (1010)

   1c. cerebral palsy — ☐ 1 Yes ☐ 0 No (1020)

   1d. tuberculosis — ☐ 1 Yes ☐ 0 No (1030)

   1e. immunodeficiency — ☐ 1 Yes ☐ 0 No (1040)

2. Does the child have a cardiac disorder not including a small, insignificant hole in the heart (VSD, ASD) or an insignificant heart murmur? — ☐ 1 Yes ☐ 0 No (1050)

3. Was the child born at greater than 35 weeks gestation? — ☐ 1 Yes ☐ 0 No (1060)

4. Did the child require more than 5 days of oxygen in the neonatal period? — ☐ 1 Yes ☐ 0 No (1070)

5. Has the child required mechanical ventilation at any time since birth? — ☐ 1 Yes ☐ 0 No (1080)

6. Has the child been diagnosed with a significant developmental delay or a failure to thrive? — ☐ 1 Yes ☐ 0 No (1090)

7. Does the child have any chronic lung disease? — ☐ 1 Yes ☐ 0 No (1100)

8. Does the child's family have plans to move out of the area within the next three years? — ☐ 1 Yes ☐ 0 No (1110)

9. During the past year, has the child used 4 months or more of inhaled steroids for the treatment of asthma? — ☐ 1 Yes ☐ 0 No (1120)

10. During the past year, has the child had 4 courses or more of systemic corticosteroids? — ☐ 1 Yes ☐ 0 No (1130)

11. Has the child ever received immunotherapy? — ☐ 1 Yes ☐ 0 No (1140)

12. Has the child ever received IV gamma globulins or immunosuppressants? — ☐ 1 Yes ☐ 0 No (1150)

13. Has the child ever had an asthma exacerbation resulting in intubation and mechanical ventilation? — ☐ 1 Yes ☐ 0 No (1160)

14. Has the child ever had a seizure (during an asthma episode) that the physician thought was due to asthma? — ☐ 1 Yes ☐ 0 No (1170)

15. Is the child currently allergic to soybean products? ☐ 1 Yes ☐ 0 No (1175)

16. Does the parent/legal guardian believe that the child and family will be able to comply with the study schedule and study assessments? ☐ 1 Yes ☐ 0 No (1180)

17. Is the child eligible? ***If any of the shaded boxes are selected, the child is ineligible.*** ☐ 1 Yes ☐ 0 No (1190)

➜ ***If NO, please complete the Termination of Study Participation (P1_TERM) form.***

Physician/CC signature: _____ (1200)

Date: __ __ / __ __ / __ __ __ __ (1210)

Childhood Asthma Research & Education
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PEAK
ELIGIBILITY CHECKLIST 3

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

(Coordinator completed)
Confirm that ELIG1 and ELIG2 are completed and the child is currently eligible.

Review P1_Diary regarding Questions #1-5.

1. Has the child experienced, on average, more than 4 days of symptoms per week during the past 28 days? ☐ 1 Yes ☐ 0 No (1000)

2. Has the child required, on average, more than 4 days of albuterol treatment per week during the past 28 days? ☐ 1 Yes ☐ 0 No (1010)

3. Has the child required any controller medication during the past 28 days? ☐ 1 Yes ☐ 0 No (1020)

4. Has the child taken any investigational medication prior to randomization during the past 28 days? ☐ 1 Yes ☐ 0 No (1030)

5. Has the child been hospitalized during the past 28 days? ☐ 1 Yes ☐ 0 No (1040)

6. Determine the child's percent compliance with the study medication.

   6a. Number of days since the previous visit ___ ___ days (1050)

   6b. Number of days the child was compliant ___ ___ days (1060)

   6c. Calculate the child's percent compliance ___ ___ ___ .___% (1070)

7. Has the child and parent/guardian demonstrated at least 80% compliance of study medication use during run-in? ☐ 1 Yes ☐ 0 No (1080)

8. Is there any reason for which this child should not be included in this study? If ***YES***, describe: _____
   _____ ☐ 1 Yes ☐ 0 No (1090)

9. Is the child eligible? ***If any of the shaded boxes are selected, the child is ineligible.*** ☐ 1 Yes ☐ 0 No (1100)

   Ü ***If the child is eligible and will participate in PEAK, randomize the child. Otherwise, please complete the Termination of Study Participation (P1_TERM) form.***

10. Drug Packet Number (record on Log) **1** - ___ - ___ ___ ___
    (1108) (1109) (1110)

Physician/CC signature: _____

Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (1130)

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EXHALED NITRIC OXIDE

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

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

(Technician completed)

Exhaled Nitric Oxide measurements should be taken prior to performing spirometry and IOS procedures.

EXCLUSIONS AND CONFOUNDERS

1. During the past 24 hours, has the child used sustained-release theophylline? ☐ 1 Yes ☐ 0 No (1000)

2. During the past 12 hours, has the child used a long-acting bronchodilator (i.e., salmeterol)? ☐ 1 Yes ☐ 0 No (1010)

3. During the past 4 hours, has the child used a short-acting bronchodilator? ☐ 1 Yes ☐ 0 No (1020)

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

5. Has the child smoked cigarettes or any other substance in the past month? ☐ 1 Yes ☐ 0 No (1035)

   5a. If **YES**, has the child smoked within the past hour? ☐ 1 Yes ☐ 0 No (1036)

6. Is there any other reason the child should not proceed with the exhaled nitric oxide procedure? ☐ 1 Yes ☐ 0 No (1040)

   If **YES**, explain _____
   _____

7. Did the child eat or drink in the past hour? ☐ 1 Yes ☐ 0 No (1045)

8. Is the child eligible to proceed with the exhaled nitric oxide procedure? ☐ 1 Yes ☐ 0 No (1050)
   If any of the shaded boxes are filled in, the child is NOT eligible for exhaled nitric oxide testing.

   ➜ ***If NO, do NOT complete Questions #9 - #15a.***
   If this is a regular protocol visit, the exhaled nitric oxide procedure should be rescheduled within the visit window.

9. Was the ENO procedure performed? ☐ 1 Yes ☐ 0 No (1055)

   9a. If **NO**, indicate the primary reason
   ☐ 1 Child/Parent refused (1056)
   ☐ 2 Equipment failure
   ☐ 3 Other _____

If Question #9 is answered NO, STOP HERE and do NOT complete Questions #10 - #15a.

		Time (based on 24 - hour clock)	**Measured FENO**
10.	ENO Measurement #1	___ ___ ___ ___ (1060)	___ ___ ___ . ___ ppb (1070)
11.	ENO Measurement #2	___ ___ ___ ___ (1080)	___ ___ ___ . ___ ppb (1090)
12.	ENO Measurement #3	___ ___ ___ ___ (1100)	___ ___ ___ . ___ ppb (1110)
13.	Average FE_{NO}		___ ___ ___ . ___ ppb (1120)
14.	Average V_{NO}		___ ___ ___ . ___ nl/min (1130)

15. Test Profile

- ❑ 1 10 sec ATS (1140)
- ❑ 2 6 sec ATS
- ❑ 3 6 sec Non - ATS
- ❑ 4 Modified by User - Only 2 ATS acceptable
- ❑ 5 Modified by User - Other

15a. If Question #15 is answered 5, please explain.

_____

_____

_____

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PEAK FLUTICASONE MEDICATION FORM

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

(Coordinator completed)

Fluticasone Checklist

____1. Schedule a clinic visit to start fluticasone.

1a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1000)

____2. Schedule a telephone call in 2 weeks after scheduled clinic visit (above) to review the Two Week Fluticasone Call Section (P1_FLUT).

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1010)

____3. Instruct the parents to call if the child's condition worsens.

Two Week Fluticasone Call Section

1. Has the child been hospitalized for asthma in the past 2 weeks? ❑1 Yes ❑0 No (1020)

1a. If **YES**, was this the second hospitalization in the past 12 months? ❑1 Yes ❑0 No (1030)
➜If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.

2. Has the child used oral corticosteroids (prednisolone) in the past 2 weeks? ❑1 Yes ❑0 No (1040)
➜If YES, STOP HERE and go to Physician Discretion Form (P1_PHYS).

3. Has the child required, on average, more than 4 days of albuterol treatment per week during the past 2 weeks (an albuterol treatment is defined as 2 puffs by MDI or one treatment by nebulizer)? ❑1 Yes ❑0 No (1050)
➜If YES, STOP HERE and go to Physician Discretion Form (P1_PHYS).

4. Has the child had nighttime symptoms of asthma which caused him/her to wake up, on average, at least once per week during the past 2 weeks? ❑1 Yes ❑0 No (1060)
➜If YES, STOP HERE and go to Physician Discretion Form (P1_PHYS).

If all questions are answered NO (Questions #1-4), complete the following checklist.

____5. Continue Fluticasone for 2 months.

____6. Schedule telephone call for two months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.

6a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1070)

____7. If the child has an unscheduled physician visit, hospitalization or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

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HOME ENVIRONMENT QUESTIONNAIRE

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

(Coordinator 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. How long has the child lived in his/her current home? (*Check one box only*)

- ❑1 Has lived here since birth (1010)
- ❑2 Moved here before age 2
- ❑3 Moved here when 2 years or older, but before starting first grade
- ❑4 Moved here in first grade or later

3. Are any of the following located at the child's home?

3a.	Barns	❑1 Yes	❑0 No	(1020)
3b.	Hay	❑1 Yes	❑0 No	(1030)
3c.	Woodsheds	❑1 Yes	❑0 No	(1040)
3d.	Firewood	❑1 Yes	❑0 No	(1050)
3e.	Chicken coops	❑1 Yes	❑0 No	(1060)
3f.	Horses	❑1 Yes	❑0 No	(1070)

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. About how old is the child's current home? *(Estimate if uncertain)* ___ ___ ___ years (1090)

6. Does the child's home utilize a portable heater? ❑1 Yes ❑0 No (1100)

7. Does the child's home utilize a wood burning stove as a primary source of heat? ❑1 Yes ❑0 No (1110)

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

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

9. Which type of cooling system is utilized in the child's home? *(Check one box only)* (1130)

   ➜ ***If NOT Window units (options 1, 3 and 6), skip to Question #11.***

   ❑1 Window unit(s)
   ❑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 utilize 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 utilize a humidifier? *(Include humidifier built into the heating system of the child's home)* ❑1 Yes ❑0 No ❑9 Don't know (1190)

12. Does the child's home utilize a de-humidifier? *(Include de-humidifier built into the cooling system of the child's home)* ❑1 Yes ❑0 No ❑9 Don't know (1200)

13. 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 (1210)

14. 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 (1220)

    ➜ ***If NO or Don't know, skip to Question #16.***

15. Which room(s) have been affected with mold or mildew?

15a.	Bathroom(s)	❑ 1 Yes	❑ 0 No	(1230)
15b.	Bedroom(s)	❑ 1 Yes	❑ 0 No	(1240)
15c.	Living or family room	❑ 1 Yes	❑ 0 No	(1250)
15d.	Kitchen	❑ 1 Yes	❑ 0 No	(1260)
15e.	Basement or attic	❑ 1 Yes	❑ 0 No	(1270)
15f.	Other _____	❑ 1 Yes	❑ 0 No	(1280)

16. Do you ever see cockroaches in the child's home? ❑ 1 Yes ❑ 0 No (1290)

➜ ***If NO, skip to Question #18.***

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

17a.	Bathroom(s)	❑ 1 Yes	❑ 0 No	(1300)
17b.	Bedroom(s)	❑ 1 Yes	❑ 0 No	(1310)
17c.	Living or family room	❑ 1 Yes	❑ 0 No	(1320)
17d.	Kitchen	❑ 1 Yes	❑ 0 No	(1330)
17e.	Basement or attic	❑ 1 Yes	❑ 0 No	(1340)
17f.	Other _____	❑ 1 Yes	❑ 0 No	(1350)

CHARACTERISTICS OF CHILD'S BEDROOM

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

18. Does the child share his/her bedroom with another person? ❑ 1 Yes ❑ 0 No (1360)

18a. If ***YES***, how many others? ___ ___ (1370)

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

❑ 1 Synthetic carpet (1380)
❑ 2 Wool carpet
❑ 3 Vinyl tile or linoleum
❑ 4 Wood
❑ 5 Ceramic tile
❑ 6 Other _____
❑ 7 Don't know

19a. If ***SYNTHETIC OR WOOL CARPET***, what type of padding is under the carpet in the child's bedroom? *(Check one box only)*

- ❑ 1 None (1390)
- ❑ 2 Foam
- ❑ 3 Other _____
- ❑ 4 Don't know

20. What type of mattress is on the child's bed? *(Check one box only)*
➜ *If NONE, skip to Question #23.*

- ❑ 1 None (1400)
- ❑ 2 Inner spring mattress
- ❑ 3 Foam mattress
- ❑ 4 Waterbed
- ❑ 5 Air mattress
- ❑ 6 Other _____
- ❑ 7 Don't know

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

____ ____ years (1410)

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

❑ 1 Yes ❑ 0 No (1420)

23. Does the child's bed have a box spring?
➜ *If NO, skip to Question #25.*

❑ 1 Yes ❑ 0 No (1430)

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

❑ 1 Yes ❑ 0 No (1440)

25. What type of pillow is used on the child's bed? *(Check one box only)*
➜ *If NONE, skip to Question #28.*

- ❑ 1 None (1450)
- ❑ 2 Feather/down
- ❑ 3 Foam
- ❑ 4 Dacron/synthetic
- ❑ 5 Other _____
- ❑ 6 Don't know

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

____ ____ years (1460)

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

❑ 1 Yes ❑ 0 No (1470)

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

❑ 1 Yes ❑ 0 No (1480)

PETS

29. Does the child's household own any pets? ❑1 Yes ❑0 No (1490)

    ➜ ***If NO, skip to Question #31.***

30. Enter the number of pets that the household owns. *(Enter '00' if none)*

    30a. Cat ___ ___ (1500)

    30b. Dog ___ ___ (1510)

    30c. Rabbit, guinea pig, hamster, gerbil, or mouse ___ ___ (1520)

    30d. Bird ___ ___ (1530)

    30e. Other _____ ___ ___ (1540)

31. Are any pets allowed into the child's home? ❑1 Yes ❑0 No (1550)

    ➜ ***If NO, skip to Question #34.***

32. Which pets are allowed into the child's home?

    32a. Cat ❑1 Yes ❑0 No ❑9 N/A (1560)

    32b. Dog ❑1 Yes ❑0 No ❑9 N/A (1570)

    32c. Rabbit, guinea pig, hamster, gerbil, or mouse ❑1 Yes ❑0 No ❑9 N/A (1580)

    32d. Bird ❑1 Yes ❑0 No ❑9 N/A (1590)

    32e. Other _____ ❑1 Yes ❑0 No ❑9 N/A (1600)

33. Which pets are allowed into the child's bedroom?

    33a. Cat ❑1 Yes ❑0 No ❑9 N/A (1610)

    33b. Dog ❑1 Yes ❑0 No ❑9 N/A (1620)

    33c. Rabbit, guinea pig, hamster, gerbil, or mouse ❑1 Yes ❑0 No ❑9 N/A (1630)

    33d. Bird ❑1 Yes ❑0 No ❑9 N/A (1640)

    33e. Other _____ ❑1 Yes ❑0 No ❑9 N/A (1650)

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

    34a. Cat ❑1 Yes ❑0 No ❑9 N/A (1660)

    34b. Dog ❑1 Yes ❑0 No ❑9 N/A (1670)

    34c. Rabbit, guinea pig, hamster, gerbil, or mouse ❑1 Yes ❑0 No ❑9 N/A (1680)

    34d. Bird ❑1 Yes ❑0 No ❑9 N/A (1690)

    34e. Other _____ ❑1 Yes ❑0 No ❑9 N/A (1700)

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HOME ENVIRONMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant Completed)

1. Who is completing the questionnaire? *(Check one box only.)* **(1000)**
   - ❑ 1 Participant
   - ❑ 2 Mother
   - ❑ 3 Father
   - ❑ 4 Stepparent
   - ❑ 5 Grandparent
   - ❑ 6 Legal Guardian (but not parent)
   - ❑ 7 Other _____

GENERAL HOUSE CHARACTERISTICS

('House' is meant to refer to the place where the participant lives most of the time.)

2. Has the participant lived in his/her current house since birth? **(1010)** ❑ 1 Yes ❑ 0 No

   2a. If ***NO***, how long has the participant lived in the current house? *(Estimate if uncertain.)* ___ ___ years **(1020)** ___ ___ months **(1030)**

3. Which best describes the participant's current house? (*Check one box only.*) **(1040)**
   - ❑ 1 A one-family house detached from any other house
   - ❑ 2 A one-family house attached to one or more houses
   - ❑ 3 A duplex
   - ❑ 4 A building for 3 or more families
   - ❑ 5 A mobile home or trailer
   - ❑ 6 Other _____

4. How old is the participant's current house? *(Estimate if uncertain. Enter '1' if less than a year.)* **(1050)** ___ ___ ___ years

5. Does the participant's house use a portable heater? **(1060)** ❑ 1 Yes ❑ 0 No

6. Does the participant's house use a wood burning stove as a primary source of heat? **(1070)** ❑ 1 Yes ❑ 0 No

7. Does the participant's house use an air conditioner? *(Check a white or gray box.)* **(1080)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

   ➔ ***If you checked a gray box, skip to Question #10.***

8. Which type of air conditioner is used in the participant's house? *(Check one box only, white or gray.)*
   ➔ ***If you checked a gray box, skip to Question #10.***

(1090)
- ☐ 1 Window unit(s)
- ☐ 2 Central air
- ☐ 3 Central air and window unit(s)
- ☐ 4 Other_____
- ☐ 9 Don't know

9. Which rooms use a window unit?

9a. Participant's bedroom	**(1100)**	☐ 1 Yes	☐ 0 No
9b. Other bedrooms	**(1110)**	☐ 1 Yes	☐ 0 No
9c. Living or family room	**(1120)**	☐ 1 Yes	☐ 0 No
9d. Kitchen	**(1130)**	☐ 1 Yes	☐ 0 No
9e. Other _____	**(1140)**	☐ 1 Yes	☐ 0 No

10. Does the participant's house use an evaporative cooler (swamp cooler)?
    ➔ ***If you checked a gray box, skip to Question #13.***

(1150) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

11. Which type of evaporative cooler is used in the participant's house? *(Check one box only, white or gray.)*
    ➔ ***If you checked a gray box, skip to Question #13***.

(1160)
- ☐ 1 Window unit(s)
- ☐ 2 Central unit
- ☐ 3 Central and window unit(s)
- ☐ 4 Other_____
- ☐ 9 Don't know

12. Which rooms use a window unit?

12a. Participant's bedroom	**(1170)**	☐ 1 Yes	☐ 0 No
12b. Other bedrooms	**(1180)**	☐ 1 Yes	☐ 0 No
12c. Living or family room	**(1190)**	☐ 1 Yes	☐ 0 No
12d. Kitchen	**(1200)**	☐ 1 Yes	☐ 0 No
12e. Other _____	**(1210)**	☐ 1 Yes	☐ 0 No

13. Does the participant's house use a humidifier? *(Include humidifier built into the heating system of the participant's house.)*
    ➔ ***If you checked a gray box, skip to Question #16.***

(1220) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

14. Which type of humidifier is used in the participant's house? **(1230)**
(Check one box only, white or gray.)
➔ ***If you checked a gray box, skip to Question #16.***

- ☐ 1 Whole house
- ☐ 2 Room unit
- ☐ 3 Whole house and room unit

15. Which rooms use a humidifier?

15a. Participant's bedroom	**(1260)**	☐ 1 Yes	☐ 0 No
15b. Other bedrooms	**(1270)**	☐ 1 Yes	☐ 0 No
15c. Living or family room	**(1280)**	☐ 1 Yes	☐ 0 No
15d. Kitchen	**(1290)**	☐ 1 Yes	☐ 0 No
15e. Other _____	**(1300)**	☐ 1 Yes	☐ 0 No

16. Does the participant's house use a dehumidifier? *(Include dehumidifier built into the cooling system of the participant's house.)* **(1310)** ☐ 1 Yes ☐ 0 No ☐ 9 Don't know
➔ ***If you checked a gray box, skip to Question #19.***

17. Which type of dehumidifier is used in the participant's house? **(1320)**
(Check one box only, white or gray.)
➔ ***If you checked a gray box, skip to question #19.***

- ☐ 1 Whole house
- ☐ 2 Room unit
- ☐ 3 Whole house and room unit

18. Which rooms use a dehumidifier?

18a. Participant's bedroom	**(1350)**	☐ 1 Yes	☐ 0 No
18b. Other bedrooms	**(1360)**	☐ 1 Yes	☐ 0 No
18c. Living or family room	**(1370)**	☐ 1 Yes	☐ 0 No
18d. Kitchen	**(1380)**	☐ 1 Yes	☐ 0 No
18e. Basement	**(1390)**	☐ 1 Yes	☐ 0 No
18f. Other _____	**(1400)**	☐ 1 Yes	☐ 0 No

19. Has there been water damage to the participant's house, basement, or its contents during the past 12 months? **(1410)** ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

20. Has there been any mold or mildew, on any surfaces, inside the participant's house in the past 12 months? **(1420)** ☐ 1 Yes ☐ 0 No ☐ 9 Don't know
➔ ***If you checked a gray box, skip to Question #22.***

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

21a. Bathroom(s)	**(1430)**	❑ 1 Yes	❑ 0 No
21b. Basement or attic	**(1440)**	❑ 1 Yes	❑ 0 No
21c. Kitchen	**(1450)**	❑ 1 Yes	❑ 0 No
21d. Participant's bedroom	**(1460)**	❑ 1 Yes	❑ 0 No
21e. Other bedrooms	**(1470)**	❑ 1 Yes	❑ 0 No
21f. Living or family room	**(1480)**	❑ 1 Yes	❑ 0 No
21g. Other_____	**(1490)**	❑ 1 Yes	❑ 0 No

22. Do you ever see cockroaches in the participant's house? **(1500)** ❑ 1 Yes ❑ 0 No
➔ ***If you checked a gray box, skip to Question #24.***

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

23a. Kitchen	**(1510)**	❑ 1 Yes	❑ 0 No
23b. Basement or attic	**(1520)**	❑ 1 Yes	❑ 0 No
23c. Bathroom(s)	**(1530)**	❑ 1 Yes	❑ 0 No
23d. Living or family room	**(1540)**	❑ 1 Yes	❑ 0 No
23e. Participant's bedroom	**(1550)**	❑ 1 Yes	❑ 0 No
23f. Other bedrooms	**(1560)**	❑ 1 Yes	❑ 0 No
23g. Garage	**(1570)**	❑ 1 Yes	❑ 0 No
23h. Other _____	**(1580)**	❑ 1 Yes	❑ 0 No

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

24. Does the participant share his/her bedroom with another person? **(1590)** ❑ 1 Yes ❑ 0 No

24a. If ***YES***, how many others? **(1600)** ___ ___

25. What is the floor covering in the participant's bedroom? **(1610)**
(Check one box only, white or gray)
➔ ***If you checked a gray box, skip to Question #26.***

- ❑ 1 Rug/carpet
- ❑ 2 Vinyl tile or linoleum
- ❑ 3 Wood
- ❑ 4 Ceramic tile
- ❑ 5 Other _____
- ❑ 9 Don't know

25a. If ***carpeted***, what type of padding is under the carpet in the participant's bedroom?
(Check one box only.)

(1620)
- ❑ 1 None
- ❑ 2 Foam
- ❑ 3 Other _____
- ❑ 9 Don't know

26. What type of mattress is on the participant's bed?
(Check one box only, white or gray.)
➔ ***If you checked a gray box, skip to Question #29.***

(1630)
- ■ 1 None
- ❑ 2 Inner spring mattress
- ❑ 3 Foam mattress
- ❑ 4 Waterbed
- ❑ 5 Air mattress
- ❑ 6 Other _____
- ❑ 9 Don't know

27. How old is the mattress used on the participant's bed?
(Estimate or enter '99' if uncertain. Enter '1' if less than a year.)

(1640) ___ ___ years

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

(1650) ❑ 1 Yes ❑ 0 No

29. Does the participant's bed have a box spring?
➔ ***If you checked a gray box, skip to Question #31.***

(1660) ❑ 1 Yes ■ 0 No

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

(1670) ❑ 1 Yes ❑ 0 No

31. What type of pillow does the participant usually sleep with?
(Check one box only, white or gray.)
➔ ***If you checked a gray box, skip to Question #34.***

(1680)
- ■ 1 None
- ❑ 2 Feather/down
- ❑ 3 Foam
- ❑ 4 Dacron/synthetic
- ❑ 5 Other _____
- ❑ 9 Don't know

32. How old is the pillow the participant usually sleeps with?
(Estimate or enter '99' if uncertain. Enter '1' if less than a year.)

(1690) ___ ___ years

33. Is the pillow completely enclosed in an allergy-proof, encasing cover? **(1700)** ☐ 1 Yes ☐ 0 No

34. How many times per month are the participant's bed covers or sheets washed in hot water? **(1710)** ___ ___ times

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

35a. Barns	**(1720)**	☐ 1 Yes	☐ 0 No
35b. Hay	**(1730)**	☐ 1 Yes	☐ 0 No
35c. Woodsheds	**(1740)**	☐ 1 Yes	☐ 0 No
35d. Firewood	**(1750)**	☐ 1 Yes	☐ 0 No
35e. Chicken coops	**(1760)**	☐ 1 Yes	☐ 0 No
35f. Corral	**(1770)**	☐ 1 Yes	☐ 0 No

ANIMALS

36. Does your family have any animals? **(1780)** ☐ 1 Yes ☐ 0 No
➔ ***If you checked a gray box, skip to Question #38.***

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

37a. Cat	**(1790)**	___ ___
37b. Dog	**(1800)**	___ ___
37c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1810)**	___ ___
37d. Bird	**(1820)**	___ ___
37e. Other _____	**(1830)**	___ ___

38. Are there any animals in the participant's house? **(1840)** ☐ 1 Yes ☐ 0 No
➔ ***If you checked a gray box, skip to Question #41.***

39. Which animals are in the participant's house?

39a. Cat	**(1850)**	☐ 1 Yes	☐ 0 No
39b. Dog	**(1860)**	☐ 1 Yes	☐ 0 No
39c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1870)**	☐ 1 Yes	☐ 0 No
39d. Bird	**(1880)**	☐ 1 Yes	☐ 0 No
39e. Other _____	**(1890)**	☐ 1 Yes	☐ 0 No

40. Which animals are in the participant's bedroom?

40a. Cat	**(1900)**	❑ 1 Yes	❑ 0 No
40b. Dog	**(1910)**	❑ 1 Yes	❑ 0 No
40c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1920)**	❑ 1 Yes	❑ 0 No
40d. Bird	**(1930)**	❑ 1 Yes	❑ 0 No
40e. Other _____	**(1940)**	❑ 1 Yes	❑ 0 No

41. In general, and on a regular basis, is the participant exposed to any of the following animals?

41a. Cat	**(1950)**	❑ 1 Yes	❑ 0 No
41b. Dog	**(1960)**	❑ 1 Yes	❑ 0 No
41c. Rabbit, guinea pig, hamster, gerbil, or mouse	**(1970)**	❑ 1 Yes	❑ 0 No
41d. Bird	**(1980)**	❑ 1 Yes	❑ 0 No
41e. Farm animals	**(1990)**	❑ 1 Yes	❑ 0 No
41f. Other _____	**(2000)**	❑ 1 Yes	❑ 0 No

Clinic Coordinator Completed

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH / NHLBI

PEAK
SERUM IgE
(Visits 0, 8, 11)

Subject ID: 0 1 - ___ - ___ ___ ___
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

PEAK SCHEDULED INHALERS

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

(Coordinator completed)

1. What type of visit is this?

❑1 Scheduled visit (1000)
❑2 Unscheduled visit

SCHEDULED INHALER

Questions #2-4 should only be completed at scheduled visits. Please complete the Compliance Worksheet (COMPLY) in order to complete this section of the form.

Complete Questions #2-4 at Visits 2-8 only.

Evaluation of Subject Compliance

2. Number of days since the previous visit ___ ___ days (1010)

3. Number of days the correct number of puffs were taken since the previous visit ___ ___ days (1020)

4. Calculate the child's percent compliance ___ ___ ___ . ___ % (1030)

➜ ***If there is evidence of noncompliance (< 80%) and the child has been randomized, re-emphasize to the child and guardian the importance of maintaining the daily dosing schedule.***

SCHEDULED INHALER

Affix the new drug label below:

Copy the drug label number below:

1 (1038) **-** __ (1039) **-** ___ ___ ___ (1040)

Coordinator Signature: _____ (1050)
Date: __ __/ __ __/ __ __ __ __ (1060)

By signing in the source documentation box you are:

1) Confirming that the label on the inhaler matches the number on the outside of the packet and the outside of the kit.
2) Confirming that the subject name and ID number written on the outside of the kit correspond 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

PEAK SCHEDULED INHALERS

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

(Coordinator completed)

1. What type of visit is this?

❑ 1 Scheduled visit (1000)
❑ 2 Unscheduled visit

SCHEDULED INHALER

Affix the new drug label below:

Copy the drug label number below:

1 - __ - __ __ __
(1038) (1039) (1040)

By signing in the source documentation box you are:

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

Coordinator Signature: _____ (1050)
Date: __ __/ __ __/ __ __ __ __ (1060)

(Coordinator completed)

IOS EXCLUSIONS AND CONFOUNDERS

1. During the past 24 hours, has the participant used sustained- release theophylline? ☐ 1 Yes ☐ 0 No (1000)

2. During the past 12 hours, has the participant used a long-acting bronchodilator (i.e., salmeterol)? ☐ 1 Yes ☐ 0 No (1010)

3. During the past 4 hours, has the participant used a short-acting bronchodilator? ☐ 1 Yes ☐ 0 No (1020)

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

5. Is there any other reason the participant should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1035)
   If **YES,** explain _____
   _____

6 Is the participant eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1040)
If any of the shaded boxes are filled in, the participant is NOT eligible for pulmonary function testing.

➜ ***If NO, STOP HERE.***
If this is a regular protocol visit, the pulmonary function testing should be rescheduled within the visit window.

7. Standing height *(barefoot or thin socks)* ___ ___ ___ . ___ cm (1050)

8. Did the participant refuse to perform the procedure? ☐ 1 Yes ☐ 0 No (1055)

➜ ***If YES, STOP HERE.***

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

9. Time IOS started *(based on 24-hour clock)* ___ ___ ___ ___ (1060)

10. Results of first effort

10a. R_5 ____ ____ . ____ ____ kPa/l/s (1080)

10b. R_{10} ____ ____ . ____ ____ kPa/l/s (1085)

10c. R_{15} ____ ____ . ____ ____ kPa/l/s (1090)

10d. R_{35} ____ ____ . ____ ____ kPa/l/s (1100)

10e. X_5 ____ ____ . ____ ____ kPa/l/s (1110)

10f. Resonant Frequency ____ ____ . ____ ____ Hz (1120)

10g. Area X_A ____ ____ . ____ ____ kPa/l (1130)

11. Results of second effort

11a. R_5 ____ ____ . ____ ____ kPa/l/s (1290)

11b. R_{10} ____ ____ . ____ ____ kPa/l/s (1295)

11c. R_{15} ____ ____ . ____ ____ kPa/l/s (1300)

11d. R_{35} ____ ____ . ____ ____ kPa/l/s (1310)

11e. X_5 ____ ____ . ____ ____ kPa/l/s (1320)

11f. Resonant Frequency ____ ____ . ____ ____ Hz (1330)

11g. Area X_A ____ ____. ____ ____ kPa/l (1340)

12. Results of third effort

12a. R_5 ____ ____ . ____ ____ kPa/l/s (1350)

12b. R_{10} ____ ____ . ____ ____ kPa/l/s (1355)

12c. R_{15} ____ ____ . ____ ____ kPa/l/s (1360)

12d. R_{35} ____ ____ . ____ ____ kPa/l/s (1370)

12e. X_5 ____ ____ . ____ ____ kPa/l/s (1380)

12f. Resonant Frequency ____ ____ . ____ ____ Hz (1390)

12g. Area X_A ____ ____ . ____ ____ kPa/l (1400)

13. In your judgement, was the participant's prebronchodilator technique acceptable? ❑1 Yes ❑0 No (1530)

13a. If **NO**, why was it unacceptable?

Coherence < 0.80 (for R_{10})	❑1 Yes	❑0 No (1540)
Poor repeatability (R_{10} values vary by more than 20%)	❑1 Yes	❑0 No (1550)
Less than 3 good tests	❑1 Yes	❑0 No (1560)
Inconsistent tidal breathing	❑1 Yes	❑0 No (1570)
Participant refusal during test	❑1 Yes	❑0 No (1580)
Other (specify) _____	❑1 Yes	❑0 No (1590)

13b. If **YES**, grade the participant's technique.

Acceptable, good test ❑1 (1600)

Acceptable, questionable test ❑2

13bi. If answered 2, please explain.

_____

_____

_____

POSTBRONCHODILATOR PULMONARY FUNCTION TESTING
(Postbronchodilator IOS should be performed 15 minutes after dose is administered)

14. Time bronchodilator given (*based on 24-hour clock*) ___ ___ ___ ___ (1140)

15. Time postbronchodilator IOS started (*based on 24-hour clock*) ___ ___ ___ ___ (1150)

16. Results of first effort

16a. R_5 ___ ___ . ___ ___ kPa/l/s (1160)

16b. R_{10} ___ ___ . ___ ___ kPa/l/s (1165)

16c. R_{15} ___ ___ . ___ ___ kPa/l/s (1170)

16d. R_{35} ___ ___ . ___ ___ kPa/l/s (1180)

16e. X_5 ___ ___ . ___ ___ kPa/l/s (1190)

16f. Resonant Frequency ___ ___ . ___ ___ Hz (1200)

16g. Area X_A ___ ___ . ___ ___ kPa/l (1210)

17. Results of second effort

17a. R_5 ___ ___ . ___ ___ kPa/l/s (1410)

17b. R_{10} ___ ___ . ___ ___ kPa/l/s (1415)

17c. R_{15} ___ ___ . ___ ___ kPa/l/s (1420)

17d. R_{35} ___ ___ . ___ ___ kPa/l/s (1430)

17e. X_5 ___ ___ . ___ ___ kPa/l/s (1440)

17f. Resonant Frequency ___ ___ . ___ ___ Hz (1450)

17g. Area X_A ___ ___ . ___ ___ kPa/l (1460)

18. Results of third effort

18a. R_5 ___ ___ . ___ ___ kPa/l/s (1470)

18b. R_{10} ___ ___ . ___ ___ kPa/l/s (1475)

18c. R_{15} ___ ___ . ___ ___ kPa/l/s (1480)

18d. R_{35} ___ ___ . ___ ___ kPa/l/s (1490)

18e. X_5 ___ ___ . ___ ___ kPa/l/s (1500)

18f. Resonant Frequency ___ ___ . ___ ___ Hz (1510)

18g. Area X_A ___ ___ . ___ ___ kPa/l (1520)

19. In your judgement, was the participant's postbronchodilator technique acceptable? ❑1 Yes ❑0 No (1220)

19a. If **NO**, why was it unacceptable?

Coherence < 0.80 (for R_{10}) ❑1 Yes ❑0 No (1230)

Poor repeatability (R_{10} values vary by more than 20%) ❑1 Yes ❑0 No (1235)

Less than 3 good tests ❑1 Yes ❑0 No (1240)

Inconsistent tidal breathing ❑1 Yes ❑0 No (1250)

Participant refusal during test ❑1 Yes ❑0 No (1260)

Other (specify) _____ ❑1 Yes ❑0 No (1270)

19b. If **YES**, grade the participant's technique.

Acceptable, good test ❑1 (1280)

Acceptable, questionable test ❑2

19bi. If answered 2, please explain.

_____

_____

_____

IOS STANDARDS

20. How was the participant positioned?

❑1 Sitting on chair (1610)

❑2 Sitting on lap

❑3 Standing

❑4 Other

If Other, please explain. _____

_____

_____

21. Were the participant's cheeks held? ❑1 Yes ❑0 No (1620)

21a. If **YES**, how were the participant's cheeks held?

❑1 Parent/guardian held the cheeks (1630)

❑2 Technician held the cheeks

❑3 Participant held his/her own cheeks

❑4 Other

If Other, please explain. _____

_____

_____

22. Were nose clips used? ❑1 Yes ❑0 No (1640)

22a. If **YES**, how effective were the nose clips?

❑1 The nose clips sealed the nostrils completely (1650)

❑2 The nose clips sealed the nostrils partially

❑3 The nose clips came off during the procedure

❑4 Other

If Other, please explain. _____

_____

_____

22b. If **NO**, was the nose occluded? ❑1 Yes ❑0 No (1660)

22bi. If **YES**, how was the nose occluded?

❑1 Parent/guardian occluded the nose (1670)

❑2 Technician occluded the nose

❑3 Participant occluded his/her own nose

❑4 Other

If Other, please explain. _____

_____

_____

23. Were there problems with the use of the standard mouthpiece? ❑1 Yes ❑0 No (1680)

If **YES**, please explain. _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PEAK LABORATORY TESTS

Visits 0, 8 and 11 (ENR, T24, 036)

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

(Coordinator completed)

1. Eosinophils ___ ___ . ___ % (1000)

Childhood Asthma Research & Education
NIH/NHLBI

BASELINE MEDICAL AND FAMILY HISTORY

Subject ID: ___ ___ - ___ - ___ ___ ___
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. What is the child's ethnic background? (*Check one box only*)

- ❑1 American Indian or Alaskan Native (1020)
- ❑2 Asian or Pacific Islander
- ❑3 Black, not of Hispanic origin
- ❑4 White, not of Hispanic origin
- ❑5 Hispanic
- ❑6 Other _____

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

- ❑1 Male (1030)
- ❑2 Female

CHILD'S MEDICAL HISTORY

5. Has a doctor or other health practitioner ever said that the child has heart disease?

❑1 Yes ❑0 No (1040)

6. 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)

6a. If ***YES***, list the child's illnesses:

_____
_____
_____

SYMPTOM HISTORY

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

   7a. If ***YES***, what were the child's symptoms:

   7ai. Wheezing ❑1 Yes ❑0 No (1061)

   7aii. Coughing ❑1 Yes ❑0 No (1062)

   7aiii. Shortness of breath ❑1 Yes ❑0 No (1063)

   7aiv. Chest tightness ❑1 Yes ❑0 No (1064)

   7av. Other _____ ❑1 Yes ❑0 No (1065)

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 and on a regular basis, 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.***

   9a. During the past 12 months, how would you generally describe these chronic symptoms? *(Check one box only)*

   ❑1 Mild (1170)
   ❑2 Moderate
   ❑3 Severe

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, eye, 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)

ECZEMA SYMPTOMS

16. Has the child ever been diagnosed with eczema by a physician?

❑ 1 Yes ❑ 0 No (1240)

➜ ***If NO, skip to Question #19.***

17. Which parts of the child's body were ever affected by eczema?

17a. Head — ❑ 1 Yes ❑ 0 No (1250)

17b. Arms/Hands — ❑ 1 Yes ❑ 0 No (1260)

17c. Trunk (mid-section or torso) — ❑ 1 Yes ❑ 0 No (1270)

17d. Legs/Feet — ❑ 1 Yes ❑ 0 No (1280)

17e. Other _____ — ❑ 1 Yes ❑ 0 No (1285)

18. How would you describe your child's worst case of eczema? *(Check one box only)*

- ❑ 1 Mild (1290)
- ❑ 2 Moderate
- ❑ 3 Severe

FAMILY HISTORY

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

19a. Asthma? — ❑ 1 Yes ❑ 0 No ❑ 9 Don't know (1300)

19b. Hay fever, eczema, or other atopic disorder? — ❑ 1 Yes ❑ 0 No ❑ 9 Don't know (1310)

19c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis? — ❑ 1 Yes ❑ 0 No ❑ 9 Don't know (1320)

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

20a.	Asthma?	❑1 Yes	❑0 No	❑9 Don't know (1330)
20b.	Hay fever, eczema, or other atopic disorder?	❑1 Yes	❑0 No	❑9 Don't know (1340)
20c.	Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?	❑1 Yes	❑0 No	❑9 Don't know (1350)

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

➜ ***If NO, skip to Question #23.***

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

22a.	Asthma?	❑1 Yes	❑0 No	❑9 Don't know (1370)
22b.	Hay fever, eczema, or other atopic disorder?	❑1 Yes	❑0 No	❑9 Don't know (1380)
22c.	Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?	❑1 Yes	❑0 No	❑9 Don't know (1390)

PASSIVE SMOKING EXPOSURE

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

➜ ***If NO or DON'T KNOW, skip to Question #25.***

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

24a.	First 3 months	❑1 Yes	❑0 No	❑9 Don't know (1410)
24b.	Middle 3 months	❑1 Yes	❑0 No	❑9 Don't know (1420)
24c.	Last 3 months	❑1 Yes	❑0 No	❑9 Don't know (1430)

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

25a.	Did the child's mother (or stepmother or female guardian) smoke?	❑1 Yes	❑0 No	❑9 Don't know (1440)
25b.	Did the child's father (or stepfather or male guardian) smoke?	❑1 Yes	❑0 No	❑9 Don't know (1450)
25c.	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)

26. 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 #26a - #26c.***

26a.	Did the child's mother (or stepmother or female guardian) smoke?	❑1 Yes	❑0 No	❑9 Don't know (1470)
26b.	Did the child's father (or stepfather or male guardian) smoke?	❑1 Yes	❑0 No	❑9 Don't know (1480)
26c.	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)

Childhood Asthma Research & Education
NIH / NHLBI

PEAK MONTELUKAST MEDICATION FORM

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

(Coordinator completed)

Montelukast Checklist

____1. Schedule a clinic visit to start montelukast.

1a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1000)

____2. Schedule a telephone call in 2 weeks from scheduled clinic visit (above) to review the Two Week Montelukast Call Section (P1_MONT).

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1010)

____3. Instruct the parents to call if the child's condition worsens.

Two Week Montelukast Call Section

1. Has the child been hospitalized for asthma in the past 2 weeks? ❑1 Yes ❑0 No (1020)
   ➜***If NO, skip to Question #2***

   1a. If **YES**, was this the second hospitalization in the past 12 months? ❑1 Yes ❑0 No (1030)
   ➜***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.***

      1ai. If **NO**, was fluticasone started? ❑1 Yes ❑0 No (1040)
      ➜***If NO, STOP HERE and go to Fluticasone Medication Form (P1_FLUT)***.

      ➜***If YES, STOP HERE. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

2. Has the child used oral corticosteroids (prednisolone) in the past two weeks? ❑1 Yes ❑0 No (1050)
   ➜***If YES, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

3. Has the child required, on average, more than 4 days of of albuterol treatment per week during the past 2 weeks (an albuterol treatment is defined as 2 puffs by MDI or one treatment by nebulizer)? ❑1 Yes ❑0 No (1060)
   ➜***If YES, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

4. Has the child had nighttime symptoms of asthma which caused him/her to wake up, on average, at least once per week during the past 2 weeks?
   ➜***If YES, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

❑$_1$ Yes ❑$_0$ No (1070)

If all questions are answered NO (Questions #1-4), complete the following checklist.

____5. Continue montelukast for 2 months.

____6. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.

6a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1080)
month day year

____7. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

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PHYSICAL EXAMINATION

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

MEASUREMENTS

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

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

   3a. First measurement ____ ____ ____ . ____ cm (1020)

   3b. Second measurement ____ ____ ____ . ____ cm (1030)

   3c. Third measurement ____ ____ ____ . ____ cm (1040)

   3d. Average height measurement ____ ____ ____ . ____ cm (1041)

   ➜ ***If required, plot average height on sensitive growth chart. See study MOP for further details.***

   3e. In your judgement, was the subject's height measurement acceptable? ❑1 Yes ❑0 No (1045)

   3ei. If **NO**, why was it unacceptable? _____

   _____

4. Weight *(shoes off, light clothing)* ____ ____ ____ . ____ kg (1050)

5. Resting blood pressure ____ ____ ____ / ____ ____ ____ mm Hg (systolic (1060) / diastolic (1070))

PULMONARY AUSCULTATION

6. Is chest auscultation clear? ❑1 Yes ❑0 No (1080)
   ➜ ***If YES, skip to Question #7.***

   6a. Slight expiratory wheeze ❑1 Yes ❑0 No (1090)

   6b. Loud expiratory wheeze ❑1 Yes ❑0 No (1100)

   6c. Inspiratory and expiratory wheezes ❑1 Yes ❑0 No (1110)

   6d. Acute respiratory distress ❑1 Yes ❑0 No (1120)

   6e. Rales and/or rhonchi ❑1 Yes ❑0 No (1130)

   6f. Crackles ❑1 Yes ❑0 No (1140)

   6g. Other _____ ❑1 Yes ❑0 No (1150)

7. Does the subject have evidence of oral candidiasis? ❑1 Yes ❑0 No (1155)

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

NOSE/EYE/SINUS SYMPTOMS

8. In the past month, has the child had any symptoms affecting his/her nose, eyes, or sinuses? ❑1 Yes ❑0 No (1160)

➜ ***If NO, skip to Question #11***

8a. In general, how would you describe the child's symptoms? *(Check one box only)*
❑1 Mild (1170)
❑2 Moderate
❑3 Severe

9. How frequently has the child used antihistamines and/or decongestants to treat the 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

10. How frequently has the child used nasal steroids to treat the nose, eye, 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

MALE TANNER STAGING

11. Genital stage *(range 1 - 5)* ____ (1200)

12. Testicular volume *(smallest of right and left)* ____ ____ cc (1210)

13. Pubic hair stage *(range 1 - 5)* ____ (1220)

FEMALE TANNER STAGING

14. Breast stage *(range 1 - 5)* ____ (1230)

15. Pubic hair stage *(range 1 - 5)* ____ (1240)

16. Has menarche occurred? ❑1 Yes ❑0 No (1250)

➜ ***If NO, do not complete Question #17.***

17. What was the child's age at menarche? ____ ____ years (1260)

Physician/CC signature: _____ (1270)

Date: __ __ / __ __ / __ __ __ __ (1280)

Childhood Asthma Research & Education
NIH / NHLBI

PEAK
PHYSICIAN DISCRETION FORM

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

(Coordinator completed)

1. Physician discretion is being used because: (1120)

❑1 The participant has continued symptoms despite the initiation of controller medication per protocol.

❑2 The participant has had frequent asthma exacerbations (requiring prednisolone or unscheduled physician visits less than 6 weeks apart).

➜***Go to the Montelukast Form (P1_MONT).***

❑3 The physician feels other medications are necessary for the welfare of the family and the participant.

➜***Note: Option #3 must be discussed with the Tucson PI's. Go to the Montelukast Form (P1_MONT) unless other medication is given.***

Physician Discretion Checklist

____1. Schedule a clinic visit to have the physician start treatment per NIH Asthma Guidelines.
➜***If a medication is prescribed, please document this on the appropriate CMED form.***

1a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1000)

____2. Schedule a telephone call in 2 weeks from scheduled clinic visit (above) to review Two Week Physician Discretion Call Section (P1_PHYS).

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (month / day / year) (1010)

____3. Instruct the parents to call if the child's condition worsens.

Two Week Physician Discretion Call Section

2. Has the child been hospitalized for asthma during the past 2 weeks? ❑1 Yes ❑0 No (1020)

2a. If **YES**, was this the second hospitalization during the past 12 months? ❑1 Yes ❑0 No (1030)
➜***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.***

2ai. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (1040)
month day year

➜***After scheduling clinic visit, STOP HERE.***

3. Has the child used oral corticosteroids (prednisolone) during the past 2 weeks? ❑1 Yes ❑0 No (1050)
➜***If YES, schedule a clinic visit for the physician to review asthma therapy.***

3a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (1060)
month day year

➜***After scheduling clinic visit, STOP HERE.***

4. Has the child required, on average, more than 4 days of albuterol treatment per week during the past 2 weeks (an albuterol treatment is defined as 2 puffs by MDI or one treatment by nebulizer)? ❑1 Yes ❑0 No (1070)
➜***If YES, schedule a clinic visit for the physician to review asthma therapy.***

4a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (1080)
month day year

➜***After scheduling clinic visit, STOP HERE.***

5. Has the child had nighttime symptoms of asthma which caused him/her to wake up, on average, once per week during the past 2 weeks? ❑1 Yes ❑0 No (1090)
➜***If YES, schedule a clinic visit for the physician to review asthma therapy.***

5a. Date of scheduled clinic visit: ___ ___ / ___ ___ / ___ ___ ___ ___ (1100)
month day year

➜***After scheduling clinic visit, STOP HERE.***

If all questions are answered NO (Questions #2-5), complete the following checklist.

____6. Continue Physician Discretion treatment for 2 months.

____7. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.

7a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1110)
month day year

____8. If the child has an unexpected physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Childhood Asthma Research & Education
NIH / NHLBI

PEAK PRELONE MEDICATION FORM

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

(Coordinator completed)

Prelone Checklist

____1. Start on albuterol nebulizers every 4-6 hours regularly for 4 days, then as needed.

____2. Administer prednisolone at 2mg/kg per day for two days and then 1 mg/kg per day for 2 days.

____3. During the past 12 months, including the burst prescribed in #2 above, how many corticosteroid bursts have been given? ___ ___ bursts (1060)

➜***If less than 4 corticosteroid bursts were given, continue checklist.***

➜***If 4 to 6 corticosteroid bursts were given, STOP HERE and go*** **to Montelukast Medication Form (P1_MONT).**

➜***If greater than 6 corticosteroid bursts were given, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

____4. Schedule a telephone call to review the Two Week Prelone Call Section (P1_PREL).

4a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1000) (month / day / year)

____5. Instruct the parents to call if the child's condition worsens.

Two Week Prelone Call Section

1. Has the child been hospitalized for asthma in the past 2 weeks? ❑1 Yes ❑0 No (1010)

➜***If NO, skip to Question #2.***

1a. If **YES**, was this the second hospitalization in the past 12 months? ❑1 Yes ❑0 No (1020)

➜***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) Form.***

1ai. If **NO**, was fluticasone started? ❑1 Yes ❑0 No (1030)

➜***If YES, STOP HERE. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) Form.***

➜***If NO, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

2. Has the child required, on average, more than 4 days of albuterol treatment per week during the past two weeks (an albuterol treatment is defined as two puffs by MDI or one treatment by nebulizer)? ❑1 Yes ❑0 No (1040)

   2a. If **YES**, has the child experienced these symptoms for more than 4 weeks despite a corticosteroid burst? ❑1 Yes ❑0 No (1045)

   ➜***If YES, STOP HERE and go to Montelukast Medication Form (P1_MONT).***

   ➜***If NO, repeat Prelone Checklist at the top of this form.***

3. Has the child had nighttime symptoms of asthma which caused him/her to wake up, on average, at least once per week during the past 2 weeks? ❑1 Yes ❑0 No (1050)

   3a. If **YES**, has the child experienced these symptoms for more than 4 weeks despite a corticosteroid burst? ❑1 Yes ❑0 No (1055)

   ➜***If YES, STOP HERE and go to Montelukast Medication Form (P1_MONT).***

   ➜***If NO, repeat Prelone Checklist at the top of this form.***

If questions 1, 2, and 3 are answered NO, instruct the parents to call if the child has an unexpected physician visit, hospitalization, or if the child develops persistent coughing or wheeze before their next telephone or visit contact.

Childhood Asthma Research & Education
NIH/NHLBI

PEAK PERSISTENT SYMPTOMS EVALUATION

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

(Coordinator completed)

1. During the past 4 weeks, has the child averaged more than 4 days per week of daytime cough or wheeze requiring albuterol? ☐ 1 Yes ☐ 0 No (1000)

2. During the past 4 weeks, has the child awakened from sleep because of asthma symptoms averaging at least once per week? ☐ 1 Yes ☐ 0 No (1010)

3. During the past 4 weeks, has the child had exacerbations that affect activity averaging at least once per week ? ☐ 1 Yes ☐ 0 No (1020)

4. Has the child had persistent symptoms? ***If any of the shaded boxes are selected, the child has had persistent symptoms.*** ☐ 1 Yes ☐ 0 No (1030)

➜ ***If YES, go to Prelone Medication Form (P1_PREL).***

➜ ***If NO, STOP HERE. Symptoms have been occurring for less than 1 month. Continue asthma medications for 2 months. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form .***

Childhood Asthma Research & Education
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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

COPY

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

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Childhood Asthma Research & Education
NIH / NHLBI

PEDIATRIC QUALITY OF LIFE
Ages 5-7

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 more than one block (1000)	0	1	2	3	4
2. Running (1010)	0	1	2	3	4
3. Participating in sports activity or exercise (1020)	0	1	2	3	4
4. Lifting something heavy (1030)	0	1	2	3	4
5. Taking a bath or shower by him or herself (1040)	0	1	2	3	4
6. Doing chores, like picking up his or her toys (1050)	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 scared (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 about what will happen to him or her (1120)	0	1	2	3	4

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

COPY

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

SOCIAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
19. Paying attention in class (1180)	0	1	2	3	4
20. Forgetting things (1190)	0	1	2	3	4
21. Keeping up with school activities (1200)	0	1	2	3	4
22. Missing school because of not feeling well (1210)	0	1	2	3	4
23. Missing school to go to the doctor or hospital (1220)	0	1	2	3	4

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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)

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	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)

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Childhood Asthma Research & Education
NIH / NHLBI

PEAK CONTROLLER SYMPTOM EVALUATION & REDUCTION

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

(Coordinator completed)

1. During the past month, has the child had any unscheduled physician office, ER, or urgent care visits for asthma symptoms? ❑1 Yes ❑0 No (1000)
   ➜ ***If YES, STOP HERE. Restart previous asthma medications. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

2. During the past month, has the child been hospitalized for asthma? ❑1 Yes ❑0 No (1010)
   ➜ ***If NO, skip to Question #3.***

   2a. Was this the second hospitalization during the past 12 months? ❑1 Yes ❑0 No (1020)
   ➜ ***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form. Refer to MOP for follow up procedures at Visit 8.***

   ➜ ***If NO, STOP HERE. Restart previous asthma medications. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

3. During the past month, has the child used oral or systemic corticosteroids (prednisolone)? ❑1 Yes ❑0 No (1030)
   ➜ ***If YES, STOP HERE. Restart previous asthma medications. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

4. During the past 2 weeks, has the child used rescue albuterol treatment averaging more than 4 days per week? ❑1 Yes ❑0 No (1040)
   ➜ ***If YES, STOP HERE. Restart previous asthma medications. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

5. During the past 2 weeks, has the child had nighttime symptoms of asthma causing him/her to wake up averaging at least once per week? ❑1 Yes ❑0 No (1050)
   ➜ ***If YES, STOP HERE. Restart previous asthma medications. Schedule a telephone call in 2 months to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

6. What is the child's current treatment? *(Check one box only)*

No asthma medication (with or without study medication) ☐1 (1060)
➜ ***Reduction is complete. Continue study medication if appropriate.***

Montelukast or other leukotriene antagonist (with or without study medication) ☐2
➜ ***If checked, go to Leukotriene Checklist (P1_REDUCT_EVAL).***

Fluticasone or other inhaled corticosteroid (with or without study medication) ☐3
➜ ***If checked, go to Inhaled Steroid Checklist (P1_REDUCT_EVAL).***

Half dose fluticasone or other half dose inhaled corticosteroid (with or without study medication) ☐4
➜ ***If checked, go to Leukotriene Checklist (P1_REDUCT_EVAL).***

Fluticasone or other inhaled corticosteroid AND other asthma medication (with or without study medication) ☐5
➜ ***If checked, go to Other Asthma Medication Checklist (P1_REDUCT_EVAL).***

Montelukast AND other asthma medication (with or without study medication) ☐6
➜ ***If checked, go to Other Asthma Medication Checklist (P1_REDUCT_EVAL).***

Fluticasone or other inhaled corticosteroid AND montelukast or other leukotriene antagonist (with or without study medication) ☐7
➜ ***If checked, go to Fluticasone and Montelukast Checklist (P1_AFTRT_EVAL).***

Fluticasone or other inhaled corticosteroid AND montelukast or other leukotriene antagonist AND other asthma medication (with or without study medication) ☐8
➜ ***If checked, go to Fluticasone and Montelukast and Other Asthma Medication Checklist (P1_AFTRT_EVAL).***

Leukotriene Checklist

____1. Discontinue current dose of asthma medication (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1070)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Inhaled Steroid Checklist

____1. Decrease fluticasone or other inhaled corticosteroid to half the original dose for 4 weeks.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1080)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Other Asthma Medication Checklist

____1. Discontinue other asthma medication (except study medication) without weaning.

____2. Continue montelukast or fluticasone.

____3. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

3a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1090)
month day year

____4. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Fluticasone and Montelukast Checklist

____1. Discontinue montelukast (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1100)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

Fluticasone and Montelukast and Other Asthma Medication Checklist

____1. Discontinue other asthma medication (except study medication) without weaning.

____2. Schedule a telephone call in 4 weeks to review Controller Symptom Evaluation and Reduction (P1_REDUCT_EVAL) form.

2a. Date of scheduled telephone call: ___ ___ / ___ ___ / ___ ___ ___ ___ (1110)
month day year

____3. If the child has an unscheduled physician visit, hospitalization, or develops persistent cough or wheeze, instruct the parents to call before their next scheduled telephone call or visit contact.

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)

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

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)

MEASUREMENTS

2. Time measurements started *(based on 24-hour clock)* ___ ___ ___ ___ (1010)

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

   3a. First measurement ___ ___ ___ . ___ cm (1020)

   3b. Second measurement ___ ___ ___ . ___ cm (1030)

   3c. Third measurement ___ ___ ___ . ___ cm (1040)

   3d. Average height measurement ___ ___ ___ . ___ cm (1041)

   ➜ ***If required, plot average height on sensitive growth chart. See study MOP for further details.***

   3e. In your judgement, was the subject's height measurement acceptable? ❑1 Yes ❑0 No (1045)

   3ei. If **NO**, why was it unacceptable? _____

   _____

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

PULMONARY AUSCULTATION

5. Is chest auscultation clear? ❑1 Yes ❑0 No (1060)
   ➜ ***If YES, skip to Question #6.***

   5a. Slight expiratory wheeze ❑1 Yes ❑0 No (1070)

   5b. Loud expiratory wheeze ❑1 Yes ❑0 No (1080)

   5c. Inspiratory and expiratory wheezes ❑1 Yes ❑0 No (1090)

   5d. Acute respiratory distress ❑1 Yes ❑0 No (1100)

   5e. Rales and/or rhonchi ❑1 Yes ❑0 No (1110)

   5f. Crackles ❑1 Yes ❑0 No (1120)

   5g. Other _____ ❑1 Yes ❑0 No (1130)

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

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

NOSE/EYE/SINUS SYMPTOMS

7. Does the child currently have any symptoms that affect his/her nose, eyes, or sinuses? ☐1 Yes ☐0 No (1140)

   ➜ ***If NO, skip to Question #14.***

8. In general, how would you describe the child's symptoms? *(Check one box only)*

   ☐1 Mild (1150)
   ☐2 Moderate
   ☐3 Severe

9. Since the last clinic visit, 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 (1160)
   ☐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

10. Since the last clinic visit, how frequently has the child used nasal steroids to treat nose, eye, and sinus symptoms? *(Check one box only)*

    ☐1 Almost every day (1170)
    ☐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. Since the last clinic visit, 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)* ____ ____ (1180)

12. Since the last clinic visit, how many times has the child had a sinus infection that required treatment with antibiotics? *(Enter '00' if none)* ____ ____ (1190)

13. Since the last clinic visit, how many times has the child had a sinus infection that required treatment with an oral steroid? *(Enter '00' if none)* ____ ____ (1200)

ECZEMA SYMPTOMS

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

➜ ***If NO, skip to Question #17.***

15. Which parts of the child's body are affected by eczema?

15a. Head ❑1 Yes ❑0 No (1220)

15b. Arms/Hands ❑1 Yes ❑0 No (1230)

15c. Trunk (mid-section or torso) ❑1 Yes ❑0 No (1240)

15d. Legs/Feet ❑1 Yes ❑0 No (1250)

15e. Other _____ ❑1 Yes ❑0 No (1255)

16. In general, how would you describe the child's eczema? ❑1 Mild (1260)

(Check one box only) ❑2 Moderate

❑3 Severe

Physician/CC signature: _____ (1270)

Date: __ __ / __ __ / __ __ __ __ (1280)

ADVERSE EVENTS

17. ***Ask the respondent:*** Has the child experienced any new medical conditions since the last clinic visit? ❑1 Yes ❑0 No (1300)

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

Childhood Asthma Research & Education
NIH / NHLBI

PEAK SHORT MEDICAL, ALLERGY, AND FAMILY HISTORY FORM

Subject ID: ___ ___ - ___ - ___ ___ ___
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 MEDICAL HISTORY

2. 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 (1010)

   2a. If ***YES***, list the child's illnesses: _____ _____ _____

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

   3a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1020)
   3b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1030)
   3c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1040)

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

   4a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1050)
   4b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1060)
   4c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1070)

5. Does the child have a [BIOLOGICAL] sibling? *(Include half siblings)* ❑1 Yes ❑0 No (1080)
   ➜ ***If NO, skip to Question #7.***

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

   6a. Asthma? ❑1 Yes ❑0 No ❑9 Don't know (1090)
   6b. Hay fever, eczema, or other atopic disorder? ❑1 Yes ❑0 No ❑9 Don't know (1100)
   6c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis? ❑1 Yes ❑0 No ❑9 Don't know (1110)

7. Between the time the child turned two years old and he/she started first grade (or the present time if not in first grade yet):

7a.	Did the child's mother (or stepmother or female guardian) smoke?	❑ 1 Yes	❑ 0 No	❑ 9 Don't know (1120)
7b.	Did the child's father (or stepfather or male guardian) smoke?	❑ 1 Yes	❑ 0 No	❑ 9 Don't know (1130)
7c.	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 (1140)

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	
8.	Exposure to house dust?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1150)
9.	Exposure to animals?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1160)
10.	Emotional factors? (i.e., stress)	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1170)
11.	Exercise/play?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1180)
12.	Exposure to damp, musty area? (i.e., damp basement)	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1190)
13.	Exposure to tobacco smoke?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1200)
14.	Exposure to a change in the weather?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1210)
15.	Respiratory infections?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1220)
16.	Exposure to chemicals? (i.e., perfume, household cleaners)	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1230)
17.	Food?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1240)
18.	Exposure to cold air?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1250)
19.	Aspirin?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1260)
20.	Exposure to spring and fall pollens?	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	(1270)

ALLERGY HISTORY

21. 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 (1280)

➜ ***If NO, skip to Question #22.***

21a. At what age did the child FIRST have hay fever? ___ ___ (1285) years ___ ___ (1290) months

21b. During the past 12 months, did the child have hay fever? ❑1 Yes ❑0 No (1300)

21c. Has the child ever seen a doctor or other health practitioner because of hay fever? ❑1 Yes ❑0 No (1310)

22. Has the child ever had atopic dermatitis (eczema)? ❑1 Yes ❑0 No (1320)

➜ ***If NO, skip to Question #23.***

22a. At what age did the child FIRST have atopic dermatitis (eczema)? ___ ___ (1325) years ___ ___ (1330) months

22b. During the past 12 months, did the child have atopic dermatitis? ❑1 Yes ❑0 No (1340)

22c. Has the child ever seen a doctor or other health practitioner because of atopic dermatitis? ❑1 Yes ❑0 No (1350)

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

➜ ***If NO, skip to Question #25.***

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

24a. Medicines ❑1 Yes ❑0 No (1370)

24b. Foods ❑1 Yes ❑0 No (1380)

24c. Things you breathe in or inhale (i.e., dust, pollens, molds, animal fur, or dander) ❑1 Yes ❑0 No (1390)

24d. Stinging insects such as bees or wasps ❑1 Yes ❑0 No (1400)

24e. Other _____ ❑1 Yes ❑0 No (1410)

NOSE/EYE/SINUS SYMPTOMS

25. During the past 12 months and on a regular basis, has the child had any chronic symptoms that affected his/her nose, eyes, or sinuses?
➜ ***If NO, skip to Question #31.***

❑ 1 Yes ❑ 0 No (1420)

25a. During the past 12 months, how would you generally describe these chronic symptoms? *(Check one box only)*

❑ 1 Mild (1430)
❑ 2 Moderate
❑ 3 Severe

26. 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 (1440)
❑ 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

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

❑ 1 Almost every day (1450)
❑ 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

28. 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)*

___ ___ (1460)

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

___ ___ (1470)

30. 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)*

___ ___ (1480)

31. Has the child ever had sinus surgery?

❑ 1 Yes ❑ 0 No (1490)

ECZEMA SYMPTOMS

32. Has the child ever been diagnosed with eczema by a physician? ❑1 Yes ❑0 No (1500)
➜ ***If NO, STOP HERE.***

33. Which parts of the child's body were ever affected by eczema?

33a.	Head	❑1 Yes	❑0 No (1510)
33b.	Arms/Hands	❑1 Yes	❑0 No (1520)
33c.	Trunk (mid-section or torso)	❑1 Yes	❑0 No (1530)
33d.	Legs/Feet	❑1 Yes	❑0 No (1540)
33e.	Other _____	❑1 Yes	❑0 No (1550)

34. How would you describe your child's worst case of eczema? *(Check one box only)*

❑1 Mild (1560)
❑2 Moderate
❑3 Severe

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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

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SPIROMETRY TESTING

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

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

(Coordinator completed)

SPIROMETRY EXCLUSIONS AND CONFOUNDERS

1. During the past 24 hours, has the participant used sustained-release theophylline? ☐ 1 Yes ☐ 0 No (1000)

2. During the past 12 hours, has the participant used a long-acting bronchodilator (i.e., salmeterol)? ☐ 1 Yes ☐ 0 No (1010)

3. During the past 4 hours, has the participant used a short-acting bronchodilator? ☐ 1 Yes ☐ 0 No (1020)

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

5. Is there any other reason the participant should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1035)
   If **YES**, explain _____
   _____

6. Is the participant eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1040)
   If any of the shaded boxes are filled in, the participant is NOT eligible for pulmonary function testing.

   ➜ ***If NO, STOP HERE.***
   If this is a regular protocol visit, the pulmonary function testing should be rescheduled within the visit window.

7. Standing height *(barefoot or thin socks)* ___ ___ ___ . ___ cm (1050)

8. Did the participant refuse to perform the procedure? ☐ 1 Yes ☐ 0 No (1055)

   ➜ ***If YES, STOP HERE.***

PREBRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

9. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1060)

10. Results of best effort

10a.	FVC	___ . ___ ___ L	(1080)
10b.	FEV_1	___ . ___ ___ L	(1090)
10c.	FEV_1 (% predicted)	___ ___ ___ % predicted	(1100)
10d.	FEV_1 / FVC	___ ___ ___ %	(1110)
10e.	FEF_{25-75}	___ . ___ ___ liters/sec	(1120)
10f.	FEF_{50}	___ . ___ ___ liters/sec	(1130)
10g.	FEF_{75}	___ . ___ ___ liters/sec	(1140)
10h.	PEF (best effort)	___ ___ . ___ ___ liters/sec	(1150)
10i.	FET	___ ___ . ___ ___ sec	(1151)
10j.	FET PEF	___ . ___ ___ sec	(1152)
10k.	V backextrapolation ex	___ . ___ ___ liters	(1153)
10l.	V backextrapolation % FVC	___ ___ . ___ ___ %	(1154)
10m.	ATS Accepted	___ . 0 0	(1155)
10n.	ATS Error Code	___ ___ ___ . 0 0	(1156)

11. In your judgement, was the participant's prebronchodilator technique acceptable? ❑1 Yes ❑0 No (1290)

11a. If **NO**, why was it unacceptable? *(Check all that apply)*

Inadequate inspiratory effort	❑1 Yes	❑0 No	(1300)
Inadequate expiratory effort	❑1 Yes	❑0 No	(1310)
Inadequate duration of expiration	❑1 Yes	❑0 No	(1320)
Cough during procedure	❑1 Yes	❑0 No	(1330)
Participant refusal during test	❑1 Yes	❑0 No	(1335)
Other (specify) _____	❑1 Yes	❑0 No	(1340)

11b. If **YES**, grade the participant's technique.

Acceptable, good effort ❑1 (1350)

Acceptable, questionable effort ❑2

11bi. If answered 2, please explain.

_____

_____

POSTBRONCHODILATOR PULMONARY FUNCTION TESTING
(Postbronchodilator spirometry should be performed 15 minutes after dose is administered)

12. Time bronchodilator given *(based on 24-hour clock)* ____ ____ ____ ____ (1160)

13. Time postbronchodilator spirometry started (*based on 24-hour clock*) ____ ____ ____ ____ (1170)

14. Results of best effort

14a. FVC ____ . ____ ____ L (1180)

14b. FEV_1 ____ . ____ ____ L (1190)

14c. FEV_1 (% predicted) ____ ____ ____ % predicted (1200)

14d. FEV_1 / FVC ____ ____ ____ % (1210)

14e. FEF_{25-75} ____ . ____ ____ liters/sec (1220)

14f. FEF_{50} ____ . ____ ____ liters/sec (1230)

14g. FEF_{75} ____ . ____ ____ liters/sec (1240)

14h. PEF (best effort) ____ ____ . ____ ____ liters/sec (1250)

14i. FET ____ ____ . ____ ____ sec (1251)

14j. FET PEF ____ . ____ ____ sec (1252)

14k. V backextrapolation ex ____ . ____ ____ liters (1253)

14l. V backextrapolation % FVC ____ ____ . ____ ____ % (1254)

14m. ATS Accepted ____ . 0 0 (1255)

14n. ATS Error Code ____ ____ ____ . 0 0 (1256)

15. In your judgement, was the participant's postbronchodilator technique acceptable? ❑1 Yes ❑0 No (1260)

15a. If **NO**, why was it unacceptable? *(Check all that apply)*

Inadequate inspiratory effort	❑1 Yes	❑0 No (1270)
Inadequate expiratory effort	❑1 Yes	❑0 No (1271)
Inadequate duration of expiration	❑1 Yes	❑0 No (1272)
Cough during procedure	❑1 Yes	❑0 No (1273)
Participant refusal during test	❑1 Yes	❑0 No (1275)
Other (specify) _____	❑1 Yes	❑0 No (1274)

15b. If **YES**, grade the participant's technique.

Acceptable, good effort ❑1 (1280)

Acceptable, questionable effort ❑2

15bi. If answered 2, please explain.

_____

_____

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PEAK
TERMINATION OF STUDY PARTICIPATION

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

(Coordinator completed)

Please indicate the reason for termination of study participation. Please also complete the applicable CMED_AS, CMED_NON, and AECLIN forms and forward to the DCC.

1. ***(Visit 11 Only)***

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

   ➜ ***If YES, skip to the SIGNATURES section on page 2.***

2. ***(Visit 0 - Visit 1 Only)***

   During the run-in period, has the child experienced a significant asthma exacerbation as defined in the protocol? ❑1 Yes ❑0 No (1010)

3. ***(Visit 0 - Visit 1 Only)***

   Has the child been deemed ineligible according to any eligibility criteria **other than** a significant asthma exacerbation? ❑1 Yes ❑0 No (1020)

4. Has the parent withdrawn consent or the child withdrawn assent? ❑1 Yes ❑0 No (1030)

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

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

5. Has the child been lost to follow up? ❑1 Yes ❑0 No (1050)

6. Has the child experienced a serious adverse event not related to asthma (i.e., an adverse event resulting in death or hospitalization, etc...) ❑1 Yes ❑0 No (1060)

   ➜ ***If the event is considered 'Serious', complete the Serious Adverse Event Reporting (SERIOUS) form.***

7. Did a physician initiate the termination of study participation? ❑ 1 Yes ❑ 0 No (1070)

If ***YES***, reason: _____

SIGNATURES

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

I verify that all information collected on the CARE PEAK data collection forms for this subject is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the CARE PEAK Protocol.

_____ (1080) ___ ___ / ___ ___ / ___ ___ ___ ___
Clinic Coordinator's Signature month day year (1090)

_____ (1100) ___ ___ / ___ ___ / ___ ___ ___ ___
Principal Investigator's Signature month day year (1110)

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PEAK
PHONE/VISIT CONTACT

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

(Coordinator completed)

Review information on Subject Contact Information (CONTACT) form at every telephone/visit contact. Update Subject Contact Information (CONTACT) form when necessary.

1. Are you the primary respondent for these telephone/visit contacts?
   ➜ ***If YES, skip to Question #3.***
   ➜ ***If NO, reschedule contact when the primary respondent is available.***

❑1 Yes (1000)
❑0 No

2. Has the interview continued without the primary respondent?
   If YES, explain_____
   _____
   _____
   _____
   ➜ ***If NO, STOP HERE.***

❑1 Yes (1010)
❑0 No

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

❑1 Mother (1020)
❑2 Father
❑3 Stepparent
❑4 Grandparent
❑5 Legal guardian (but not parent)
❑6 Other_____

Questions #4-15 ask how significant the child's asthma has been during the past 14 days since ___ ___ / ___ ___ / ___ ___ ___ ___.
month day year

➜ ***If observational year (3rd year), skip to Question #5.***

4. During the past 14 days, did the child take the study medication?

❑1 Yes (1030)
❑0 No

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

___ ___ days (1040)

5. During the past 14 days, did the child experience days with asthma symptoms, unscheduled visits, hospitalizations, or need for asthma medications? *(This also includes unscheduled clinic or ER visits*)
   ➜ ***If NO, skip to Question #15.***

   ☐ 1 Yes (1050)
   ☐ 0 No

   If ***YES***, on how many days? ____ ____ days (1060)

6. During the past 14 days, how many days did the child have wheezing or cough? ____ ____ days (1070)

7. During the past 14 days, how many days did the child have to slow down his/her play or activities because of asthma, wheezing, or cough? ____ ____ days (1080)

8. During the past 14 nights, how many nights did the child wake up because of asthma, wheezing, or cough? ____ ____ nights (1090)

9. During the past 14 days, did the child take any albuterol, Proventil, Ventolin, Alupent, Metaprel, Maxair, salmeterol, or Primatene?

   ☐ 1 Yes (1100)
   ☐ 0 No

   If ***YES***, on how many days? ____ ____ days (1110)

   9a. On how many days was asthma medication taken only for pre-exercise purposes? ____ ____ days (1120)

10. During the past 14 days, did the child take any systemic or oral steroids by mouth such as prednisolone, Prelone, Pediapred, prednisone, or other corticosteroid medication?

    ☐ 1 Yes (1130)
    ☐ 0 No

    If ***YES***, on how many days? ____ ____ days (1140)

11. During the past 14 days, did the child take any Singulair?

    ☐ 1 Yes (1150)
    ☐ 0 No

    If ***YES***, on how many days? ____ ____ days (1160)

12. During the past 14 days, did the child take any inhaled medicines such as Flovent, Pulmicort, Beclovent, Vanceril, Azmacort, or Aerobid?

☐ 1 Yes (1170)
☐ 0 No

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

___ ___ days of Flovent (1180)
___ ___ days of Pulmicort (1190)
___ ___ days of other medications (1200)

13. During the past 14 days, did the child take any cromolyn or Intal by using an inhaler, puffer, or machine?

☐ 1 Yes (1210)
☐ 0 No

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

___ ___ days (1220)

14. During the past 14 days, did the child take any other medications for asthma?

☐ 1 Yes (1230)
☐ 0 No

If ***YES***, on how many days?
(Please record other asthma medications on the CMED_AS form)

___ ___ days of _____ (1235)
___ ___ days of _____ (1245)
___ ___ days of _____ (1255)

15. Since the last scheduled follow up visit (telephone or clinic visit), not counting hospitalizations, did the child have an unscheduled doctor or health care provider visit because of acute asthma? *(Include unscheduled visits to an ER, a doctor's office, a clinic, a school nurse or equivalent, or an urgent care facility)*

☐ 1 Yes (1270)
☐ 0 No

If ***YES***, how many visits?

___ ___ visits (1280)

Questions #16-19 ask if the child has required physician visits or hospitalizations since the last telephone or clinic visit contact on
___ ___ / ___ ___ / ___ ___ ___ ___.
month day year

HOSPITALIZATION EVALUATION

16. Since the last scheduled follow up visit (telephone or clinic visit), has the child been hospitalized for asthma? ☐1 Yes ☐0 No (1290)

➜ ***If NO, skip to Question #20.***

16a. If ***YES***, how many times was the child admitted for asthma? ___ ___ admissions (1300)
(Number of different admissions, not total number of nights)

16b. Was intubation ever required? ☐1 Yes ☐0 No (1310)

➜ ***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.***

16c. Did your child ever have a seizure (during an asthma episode) that the physician thought was due to asthma? ☐1 Yes ☐0 No (1320)

➜ ***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.***

17. During the past 12 months, was this the first hospitalization? ☐1 Yes ☐0 No (1330)

➜ ***If NO, skip to Question #19.***

17a. Was fluticasone started? ☐1 Yes ☐0 No (1340)

If ***YES,*** enter date started***.*** ___ ___ / ___ ___ / ___ ___ ___ ___ (1350)
month / day / year

➜ ***Skip to Question #19 and schedule a telephone call after 2 months of treatment to complete the After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

18. Were any non-study asthma medications started? ☐1 Yes ☐0 No (1360)

➜ ***If NO, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

18a. If ***YES***, how many days have passed since the child was discharged from the hospital? ___ ___ ___ days (1370)

➜ ***If 60 days or less, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

➜ ***If 61 days or greater, STOP HERE and go to After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

19. During the past 12 months, was this the second or greater hospitalization? ☐1 Yes ☐0 No (1380)
    ➜ ***If YES, STOP HERE and go to Treatment Failure (P1_TRTFAIL) form.***

Questions #20-23 ask how significant the child's asthma has been during the past 4 weeks since ___ ___ / ___ ___ / ___ ___ ___ ___.
month day year

PERSISTENT SYMPTOMS EVALUATION

20. During the past 4 weeks, has the child averaged more than 4 days per week of daytime cough or wheeze requiring albuterol? ☐1 Yes ☐0 No (1390)

21. During the past 4 weeks, has the child awakened from sleep because of asthma symptoms averaging at least once per week? ☐1 Yes ☐0 No (1400)

22. During the past 4 weeks, has the child had exacerbations that affect activity averaging at least once per week? ☐1 Yes ☐0 No (1410)

23. Has the child had persistent symptoms? ***If any of the shaded boxes are selected (Questions #20-22), the child has had persistent symptoms.*** ☐1 Yes ☐0 No (1420)
    ➜ ***If YES, STOP HERE and go to Prelone Medication Form (P1_PREL).***
    ➜ ***If NO, continue with the Phone/Visit Contact (P1_TRT_CONTACT) form.***

Question #24 asks how significant the child's asthma has been since the last telephone or clinic visit on ___ ___ / ___ ___ / ___ ___ ___ ___.
month day year

EXACERBATION EVALUATION

24. Since the last scheduled follow up visit (telephone or clinic visit), has the child required oral or systemic steroids for an asthma exacerbation? ☐1 Yes ☐0 No (1430)

    If ***YES***, during the past 12 months, how many bursts have been given? ___ ___ bursts (1440)
    ➜ ***If less than 4 corticosteroid bursts were given, STOP HERE.***
    ➜ ***If 4 to 6 corticosteroid bursts were given, STOP HERE and go to Montelukast Medication Form (P1_MONT).***
    ➜ ***If greater than 6 corticosteroid bursts were given, STOP HERE and go to Fluticasone Medication Form (P1_FLUT).***

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PEAK
TREATMENT FAILURE

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

(Coordinator completed)

1. Has the child required 2 hospitalizations for asthma within a 12 month period? ☐ 1 Yes ☐ 0 No (1030)

2. Has the child required intubation for an acute asthma exacerbation at any time? ☐ 1 Yes ☐ 0 No (1040)

3. Has the child had a hypoxic seizure during an asthma exacerbation at any time? ☐ 1 Yes ☐ 0 No (1050)

4. Is the child a treatment failure? ***If any of the shaded boxes are selected, the child is a treatment failure.*** ☐ 1 Yes ☐ 0 No (1060)

   ➜ ***If YES, please complete this form. Continue with the Physician Discretion Form (P1_PHYS).***

5. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (1070)
   month day year

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PEAK TREATMENT FAILURE ASSESSMENT Visit 8 (T24)

Subject ID: 0 1 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 8
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

1. Was treatment failure status assigned during the first 24 months of the study because of intubation for an asthma exacerbation? ❑1 Yes ❑0 No (1000)
   ➜ ***If YES, STOP HERE and continue current asthma medication without change.***

2. Was treatment failure status assigned during the first 24 months of the study because of a hypoxic seizure for asthma? ❑1 Yes ❑0 No (1010)
   ➜ ***If YES, STOP HERE and continue current asthma medication without change.***

3. Was the only reason for assignment to treatment failure status the occurrence of 2 hospitalizations for asthma within a 12 month period? ❑1 Yes ❑0 No (1020)
   ➜ ***If YES, go to After Treatment Symptom Evaluation and Reduction (P1_AFTRT_EVAL) form.***

   ➜ ***If NO, continue current asthma medication without change.***