Childhood Asthma Research & Education
NIH / NHLBI

CLINICAL ADVERSE EVENTS 2

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

(Clinic Coordinator completed)

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

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

❑0 None

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

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

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

❑ Data Entered?

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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*

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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

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CAP/FEIA RESULTS

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

(Clinic Coordinator completed)

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

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

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

(Coordinator completed)

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

❑0 None

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

❑ Data Entered?

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PACT COMPLIANCE CHECKLIST

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following adherence criteria at Visits 2 through 7.

1. **Capsule count**

1a. Number of capsules dispensed in eDEM™ vial ___ ___ ___ capsules (1120)

1b. Number of capsules returned in eDEM™ vial ___ ___ ___ capsules (1130)

1c. Number of scheduled doses ___ ___ ___ doses (1140)

1d. Actual number of capsules taken (Question #1a - Question #1b) ___ ___ ___ capsules (1150)

1e. Percent adherence = $\frac{\textit{Question \#1d}}{\textit{Question \#1c}}$ x *100* ___ ___ ___ . ___ % (1160)

2. **eDEM™ Monitor**

The information for Question #2a - Question #2c is obtained from the eDEM™ Monitor Report.

2a. Number of monitored days ___ ___ ___ days (1000)

2b. Number of doses taken ___ ___ ___ doses (1010)

2c. % Prescribed number of doses taken ___ ___ ___ . ___ % (1020)

Diskus®

3. Visit 2

3a. Number of scheduled inhalations ___ ___ ___ doses (1200)

3b. Dose counter number on the AM Diskus® ___ ___ doses (1210)

➜ ***Please add the number of practice puffs used at Visit 1 to the dose counter. Record the new value in Question #3b.***

3c. Dose counter number on the PM Diskus® ___ ___ doses (1220)

3d. Unused Doses (Sum of #3b and #3c) ___ ___ ___ doses (1230)

3e. Total number of Used Doses (120 - *Question #3d)* ___ ___ ___ total doses (1240)

3f. Percent adherence = $\frac{\textit{Question \#3e}}{\textit{Question \#3a}}$ *x 100* ___ ___ ___ . ___ % (1250)

4. Visits 3 - 7

Clinic Use Only

1. Dose counter number on each Diskus® device distributed to the subject:

___ ___ doses ___ ___ doses ___ ___ doses ___ ___ doses

___ ___ doses ___ ___ doses ___ ___ doses ___ ___ doses

2. Unused doses = sum of #1 in the gray box = ___ ___ ___ doses
3. Total possible doses = 60 x the number of Diskus® devices distributed = ___ ___ ___ doses

4a. Number of scheduled inhalations ___ ___ ___ doses (1070)

4b. Unused Doses (#2 from the gray box) ___ ___ ___ doses (1170)

4c. Total number of Used Doses (#3 from the gray box - *Question #4b)* ___ ___ ___ total doses (1180)

4d. Percent adherence = $\frac{\textit{Question \#4c}}{\textit{Question \#4a}}$ *x 100* ___ ___ ___ . ___ % (1190)

➜ If the percent adherence for the Capsule count, the eDEM™ monitor or the Diskus® is less than 75%, re-emphasize the importance of maintaining the daily dosing schedule.

Personal Best PEFR: Visits 3 - 6 only

5. Determining Personal Best PEFR

5a. Personal Best determined at previous visit ___ ___ ___ l/min (1500)

Pool of Values - Personal Best PEFR from previous visit, all **acceptable** Peak Flow values from the AM1 device performed during the current visit, all **acceptable** Peak Flow values recorded on the Diary Card since the last visit. The Peak Flow values cannot be more than 1.2 times higher than the personal best PEFR from the previous visit.

Clinic Use Only

1. List the 3 **acceptable** Peak Flow Values from the AM1 Device performed during this Visit.

___ ___ ___ l/min ___ ___ ___ l/min ___ ___ ___ l/min

2. Question #5a x 1.2 = ___ ___ ___ x 1.2 = ___ ___ ___l/min

5b. Highest Peak Flow from Pool ___ ___ ___ l/min (1510)

5c. 2nd highest Peak Flow from Pool ___ ___ ___ l/min (1520)

5d. 3rd highest Peak Flow from Pool ___ ___ ___ l/min (1530)

5e. Is the highest Peak Flow from the Pool (Question #5b) equal to the participant's Personal Best from the last visit (Question #5a)? ❑1 Yes ❑0 No (1540)

➜ ***If YES, skip to Question #5j. The Personal Best PEFR is Question #5a.***

5f. $\frac{\textit{Question \#5c}}{\textit{Question \#5b}}$ ___ . ___ ___ (1550)

5g. Is Question #5f greater than 0.9? ❑1 Yes ❑0 No (1560)

➜ ***If YES, skip to Question #5j. The Personal Best PEFR is Question #5b.***

5h. $\frac{\textit{Question \#5d}}{\textit{Question \#5c}}$ ___ . ___ ___ (1570)

5i. Is Question #5h greater than 0.9? ❑1 Yes ❑0 No (1580)

➜ ***If YES, the personal best PEFR is Question #5c.***

➜ ***If NO, the personal best PEFR is Question #5a.***

Record the personal best in Question #5j.

5j. Personal Best PEFR ___ ___ ___ l/min (1590)

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Please use black ink to complete.

PACT DIARY CARD

Subject ID: 0 3 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Return Visit Number: ___

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

Personal Peak Flow Reference Value (L/min):	_____ *Best*	Below _____ *Red Zone*	_____ to _____ *Yellow Zone*	_____ or above *Green Zone*

	Day 1: ____	Day 2: ____	Day 3: ____	Day 4: ____	Day 5: ____	Day 6: ____	Day 7: ____
Date (dmonth/dday)	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day	___ / ___ month day
Complete at Wake Up							
1. Used albuterol for asthma during the night? (1000)	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
2. Time of AM Peak Flow (1010)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. AM Peak Flow (liters/min) (1020) (Best of 3 attempts. Circle the value if you have used your RESCUE inhaler in the last 2 hours.)(1030)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Number of AM Study Drug inhalations taken (1040)	____	____	____	____	____	____	____
5. **Coordinator Completed:** AM FEV_1 (liters) (1050)	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___
Complete at Bedtime							
6. Time of PM Peak Flow (1060)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
7. PM Peak Flow (liters/min) (1070) (Best of 3 attempts. Circle the value if you have used your RESCUE inhaler in the last 2 hours.)(1080)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
8. Number of PM Study Drug inhalations taken (1090)	____	____	____	____	____	____	____
9. Number of PM Study capsules taken (1100)	____	____	____	____	____	____	____
10. **Coordinator Completed:** PM FEV_1 (liters) (1110)	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___	___ . ___ ___

Complete for the past 24 hours

Symptom Rating Scale
0 = None - No symptoms
1 = Mild - Awareness of symptoms that were easily tolerated
2 = Moderate - Symptoms with some discomfort, causing some interference of sleep or daily activities
3 = Severe - Symptoms which lead to inability to sleep or perform daily activities

Asthma Symptoms during the past 24 hours (Circle a value)	11. Coughing from asthma (1120)	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
	12. Wheezing (1130)	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
Rescue Inhaler (puffs in past 24 hours)	13. Before exercise (1140)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
	14. After exercise (1145)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
	15. For asthma symptoms or low peak flow (1150)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
16. Absent from school for asthma? (1160)		❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
17. Contacted doctor for asthma? (1170)		❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No	❑1 Yes ❑0 No
18. Parent/Legal Guardian initials (1180)								

SUBJECT NOTES - PACT DIARY CARD

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

If you experience a significant asthma attack (refer to your Action Plan Card) or significant illness, contact study personnel within 72 hours.

NON-STUDY MEDICATIONS

Please indicate any non-study medications (both prescription and over-the-counter) you use during the week.

Medication	Dosage /Frequency	Dates Taken	Reason

MEDICAL PROBLEMS

Please indicate any medical problems you have during the week, as well as the severity of each (mild, moderate, severe).

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

Childhood Asthma Research & Education
NIH / NHLBI

PACT
ELIGIBILITY CHECKLIST 1
Visit 1

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Informed Consent and Subject Assent Criteria

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. Has the participant appropriately signed and dated the assent form, or if the participant is less than 7 years old, has the participant given verbal assent? ☐ 1 Yes ☐ 0 No (1020)

4. If **YES**, record the date either the participant signed the assent form or the participant gave verbal assent. ___ ___ / ___ ___ / ___ ___ ___ ___ (1030) (month / day / year)

Medical History Criteria

5. Is the participant 6 to < 14 years old? ☐ 1 Yes ☐ 0 No (1040)

6. Has the participant smoked 11 or more cigarettes or any other substance in the past year? ☐ 1 Yes ☐ 0 No (1050)

7. Has the participant used smokeless tobacco products (chew, snuff) 11 or more times in the past year? ☐ 1 Yes ☐ 0 No (1060)

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

9. Does the participant have a chronic or active lung disease other than asthma? ☐ 1 Yes ☐ 0 No (1080)

10. Does the participant have a significant medical illness other than asthma (e.g. thyroid disease, diabetes mellitus, Cushing's, Addison's, or hepatic disease)? ☐ 1 Yes ☐ 0 No (1090)

11. Does the participant have a history of cataracts, glaucoma, or other medical disorders (such as thrush that is difficult to treat) associated with an adverse effect to glucocorticoids? ☐ 1 Yes ☐ 0 No (1100)

12. Does the participant have concurrent medical problems other than asthma that are likely to require oral prednisone during the study? ☐ 1 Yes ☐ 0 No (1110)

13. During the past year, has the participant had 4 or more corticosteroid bursts for asthma exacerbations? ☐ 1 Yes ☐ 0 No (1120)

14. During the past year, has the participant been hospitalized 2 or more times for asthma? ☐ 1 Yes ☐ 0 No (1130)

15. Has the participant ever had an asthma exacerbation resulting in intubation and mechanical ventilation? ☐ 1 Yes ☐ 0 No (1140)

16. Has the participant ever had a seizure (during an asthma episode) that the physician thought was due to asthma? ☐ 1 Yes ☐ 0 No (1150)

17. Is the participant receiving allergy shots? ☐ 1 Yes ☐ 0 No (1160)

    17a. If ***YES***, has the dose been changed in the past 3 months? ☐ 1 Yes ☐ 0 No (1170)

18. Has the participant ever had an adverse reaction to fluticasone proprionate, montelukast, salmeterol, or any of their ingredients? ☐ 1 Yes ☐ 0 No (1180)

19. Has the participant had a respiratory tract infection within the past 4 weeks? ☐ 1 Yes ☐ 0 No (1190)

20. Has the participant had a significant exacerbation of asthma within the past 4 weeks? ☐ 1 Yes ☐ 0 No (1200)

If the participant is female, answer Questions #21 - #21b.

21. Has the participant had her first menstrual period? ☐ 1 Yes ☐ 0 No (1250)

    ➜ If ***YES***, please complete Questions #21a - #21b.

    21a. Is the participant currently pregnant or nursing? ☐ 1 Yes ☐ 0 No (1260)

    21b. Is the participant currently using abstinence or an acceptable birth control method? ☐ 1 Yes ☐ 0 No (1270)

Pulmonary Function Criteria

22. Is the participant able to perform reproducible spirometry? ☐ 1 Yes ☐ 0 No (1274)

23. Is the participant's pre-bronchodilator FEV_1% predicted ≥ 80%? *(Result of best effort)* ☐ 1 Yes ☐ 0 No (1275)

24. Personal best PEFR ___ ___ ___ l/min (1276)

Other Criteria

25. Does the participant's family have plans to move out of the area within the next 12 months? ☐ 1 Yes ☐ 0 No (1280)

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

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

27. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1300)

➜ ***If NO, please STOP HERE and complete the Termination of Study Participation (P3_TERM) form.***

Physician/CC signature: _____ (1310)

Date: __ __ / __ __ / __ __ __ __ (1320)

Childhood Asthma Research & Education
NIH / NHLBI

PACT
ELIGIBILITY CHECKLIST 2
Visit 1

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Was the participant treated with a single-agent controller therapy for 4 weeks prior to Visit 1 (2 weeks for Advair participants)? ☐ 1 Yes ☐ 0 No (1000)

   ➜ ***If NO, skip to Question #7.***

2. Which single-agent controller therapy was the participant taking during the last 4 weeks (2 weeks for Advair participants)? (allowable limits in parentheses)

2a.	beclomethasone CFC (≤ 336 mcg/day)	___ ___ ___	mcg/day (1010)	☐ 1 NA (1020)
2b.	beclomethasone HFA (≤ 160 mcg/day)	___ ___ ___	mcg/day (1030)	☐ 1 NA (1040)
2c.	budesonide (≤ 400 mcg/day)	___ ___ ___	mcg/day (1050)	☐ 1 NA (1060)
2d.	flunisolide (≤ 750 mcg/day)	___ ___ ___	mcg/day (1070)	☐ 1 NA (1080)
2e.	fluticasone MDI (≤ 220 mcg/day)	___ ___ ___	mcg/day (1090)	☐ 1 NA (1100)
2f.	fluticasone DPI (≤ 200 mcg/day)	___ ___ ___	mcg/day (1110)	☐ 1 NA (1120)
2g.	triamcinolone (≤ 800 mcg/day)	___ ___ ___	mcg/day (1130)	☐ 1 NA (1140)
2h.	montelukast (≤ 4 - 5 mg qd)	___ ___	mg qd (1150)	☐ 1 NA (1160)
2i.	zafirlukast (≤ 10 mg bid)	___ ___	mg bid (1170)	☐ 1 NA (1180)
2j.	theophylline (any dose allowed)	___ ___ ___ ___	mg/day (1190)	☐ 1 NA (1200)
2k.	nedocromil MDI (≤ 8 puffs/day)	___ ___	puffs/day (1210)	☐ 1 NA (1220)
2l.	cromolyn MDI (≤ 8 puffs/day)	___ ___	puffs/day (1230)	☐ 1 NA (1240)
2m.	salmeterol MDI (≤ 2 puffs bid)	___ ___	puffs bid (1250)	☐ 1 NA (1260)
2n.	salmeterol DPI (≤ 1 blister bid)	___ ___	blister bid (1270)	☐ 1 NA (1280)

3. Was the controller therapy that the participant was using within the allowable range? ☐ 1 Yes ☐ 0 No (1290)

4. During the past 4 weeks, did the participant have asthma signs or symptoms requiring albuterol (excluding for exercise) on average more than 2 times per week or more than 1 night per month of nocturnal awakenings? ☐ 1 Yes ☐ 0 No (1300)

5. Has the participant received systemic corticosteroid treatment (oral or injectable) in the past 4 weeks? ☐ 1 Yes ☐ 0 No (1310)

6. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P3_EXCLDRUG) during the designated washout periods? ☐ 1 Yes ☐ 0 No (1320)

   ➜ ***Skip to Question #10.***

To Be Completed ONLY for Subjects naive to Controller Therapy

7. During the past 4 weeks, has the participant had a combination of asthma symptoms or bronchodilator use for relief from asthma signs or symptoms on an average of 3 or more days per week? (Do not include bronchodilator use prior to exercise.) ☐ 1 Yes ☐ 0 No (1330)

8. Has the participant received any of the following treatments?

   8a. Oral inhaled corticosteroid treatment in the past 2 weeks ☐ 1 Yes ☐ 0 No (1340)

   8b. Systemic corticosteroid treatment (oral or injectable) in the past 4 weeks ☐ 1 Yes ☐ 0 No (1350)

9. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P3_EXCLDRUG) during the designated washout periods? ☐ 1 Yes ☐ 0 No (1360)

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

    ➜ ***If NO, please STOP HERE and complete the Termination of Study Participation (P3_TERM) form.***

Physician/CC signature: _____ (1380)

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

Childhood Asthma Research & Education
NIH / NHLBI

PACT
ELIGIBILITY CHECKLIST 3
Visit 2

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 2
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

If the participant is female, answer Questions #1 - #1b.

1. Has the participant had her first menstrual period? ☐ 1 Yes ☐ 0 No (1000)

   ➜ ***If YES, please complete Questions #1a - #1b.***

   1a. Is the participant currently pregnant or nursing? ☐ 1 Yes ☐ 0 No (1010)

   1b. Is the participant currently using abstinence or an acceptable birth control method? ☐ 1 Yes ☐ 0 No (1020)

Medication Use Criteria

2. Has the participant received any of the following treatments since Visit 1?

   2a. Oral inhaled corticosteroid treatment ☐ 1 Yes ☐ 0 No (1030)

   2b. Systemic corticosteroid treatment (oral or injectable) ☐ 1 Yes ☐ 0 No (1040)

3. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P3_EXCLDRUG) during the designated washout periods? ☐ 1 Yes ☐ 0 No (1050)

Run-In Drug Adherence

For Questions #4 - #5, please refer to the PACT Compliance Checklist (P3_COMPLY).

4. Has the participant shown evidence of adherence (≥75%) with the study capsules (both capsule count and eDEM™)? ☐ 1 Yes ☐ 0 No (1060)

5. Has the participant shown evidence of adherence (≥75%) with the study Diskus®? ☐ 1 Yes ☐ 0 No (1070)

Personal Best PEFR

6. Determining Personal Best PEFR

6a. Personal Best determined at Visit 1 (P3_ELIG1 Question #24) ___ ___ ___ l/min (1500)

Pool of Values - Personal Best PEFR from Visit 1, all **acceptable** Peak Flow values from the AM1 device performed during Visit 2, all **acceptable** Peak Flow values recorded on the Diary Card between Visits 1 and 2. The Peak Flow values cannot be more than 1.2 times higher than the Visit 1 personal best PEFR.

Clinic Use Only

1. List the 3 **acceptable** Peak Flow Values from the AM1 Device performed during Visit 2.

___ ___ ___ l/min ___ ___ ___ l/min ___ ___ ___ l/min

2. Question #6a x 1.2 = ___ ___ ___ x 1.2 = ___ ___ ___ l/min

6b. Highest Peak Flow from Pool ___ ___ ___ l/min (1510)

6c. 2nd highest Peak Flow from Pool ___ ___ ___ l/min (1520)

6d. 3rd highest Peak Flow from Pool ___ ___ ___ l/min (1530)

6e. Is the highest Peak Flow from the Pool (Question #6b) equal to the participant's Personal Best at Visit 1 (Question #6a)? ❑1 Yes ❑0 No (1540)

➜ ***If YES, skip to Question #6j. The Personal Best PEFR is Question #6a.***

6f. $\frac{\textit{Question \#6c}}{\textit{Question \#6b}}$ ___ . ___ ___ (1550)

6g. Is Question #6f greater than 0.9? ❑1 Yes ❑0 No (1560)

➜ ***If YES, skip to Question #6j. The Personal Best PEFR is Question #6b.***

6h. $\frac{\textit{Question \#6d}}{\textit{Question \#6c}}$ ___ . ___ ___ (1570)

6i. Is Question #6h greater than 0.9? ❑1 Yes ❑0 No (1580)

➜ ***If YES, the personal best PEFR is Question #6c.***

➜ ***If NO, the personal best PEFR is Question #6a.***

Record the personal best in Question #6j.

6j. Personal Best PEFR ___ ___ ___ l/min (1590)

Minimum Asthma Criteria

7. Number of days in assessment period ___ ___ days (1140)

   ➜ ***For participants naive to controller therapy, include all days between Visits 1 and 2.***

   ➜ ***For participants on controller therapy, include last 14 days (include all days if less than 14 available).***

8. Minimum Asthma Calculation

   8a. Number of days with asthma signs or symptoms, bronchodilator use (do not include bronchodilator use prior to exercise), or peak flow values in the Yellow Zone during the Run-In period ___ ___ (1150)

   8b. Weekly Average = $\frac{\textit{Question \#8a}}{\textit{(Question \#7)}}$ x *7* ___ ___ . ___ (1190)

   8c. Is Question #8b ≥ 3.0? ☐ 1 Yes ☐ 0 No (1200)

Adherence Criteria

9. Diary and peak flow adherence

   9a. Number of complete measurements in the defined interval (measurements that count toward adherence include AM and PM spirometry measurements, coughing and wheezing symptoms, and rescue albuterol use for asthma symptoms or low peak flow) ___ ___ ___ measurements (1210)

   9b. Percent adherence = $\frac{\textit{Question \#9a}}{\textit{(Question \#7 x 5)}}$ x *100* ___ ___ ___ . ___ % (1220)

   9c. Is Question #9b ≥ 75%? ☐ 1 Yes ☐ 0 No (1230)

10. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1240)

    ➜ ***If YES, proceed with Question #11.***

    ➜ ***If NO, please STOP HERE and complete the source documentation box on the last page, also complete the Termination of Study Participation (P3_TERM) form.***

Symptom and Peak Flow Criteria

11. Albuterol use

11a. Total number of puffs of albuterol used after exercise or for asthma symptoms or low peak flow (Questions #14 and #15 on the Diary Card) ___ ___ puffs (1250)

11b. Average number of puffs of albuterol per day $Average = \frac{Question\ \#11a}{Question\ \#7}$ ___ . ___ puffs (1260)

11c. Is Question #11b > 8.0? ☐ 1 Yes ☐ 0 No (1270)

12. Night awakenings

12a. Total number of days in the defined interval with night awakenings requiring albuterol due to asthma symptoms (Question #1 on the Diary Card) ___ ___ days (1280)

12b. Average number of days per week with night awakenings requiring albuterol due to asthma symptoms $Average = \frac{Question\ \#12a}{Question\ \#7} \times 7$ ___ . ___ (1290)

12c. Is Question #12b > 2.0? ☐ 1 Yes ☐ 0 No (1300)

Pulmonary Function Criteria

13. Is the participant's pre-bronchodilator FEV_1% predicted ≥70%? (Result of best effort) ☐ 1 Yes ☐ 0 No (1305)

14. Is the participant's methacholine PC_{20} ≤ 12.5 mg/ml? ☐ 1 Yes ☐ 0 No (1308)

Other Criteria

15. Does the parent/legal guardian believe that the participant and family will be able to comply with the study schedule and study requirements? ☐ 1 Yes ☐ 0 No (1310)

16. Is the participant able to coordinate the use of the study Diskus®? ☐ 1 Yes ☐ 0 No (1320)

17. Has the participant had difficulty swallowing the study capsule during the Run-In period? ☐ 1 Yes ☐ 0 No (1325)

18. Is there any other reason for which this participant should not be included in this study? ☐ 1 Yes ☐ 0 No (1330)

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

19. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1340)

➜ ***If NO, please STOP HERE and complete the Termination of Study Participation (P3_TERM) form.***

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

20. Drug Packet Number (record on P3_LOG) ___ (1350) - ___ ___ ___ (1360) - ___ ___ ___ (1370)

Physician/CC signature: _____ (1380)

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

Childhood Asthma Research & Education
NIH / NHLBI

PACT ELIGIBILITY CHECKLIST Advair Therapy (Visit 1)

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant shown evidence of adherence with the Diary Cards? ☐ 1 Yes ☐ 0 No (1000)

2. Since Visit 0, has the participant had symptoms too severe to be included in the PACT study? (Peak flows in the Red Zone or, on average, > 8 puffs/day albuterol) ☐ 1 Yes ☐ 0 No (1020)

3. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1040)

   ➜ ***If YES, proceed with Question #4.***

   ➜ ***If NO, please STOP HERE and complete the Termination of Study Participation (P3_TERM) form.***

Physician/CC signature: _____ (1050)
Date: __ __ / __ __ / __ __ __ __ (1060)

4. Determining Personal Best PEFR

4a. Personal Best determined at previous visit ___ ___ ___ l/min (1500)

Pool of Values - Personal Best PEFR from previous visit, all **acceptable** Peak Flow values from the AM1 device performed during the current visit, all **acceptable** Peak Flow values recorded on the Diary Card since the last visit. The Peak Flow values cannot be more than 1.2 times higher than the Visit 0 personal best PEFR.

Clinic Use Only

1. List the 3 **acceptable** Peak Flow Values from the AM1 Device performed during this Visit.

___ ___ ___ l/min ___ ___ ___ l/min ___ ___ ___ l/min

2. Question #4a x 1.2 = ___ ___ ___ x 1.2 = ___ ___ ___l/min

4b. Highest Peak Flow from Pool ___ ___ ___ l/min (1510)

4c. 2nd highest Peak Flow from Pool ___ ___ ___ l/min (1520)

4d. 3rd highest Peak Flow from Pool ___ ___ ___ l/min (1530)

4e. Is the highest Peak Flow from the Pool (Question #4b) equal to the participant's Personal Best from the last visit (Question #4a)? ❑1 Yes ❑0 No (1540)

➜ ***If YES, skip to Question #4j. The Personal Best PEFR is Question #4a.***

4f. $\frac{\textit{Question \#4c}}{\textit{Question \#4b}}$ ___ . ___ ___ (1550)

4g. Is Question #4f greater than 0.9? ❑1 Yes ❑0 No (1560)

➜ ***If YES, skip to Question #4j. The Personal Best PEFR is Question #4b.***

4h. $\frac{\textit{Question \#4d}}{\textit{Question \#4c}}$ ___ . ___ ___ (1570)

4i. Is Question #4h greater than 0.9? ❑1 Yes ❑0 No (1580)

➜ ***If YES, the personal best PEFR is Question #4c.***

➜ ***If NO, the personal best PEFR is Question #4a.***

Record the personal best in Question #4j.

4j. Personal Best PEFR ___ ___ ___ l/min (1590)

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PACT
ELIGIBILITY CHECKLIST
Controller Therapy
(Visit 1A)

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant shown evidence of adherence with the Diary Cards? ☐ 1 Yes ☐ 0 No (1000)

2. Has the participant shown evidence of adherence with the study medications? ☐ 1 Yes ☐ 0 No (1010)

3. Since Visit 1, has the participant had symptoms too severe to be included in the PACT study? (Peak flows in the Red Zone or, on average, > 8 puffs/day albuterol) ☐ 1 Yes ☐ 0 No (1020)

4. Is the participant's pre-bronchodilator FEV_1% predicted ≥ 80%? *(Result of best effort)* ☐ 1 Yes ☐ 0 No (1030)

5. Is the participant eligible? ***If any of the shaded boxes are selected, the participant is ineligible.*** ☐ 1 Yes ☐ 0 No (1040)

➜ ***If NO, please STOP HERE and complete the Termination of Study Participation (P3_TERM) form.***

Physician/CC signature: _____ (1050)
Date: __ __ / __ __ / __ __ __ __ (1060)

Childhood Asthma Research & Education
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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.

_____

_____

_____

Childhood Asthma Research & Education
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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)

Childhood Asthma Research & Education
NIH / NHLBI

PACT HEALTHCARE UTILIZATION REVIEW

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Subject Interview completed)

DO NOT ENTER. FOR REFERENCE PURPOSES ONLY.

I am going to ask you some questions based on several events which may have occurred since the previous study visit which took place on:

___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year*

1. Since the previous study visit, did the participant take any newly prescribed medicine(s) (other than study medications)? ❑1 Yes ❑0 No (1000)

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

2. Since the previous study visit, did the participant use any over-the-counter (OTC) medicine(s)? ❑1 Yes ❑0 No (1010)

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

3. Since the previous study visit, was the participant admitted to a hospital for an overnight stay of at least one night? ❑1 Yes ❑0 No (1020)

   ➜ ***If NO, skip to Question #4.***

   3a. If ***YES***, how many times was the participant admitted? ___ ___ time(s) (1030)

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

DO NOT ENTER. FOR REFERENCE PURPOSES ONLY.

Hospital Name: _____

Hospital Address: _____

_____

_____

   3b. Admission date ___ ___ / ___ ___ / ___ ___ ___ ___ (1040)
   month *day* *year*

   3c. Discharge date ___ ___ / ___ ___ / ___ ___ ___ ___ (1050)
   month *day* *year*

3d. What was the reason for this hospitalization?

❑1 Asthma (1060)
❑2 Other _____

➜ ***If the reason for the hospitalization was 'Asthma', please complete the Treatment Failure (P3_TRTFAIL) form.***

3e. Number of days in ICU/CCU/Stepdown Unit ___ ___ (1070)

3f. Number of days in regular care unit ___ ___ (1080)

3g. Was the participant placed on a ventilator? ❑1 Yes ❑0 No (1090)

3h. What was the participant's status at discharge?

❑1 Alive (2000)
❑2 Deceased

4. Since the previous study visit, did the participant go to an <u>emergency room</u> or have an <u>unscheduled/urgent care visit</u>? ❑1 Yes ❑0 No (2010)

➜ ***If NO, skip to Question #6.***

4a. If ***YES***, how many times? ___ ___ time(s) (2020)

4b. Type of visit

❑1 ER (2030)
❑2 Urgent care

4c. Date of visit ___ ___ / ___ ___ / ___ ___ ___ ___ (2040)
month day year

4d. Was the visit due to asthma? ❑1 Yes ❑0 No (2050)

➜ ***If NO, skip to Question #5.***

4e. Was spirometry performed at the visit? ❑1 Yes ❑0 No ❑9 Don't Know (2060)

4f. Was peak flow measured at the visit? ❑1 Yes ❑0 No ❑9 Don't Know (2070)

4g. Were any treatments given during the visit? ❑1 Yes ❑0 No ❑9 Don't Know (2080)

➜ ***If NO or DON'T KNOW, skip to Question #4h.***

➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

4gi. Atrovent (nebulized or MDI) ❑1 Yes ❑0 No ❑9 Don't Know (2090)

4gii. Multiple doses of MDI albuterol ❑1 Yes ❑0 No ❑9 Don't Know (3000)

4giii. Nebulizer ("breathing") treatment ❑1 Yes ❑0 No ❑9 Don't Know (3010)

4giv. IM steroids ❑1 Yes ❑0 No ❑9 Don't Know (3020)

4gv. IV steroids ❑1 Yes ❑0 No ❑9 Don't Know (3030)

4gvi. IV aminophylline ❑1 Yes ❑0 No ❑9 Don't Know (3040)

4gvii. Other _____ ❑1 Yes ❑0 No ❑9 Don't Know (3050)

4h. Were any medications prescribed at discharge? ❑1 Yes ❑0 No ❑9 Don't Know (3060)

➜ ***If NO or DON'T KNOW, skip to Question #5.***

➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

4hi. Oral steroids ❑1 Yes ❑0 No ❑9 Don't Know (3070)

4hii. Antibiotics ❑1 Yes ❑0 No ❑9 Don't Know (3080)

5. Since the previous study visit, did the participant have a second emergency room or unscheduled/urgent care visit? ❑1 Yes ❑0 No (3090)

➜ ***If NO, skip to Question #6.***

5a. Type of visit ❑1 ER (4000)
❑2 Urgent care

5b. Date of visit ___ ___ / ___ ___ / ___ ___ ___ ___ (4010)
month day year

5c. Was the visit due to asthma? ❑1 Yes ❑0 No (4020)

➜ ***If NO, skip to Question #6.***

5d. Was spirometry performed at the visit? ❑1 Yes ❑0 No ❑9 Don't Know (4030)

5e. Was peak flow measured at the visit? ❑1 Yes ❑0 No ❑9 Don't Know (4040)

5f. Were any treatments given during the visit? ❑1 Yes ❑0 No ❑9 Don't Know (4050)

➜ ***If NO or DON'T KNOW, skip to Question #5g.***

➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

5fi. Atrovent (nebulized or MDI) ❑1 Yes ❑0 No ❑9 Don't Know (4060)

5fii. Multiple doses of MDI albuterol ❑1 Yes ❑0 No ❑9 Don't Know (4070)

5fiii. Nebulizer ("breathing") treatment ❑1 Yes ❑0 No ❑9 Don't Know (4080)

5fiv. IM steroids ❑1 Yes ❑0 No ❑9 Don't Know (4090)

5fv. IV steroids ❑1 Yes ❑0 No ❑9 Don't Know (5000)

5fvi. IV aminophylline ❑1 Yes ❑0 No ❑9 Don't Know (5010)

5fvii. Other _____ ❑1 Yes ❑0 No ❑9 Don't Know (5020)

5g. Were any medications prescribed at discharge? ❑1 Yes ❑0 No ❑9 Don't Know (5030)

➜ ***If NO or DON'T KNOW, skip to Question #6.***

➜ ***If YES, please complete appropriate Concomitant Medications form, if needed.***

5gi. Oral steroids ❑1 Yes ❑0 No ❑9 Don't Know (5040)

5gii. Antibiotics ❑1 Yes ❑0 No ❑9 Don't Know (5050)

6. Since the previous study visit, did the participant have a <u>regular clinic/office visit</u> to a physician (does not apply to study visits)? ❑1 Yes ❑0 No (5060)

➜ ***If NO, skip to Question #7.***

6a. If ***YES***, how many times? ___ ___ time(s) (5070)

7. Since the previous study visit, did the participant miss at least a <u>half-day of school</u> because of his/her health (does not apply to time off for study visits)? ❑1 Yes ❑0 No ❑9 N/A (5080)

➜ ***If NO or N/A, skip to Question #8.***

7a. Since the previous study visit, how many full or half-days of school did the participant miss? *(indicate full or half days in increments of 0.5 days)* ___ ___ . ___ day(s) (5090)

7b. Of the days of school that were missed, how many were missed due to the participant's asthma? ___ ___ . ___ day(s) (6000)

7c. What was the reason for the missed activity?

7ci. Due to worsening symptoms caused by the participant's asthma? ❑1 Yes ❑0 No (6010)

7cii. To see an MD or health-care provider about the participant's asthma (does not apply to time off for study-related visits)? ❑1 Yes ❑0 No (6020)

7ciii. Due to side effects related to asthma medication? ❑1 Yes ❑0 No (6030)

➜ ***If YES, please complete Clinical Adverse Events 2 (AECLIN2) form.***

7civ. Other _____ ❑1 Yes ❑0 No (6040)

8. Since the previous study visit, did you (or other parent/guardian) miss at least a half-day of work, house work, or school because of the participant's health (does not apply to time off for study visits)? ❑1 Yes ❑0 No (6050)

➜ ***If NO, STOP HERE. Do NOT complete remainder of form.***

8a. Since the previous study visit, how many full or half-days of school/work/housework did you (or other parent/guardian) miss? *(indicate full or half days in increments of 0.5 days)* ___ ___ . ___ day(s) (6060)

8b. Of the days of school/work/housework that were missed, how many were missed due to the participant's asthma? ___ ___ . ___ day(s) (6070)

8c. Primary activity missed. (check one box only)
❑1 Work (6080)
❑2 School
❑3 Housework

8d. What was the reason for the missed activity?

8di. Due to worsening symptoms caused by the participant's asthma? ❑1 Yes ❑0 No (6090)

8dii. To see an MD or health-care provider about the participant's asthma (does not apply to time off for study-related visits)? ❑1 Yes ❑0 No (7000)

8diii. Due to side effects related to asthma medication? ❑1 Yes ❑0 No (7010)

➜ ***If YES, please complete Clinical Adverse Events 2 (AECLIN2) form.***

8div. Other _____ ❑1 Yes ❑0 No (7020)

(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

JUNIPER ASTHMA CONTROL QUESTIONNAIRE

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

(Participant or Parent/Legal Guardian completed: Questions #1 - #7)

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

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

2. On average, during the past week, how often were you awakened by your asthma during the night?
   - ❑0 Never (1010)
   - ❑1 Hardly ever
   - ❑2 A few times
   - ❑3 Several times
   - ❑4 Many times
   - ❑5 A great many times
   - ❑6 Unable to sleep because of asthma

3. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?
   - ❑0 No symptoms (1020)
   - ❑1 Very mild symptoms
   - ❑2 Mild symptoms
   - ❑3 Moderate symptoms
   - ❑4 Quite severe symptoms
   - ❑5 Severe symptoms
   - ❑6 Very severe symptoms

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

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

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

- ❑0 Not at all (1050)
- ❑1 Hardly any of the time
- ❑2 A little of the time
- ❑3 A moderate amount of the time
- ❑4 A lot of the time
- ❑5 Most of the time
- ❑6 All the time

7. On average, during the past week, how many puffs of short-acting bronchodilator (e.g. Ventolin) have you used each day?

- ❑0 None (1060)
- ❑1 1 - 2 puffs most days
- ❑2 3 - 4 puffs most days
- ❑3 5 - 8 puffs most days
- ❑4 9 - 12 puffs most days
- ❑5 13 - 16 puffs most days
- ❑6 More than 16 puffs most days

(Clinic Coordinator completed)

8. Were pre-bronchodilator FEV_1 and FEV_1 % predicted measures completed on a form for the current visit (e.g. Spirometry Testing (SPIRO) or Maximum Bronchodilator Response Testing (MAXBD) form)?

❑1 Yes ❑0 No (1110)

Respondent Initials: ___ ___ ___ (1120)

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

Childhood Asthma Research & Education
NIH / NHLBI

PACT LABORATORY TESTS

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

URINE PREGNANCY TEST (Visits 1, 2 and 7 only)

1. Pregnancy test results
(Check N/A if the participant is male, or is female and has not started menses.)

❑ 1 Positive (1000)
❑ 0 Negative
❑ 9 N/A

Participant's Initials: ___ ___ ___ (1010)
Date: ___ ___/ ___ ___/ ___ ___ ___ ___ (1020)

➜ ***If pregnancy test results are positive, subject must be terminated from study participation. Complete a Termination of Study Participation (P3_TERM) form and follow study termination procedures.***

BLOOD TESTS (Visits 2 and 7 only)

2. Total WBC ___ ___ ___ ___ ___ cu. mm (1030)

3. Eosinophils ___ ___ . ___ % (1040)

4. Hematocrit ___ ___ . ___ % (1050)

Childhood Asthma Research & Education
NIH / NHLBI

MODIFIED ASTHMA THERAPY ASSESSMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant completed)

1. Who is the respondent?

- ❑1 Participant (1000)
- ❑2 Mother
- ❑3 Father
- ❑4 Stepparent
- ❑5 Grandparent
- ❑6 Legal Guardian
- ❑7 Other _____

2. Since the last study visit, how many days did the participant:

	None	1 to 3	4 to 7	Over 7
2a. Have wheezing or difficulty breathing when playing or exercising?	❑1	❑2	❑3	❑4 (1010)
2b. Have wheezing during the day when ***not*** playing or exercising?	❑1	❑2	❑3	❑4 (1020)
2c. Wake up at night with wheezing or difficult breathing?	❑1	❑2	❑3	❑4 (1030)
2d. Miss days of school or work because of his/her asthma?	❑1	❑2	❑3	❑4 (1040)
2e. Miss any daily activities (for example, playing or exercising, going to a friend's house, or any family activity) because of his/her asthma?	❑1	❑2	❑3	❑4 (1050)

3. Do you believe:

	Yes	No	Unsure
3a. The participant's asthma was well controlled since the last study visit?	❑1	❑2	❑3 (1060)
3b. The participant is able to take the study medicine(s) as directed?	❑1	❑2	❑3 (1070)
3c. The study medicine(s) the participant takes are useful for controlling asthma?	❑1	❑2	❑3 (1080)

4. Since the last study visit, on days the participant used albuterol for *quick relief*, how many puffs a day did he or she usually take?

- ❑1 1 to 4 puffs (1090)
- ❑2 5 to 8 puffs
- ❑3 9 to 12 puffs
- ❑4 over 12 puffs

5. Since the last study visit, what was the greatest number of ***puffs of albuterol in one day*** the participant used for *quick relief* from asthma symptoms?

- ❑1 0 puffs (1100)
- ❑2 1 to 2 puffs
- ❑3 3 to 4 puffs
- ❑4 5 to 6 puffs
- ❑5 7 to 8 puffs
- ❑6 9 or more puffs

6. Since the last study visit, what was the greatest number of ***nebulizer treatments with albuterol*** the participant used in one day for *quick relief* from asthma symptoms?

- ❑1 0 treatments (1110)
- ❑2 1 treatment
- ❑3 2 treatments
- ❑4 3 or more treatments

Respondent Initials: ___ ___ ___ (1120)

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

Childhood Asthma Research & Education
NIH / NHLBI

MAXIMAL BRONCHODILATOR RESPONSE TESTING

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

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

(Coordinator completed)

SPIROMETRY CONFOUNDERS

1. During the past 2 weeks, has the child had any respiratory infections, colds, or bronchitis? ☐ 1 Yes ☐ 0 No (1000)

2. During the past 48 hours, has the child used any oral decongestants or cold remedies? ☐ 1 Yes ☐ 0 No (1010)

3. During the past 4 hours, has the child consumed caffeine? ☐ 1 Yes ☐ 0 No (1020)
   Examples: *Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello, Mountain Dew, Tea, Barq's Rootbeer*

4. During the past 8 hours, has the child used medications with caffeine? ☐ 1 Yes ☐ 0 No (1030)
   Examples: *Anacin, Darvon compound, Esgic, Exedrin, Fiorinal, Fioricet, No Doz, Norgesic, Vivarin*

SPIROMETRY EXCLUSIONS

5. During the past 12 hours, has the child used a long-acting inhaled beta-agonist (e.g. Serevent, formoterol)? ☐ 1 Yes ☐ 0 No (1040)

6. During the past 24 hours, has the child used sustained-release theophylline? ☐ 1 Yes ☐ 0 No (1050)

7. During the past 4 hours, has the child used a short-acting bronchodilator? ☐ 1 Yes ☐ 0 No (1060)

8. Is there any other reason the child should not proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1070)
   If **YES**, explain _____
   _____

9. Is the child eligible to proceed with the pulmonary function testing? ☐ 1 Yes ☐ 0 No (1080)

If any of the shaded boxes are filled in, the child is NOT eligible for pulmonary function testing.

➜ ***If NO, do NOT complete Questions #10 - #19.***
If this is a regular protocol visit, the pulmonary function testing should be rescheduled within the visit window.

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING
(Technician completed)

10. Standing height *(barefoot or thin socks)* ____ ____ ____ . ____ cm (1090)

11. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____ (1100)

12. Results of best effort

12a. FVC ____ . ____ ____ L (1110)

12b. FEV_1 ____ . ____ ____ L (1120)

12c. FEV_1 (% predicted) ____ ____ ____ % predicted (1130)

12d. FEV_1 / FVC ____ ____ ____ % (1140)

12e. FEF_{25-75} ____ . ____ ____ liters/sec (1150)

12f. FEF_{50} ____ . ____ ____ liters/sec (1160)

12g. FEF_{75} ____ . ____ ____ liters/sec (1170)

12h. Peak flow from best effort ____ ____ . ____ ____ liters/sec (1180)

12i. FET ____ ____ . ____ ____ sec (1190)

12j. FET (Peak Flow) ____ . ____ ____ sec (1200)

12k. V backextrapolation ex ____ . ____ ____ liters (1210)

12l. V backextrapolation % FVC ____ ____ . ____ ____ % (1220)

12m. ATS Accepted ___ . 0 0 (1230)

12n. ATS Error Code ___ ___ ___ . 0 0 (1240)

➜ ***Administer 4 puffs of albuterol and wait 15 minutes.***

13. Time albuterol administered *(based on 24-hour clock)* ___ ___ ___ ___ (1250)

14. Child's FEV_1 after 4 puffs of albuterol

14a. Time spirometry started *(based on 24-hour clock)* ___ ___ ___ ___ (1260)

14b. FEV_1 ___ . ___ ___ L (1270)

14c. FEV_1 (% predicted) ___ ___ ___ % predicted (1280)

➜ ***Administer 2 puffs of albuterol and wait 15 minutes.***

15. Time albuterol administered (based on 24-hour clock) ___ ___ ___ ___ (1290)

16. Child's FEV_1 after additional 2 puffs of albuterol

16a. Time spirometry started (*based on 24-hour clock*) ___ ___ ___ ___ (1300)

16b. FEV_1 ___ . ___ ___ L (1310)

16c. FEV_1 (% predicted) ___ ___ ___ % predicted (1320)

16d. Percent difference in FEV_1 $\frac{(Question\ \#16b - Question\ \#14b)}{Question\ \#14b} \times 100$ ___ ___ . ___ % (1330)

16e. Is the percent difference in Question #16d ≤ 5.0%? ❑ 1 Yes ❑ 0 No (1340)

➜ ***If YES, skip to Question #19.***

➜ ***If NO, administer 2 puffs of albuterol and wait 15 minutes.***

17. Time albuterol administered *(based on 24-hour clock)* ____ ____ ____ ____ (1350)

18. Child's FEV_1 after last 2 puffs of albuterol

18a. Time spirometry started *(based on 24-hour clock)* ____ ____ ____ ____ (1360)

18b. FEV_1 ____ . ____ ____ L (1370)

18c. FEV_1 (% predicted) ____ ____ ____ % predicted (1380)

19. In your judgement, was the child's technique acceptable? ❑1 Yes ❑0 No (1390)

19a. If ***NO***, why was it unacceptable? *(Check all that apply)*

Inadequate inspiratory effort ❑1 Yes ❑0 No (1400)

Inadequate expiratory effort ❑1 Yes ❑0 No (1410)

Inadequate duration of expiration ❑1 Yes ❑0 No (1420)

Cough during procedure ❑1 Yes ❑0 No (1430)

Other (specify) _____ ❑1 Yes ❑0 No (1440)

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

Acceptable, good effort ❑1 (1450)

Acceptable, questionable effort ❑2

19bi. If answered 2, please explain.

_____

_____

Childhood Asthma Research & Education
NIH / NHLBI

PACT SCHEDULED MEDICATIONS

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. What type of visit is this?

☐ 1 Scheduled visit (1000)
☐ 2 Unscheduled visit

MEDICATION LABEL

Affix the new drug label below:

Copy the drug label number below:

3 - ___ ___ ___ - ___ ___ ___
(1010) (1020) (1030)

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

By signing in the source documentation box you are:

1) Confirming that the label on the scheduled medications matches the number on the outside of the packet and the outside of the kit.
2) Confirming that the 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

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. Race and Ethnicity

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

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

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

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

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

- ❑1 Male (1030)
- ❑2 Female

CHILD'S MEDICAL HISTORY

5. 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 (atopic dermatitis) 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

METHACHOLINE CHALLENGE 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 4 weeks, has the child had any respiratory infections (i.e., upper respiratory infection, cold, or bronchitis)? ☐1 Yes ☐0 No (1000)

2. Has it been less than 4 weeks since the child last took an oral steroid (i.e., prednisolone, prednisone)? ☐1 Yes ☐0 No (1010)

3. During the past 4 weeks, has the child had any other severe acute illness? ☐1 Yes ☐0 No (1020)

   If ***YES***, has the child received permission from the supervising physician to proceed with the methacholine challenge testing? ☐1 Yes ☐0 No (1030)
   Name of physician _____

4. Is the child currently having an acute asthma attack? ☐1 Yes ☐0 No (1040)

5. During the past 24 hours, has the child used sustained-release theophylline? ☐1 Yes ☐0 No (1050)

6. During the past 12 hours, has the child used a long-acting bronchodilator (i.e., salmeterol)? ☐1 Yes ☐0 No (1060)

7. During the past 4 hours, has the child used a short-acting bronchodilator? ☐1 Yes ☐0 No (1070)

8. During the past 4 hours, has the child had any caffeine (i.e., chocolate, cola drinks, caffeinated coffee or tea, or medication with caffeine)? ☐1 Yes ☐0 No (1080)

9. Is the child using any anti-inflammatories? ☐1 Yes ☐0 No (1090)

   9a. If ***YES***, indicate which classes and date of last use. *(Check all that apply)*

Class	Date
☐1 Inhaled corticosteroid (1100)	___ ___ / ___ ___ / ___ ___ ___ ___ (1110)
☐2 Cromolyn/nedocromil (1120)	___ ___ / ___ ___ / ___ ___ ___ ___ (1130)
☐3 Leukotriene receptor antagonists (1140)	___ ___ / ___ ___ / ___ ___ ___ ___ (1150)

10. Does the child have a baseline (pre-diluent) FEV_1 less than 70% of predicted FEV_1? ☐ 1 Yes ☐ 0 No (1160)

11. Is there any other reason you should not proceed with the methacholine challenge? ☐ 1 Yes ☐ 0 No (1170)

If ***YES***, explain _____

_____

12. Is the child eligible to proceed with the diluent (solution #0) pulmonary function testing for the methacholine challenge? ☐ 1 Yes ☐ 0 No (1180)

If any of the shaded boxes are filled in, the child is NOT eligible for the methacholine challenge.

➜ ***If NO, do NOT complete Questions #13 - 22.***
If possible, the baseline pulmonary function testing and the methacholine challenge should be rescheduled within the visit window.

13. Standing height *(barefoot or thin socks)* ___ ___ ___. ___ cm (1190)

METHACHOLINE CHALLENGE TEST *(Technician completed)*

14. Was baseline (pre-diluent) spirometry completed? ☐ 1 Yes ☐ 0 No (1210)

Clinic Use Only

Use the prebronchodilator FEV_1 from SPIRO form as the baseline (pre-diluent) value.

A. **FEV_1** ___. ___ ___ L

B. **FEV_1 (% predicted)** ___ ___ ___% predicted

Methacholine Reversal Reference Value **Question A x 0.90 =** ___. ___ ___ L

15. Earliest expiration date of all 10 methacholine solutions ___ ___ / ___ ___ / ___ ___ ___ ___
month *day* *year* (1280)

16. FVC/FEV_1 for serial challenges (leave concentrations not administered blank)

		FEV_1	FVC
16a.	Solution 0 (diluent)	___.___ ___ L (1290)	___.___ ___ L (1300)
16b.	Solution 1 (0.098 mg/ml)	___.___ ___ L (1310)	___.___ ___ L (1320)
16c.	Solution 2 (0.195 mg/ml)	___.___ ___ L (1330)	___.___ ___ L (1340)
16d.	Solution 3 (0.391 mg/ml)	___.___ ___ L (1350)	___.___ ___ L (1360)
16e.	Solution 4 (0.781 mg/ml)	___.___ ___ L (1370)	___.___ ___ L (1380)
16f.	Solution 5 (1.563 mg/ml)	___.___ ___ L (1390)	___.___ ___ L (1400)
16g.	Solution 6 (3.125 mg/ml)	___.___ ___ L (1410)	___.___ ___ L (1420)
16h.	Solution 7 (6.25 mg/ml)	___.___ ___ L (1430)	___.___ ___ L (1440)
16i.	Solution 8 (12.5 mg/ml)	___.___ ___ L (1450)	___.___ ___ L (1460)
16j.	Solution 9 (25 mg/ml)	___.___ ___ L (1470)	___.___ ___ L (1480)

17. PC_{20} ___ ___.___ ___ ___ (1490)

17a. Time methacholine challenge was completed (*based on 24-hour clock*) ___ ___ ___ ___ (1500)

18. Subject's FEV_1 after standard reversal (2 puffs albuterol with Aerochamber) from methacholine challenge

18a. FEV_1 ___.___ ___ L (1510)

18b. Time of FEV_1 in Question #18a (*based on 24-hour clock*) ___ ___ ___ ___ (1530)

18c. Was the FEV_1 from Question #18a ≥ the Methacholine Reversal Reference Value in the gray box on page 2 of this form? ❑1 Yes ❑0 No (1540)

➔ ***If YES, STOP HERE. Continue with remaining visit procedures.***

➔ ***If NO, call physician for recommendations.***

19. Was additional treatment used in the first hour? ☐1 Yes ☐0 No (1550)
   ➜ ***If NO, skip to Question #21***
   ➜ ***If YES, please complete the appropriate Concomitant Medications form.***

   19a. Additional albuterol by MDI ☐1 Yes ☐0 No (1560)
      ➜ ***If NO, skip to Question #19b***

      19ai. Number of additional puffs of albuterol administered ☐1 two ☐2 four ☐3 >four (1570)

   19b. Nebulized beta-agonist ☐1 Yes ☐0 No (1580)

   19c. Subcutaneous epinephrine ☐1 Yes ☐0 No (1590)

   19d. Implementation of clinic emergency protocol or algorithm ☐1 Yes ☐0 No (1600)

   19e. Other _____ ☐1 Yes ☐0 No (1610)

20. Subject's FEV_1 after additional treatment within first hour.

   20a. FEV_1 ___.___ ___ L (1620)

   20b. Time of FEV_1 in Question #20a (based on 24 hour clock) ___ ___ ___ ___ (1640)

   20c. Was the FEV_1 from Question #20a ≥ the Methacholine Reversal Reference Value in the gray box on page 2 of this form? ☐1 Yes ☐0 No (1650)
      ➜ ***If YES, STOP HERE and continue with remaining visit procedures.***

21. Was additional treatment used after one hour? ☐1 Yes ☐0 No (1660)
   ➜ ***If NO, skip to Question #22***
   ➜ ***If YES, please complete the appropriate Concomitant Medications form.***

   21a. Additional albuterol by MDI ☐1 Yes ☐0 No (1670)
      ➜ ***If NO, skip to Question #21b***

      21ai. Number of additional puffs of albuterol administered ☐1 two ☐2 four ☐3 >four (1680)

   21b. Nebulized beta-agonist ☐1 Yes ☐0 No (1690)

   21c. Subcutaneous epinephrine ☐1 Yes ☐0 No (1700)

   21d. Implementation of clinic emergency protocol or algorithm ☐1 Yes ☐0 No (1710)

21e. Treatment in the emergency room ❑1 Yes ❑0 No (1720)

21f. Overnight hospitalization ❑1 Yes ❑0 No (1730)

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

21g. Other _____ ❑1 Yes ❑0 No (1740)

22. Subject's final FEV_1 after methacholine challenge.

22a. FEV_1 ____. ____ ____ L (1750)

22b. Time of FEV_1 in Question #22a (*based on 24-hour clock*) ____ ____ ____ ____ (1770)

22c. Was the FEV_1 from Question #22a ≥ the Methacholine Reversal Reference Value in the gray box on page 2 of this form? ❑1 Yes ❑0 No (1780)

➜ ***If YES, STOP HERE and continue with remaining visit procedures.***

➜ ***If NO, complete the source documentation box below.***

Physician/CC signature: _____ (1790)

Date: __ __ / __ __ / __ __ __ __ (1800)

Childhood Asthma Research & Education
NIH / NHLBI

PHYSICAL ACTIVITY QUESTIONNAIRE

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

(Participant completed)

*We are trying to find out about your level of physical activity from **the last 7 days** (in the last week). This includes sports or dance that make you sweat or make your legs feel tired, or games that make you breathe hard, like tag, skipping, running, climbing, and others.*

Remember:
--There are no right or wrong answers - this is not a test.
--Please answer all the questions as honestly and accurately as you can - this is very important.
--Some questions may be sensitive - feel free to skip questions if necessary.

1. Physical activity in your spare time: Have you done any of the following activities in the past 7 days (last week)? If yes, how many times? (*Check only one box per row.*)

	No	1 to 2	3 to 4	5 to 6	7 times or more
Skipping	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1000)
Rowing/canoeing	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1010)
In-line skating	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1020)
Tag	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1030)
Walking for exercise	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1040)
Bicycling	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1050)
Jogging or running	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1060)
Aerobics	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1070)
Swimming	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1080)
Baseball, softball	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1090)
Dance	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1100)
Football	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1110)
Badminton	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1120)
Skateboarding	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1130)
Soccer	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1140)
Street hockey	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1150)
Volleyball	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1160)

	No	1 to 2	3 to 4	5 to 6	7 times or more
Floor Hockey	❑1	❑2	❑3	❑4	❑5 (1170)
Basketball	❑1	❑2	❑3	❑4	❑5 (1180)
Ice skating	❑1	❑2	❑3	❑4	❑5 (1190)
Cross-country skiing	❑1	❑2	❑3	❑4	❑5 (1200)
Ice hockey/ringette	❑1	❑2	❑3	❑4	❑5 (1210)
Other: _____	❑1	❑2	❑3	❑4	❑5 (1220)
Other: _____	❑1	❑2	❑3	❑4	❑5 (1230)

2. In the last 7 days, during your physical education (PE) classes, how often were you very active (playing hard, running, jumping, throwing)? (*Check only one.*)

❑1 I don't do PE (1240)
❑2 Hardly ever
❑3 Sometimes
❑4 Quite often
❑5 Always

3. In the last 7 days, what did you do most of the time *at recess*? (*Check only one.*)

❑1 Sat down (talking, reading, doing school work)
❑2 Stood around or walked around (1250)
❑3 Ran or played a little bit
❑4 Ran around and played quite a bit
❑5 Ran and played hard most of the time

4. In the last 7 days, what did you normally do *at lunch* (besides eating lunch)? (*Check only one.*)

❑1 Sat down (talking, reading, doing school work)
❑2 Stood around or walked around (1260)
❑3 Ran or played a little bit
❑4 Ran around and played quite a bit
❑5 Ran and played hard most of the time

5. In the last 7 days, on how many days *right after school*, did you do sports, dance, or play games in which you were very active? (*Check only one.*)

- ❑1 None (1270)
- ❑2 1 time last week
- ❑3 2 or 3 times last week
- ❑4 4 times last week
- ❑5 5 times last week

6. In the last 7 days, on how many *evenings* did you do sports, dance, or play games in which you were very active? (*Check only one.*)

- ❑1 None (1280)
- ❑2 1 time last week
- ❑3 2 or 3 times last week
- ❑4 4 or 5 times last week
- ❑5 6 or 7 times last week

7. *On the last weekend,* how many times did you do sports, dance, or play games in which you were very active? (*Check only one.*)

- ❑1 None (1290)
- ❑2 1 time
- ❑3 2 - 3 times
- ❑4 4 - 5 times
- ❑5 6 or more times

8. Which *one* of the following describes you best for the last 7 days? Read *all five* statements before deciding on the *one* answer that describes you.

- All or most of my free time was spent doing things that involve little physical effort ❑1 (1300)
- I sometimes (1-2 times last week) did physical things in my free time (e.g. played sports, went running, swimming, bike riding, did aerobics) ❑2
- I often (3-4 times last week) did physical things in my free time ❑3
- I quite often (5-6 times last week) did physical things in my free time ❑4
- I very often (7 or more times last week) did physical things in my free time ❑5

9. Mark how often you did physical activity (like playing sports, games, doing dance, or any other physical activity) for each day last week.

	None	Little Bit	Medium	Often	Very Often
Monday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1310)
Tuesday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1320)
Wednesday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1330)
Thursday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1340)
Friday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1350)
Saturday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1360)
Sunday	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5 (1370)

10. Were you sick last week, or did anything prevent you from doing your normal physical activities?

❑ 1 Yes (1380)

❑ 2 No

If 'YES', what prevented you? _____

Childhood Asthma Research & Education
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PACT PREDNISONE MEDICATION FORM

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Interviewer ID: ___ ___ ___ ___ ___

(Coordinator completed)

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

Prednisone Checklist

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

____2. Administer prednisone at 2mg/kg per day for two days (maximum 60mg) and then 1 mg/kg per day (maximum 30mg) for 2 days.

2a. Start date of prednisone ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) (1000)

____3. Since enrolling in the PACT study, including the burst prescribed in #2 above, how many corticosteroid bursts have been given? ____ ____ bursts (1010)

➜ ***If the subject has received 3 corticosteroid bursts since enrolling in the PACT study, he/she should be assigned to treatment failure status. Please complete the Treatment Failure Form (P3_TRTFAIL) and see the PACT Manual of Operations for further details.***

____4. Instruct the parents to call if the child's condition worsens.

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PRIOR ASTHMA MEDICATION HISTORY

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

(Clinic Coordinator completed)

1. Who is the respondent?

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

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

❑ 1 Yes ❑ 0 No (1000)

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

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

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

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

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

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

Childhood Asthma Research & Education
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SERIOUS ADVERSE EVENT REPORTING FORM

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

(Coordinator completed)

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

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

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

   Describe: _____

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

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

5. Why was the event serious?

   5a. Fatal event — ☐ 1 Yes ☐ 0 No (1040)

   5b. Life-threatening event — ☐ 1 Yes ☐ 0 No (1050)

   5c. Inpatient hospitalization required — ☐ 1 Yes ☐ 0 No (1060)

   ➜ ***If NO, skip to Question #5d.***

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

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

   5d. Hospitalization prolonged — ☐ 1 Yes ☐ 0 No (1090)

   5e. Disabling or incapacitating — ☐ 1 Yes ☐ 0 No (1100)

   5f. Overdose — ☐ 1 Yes ☐ 0 No (1110)

   5g. Cancer — ☐ 1 Yes ☐ 0 No (1120)

   5h. Congenital anomaly — ☐ 1 Yes ☐ 0 No (1130)

   5i. Serious laboratory abnormality with clinical symptoms — ☐ 1 Yes ☐ 0 No (1140)

   5j. Height failure — ☐ 1 Yes ☐ 0 No (1145)

   5k. Pregnancy — ☐ 1 Yes ☐ 0 No ☐ 9 N/A (1147)

   5l. Other _____ — ☐ 1 Yes ☐ 0 No (1150)

SERIOUS

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

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

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

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

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

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

REPORTING INVESTIGATOR:

9. Name: _____

Address: _____
_____
_____

Signature: _____

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

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

Childhood Asthma Research & Education
NIH/NHLBI

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

CARE SYMPTOM-FREE DAY QUESTIONNAIRE

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

(Subject Interview completed)

1. In the <u>past 14 days</u>, how many days did you have wheezing, chest tightness, cough, or shortness of breath? ___ ___ day(s) (1000)

2. In the <u>past 14 days</u>, how many days did you have to slow down or stop activities because of asthma, wheezing, chest tightness, cough, or shortness of breath? ___ ___ day(s) (1010)

3. In the <u>past 14 days</u>, how many days did you wake up because of asthma, wheezing, chest tightness, cough, or shortness of breath? ___ ___ day(s) (1020)

4. Thinking about all three asthma signs or symptoms (wheezing, slowing down or stopping activities, and nights awakened), in the <u>past 14 days</u>, how many days did you have <u>any</u> of these day-time or night-time symptoms? ___ ___ day(s) (1030)

5. In the <u>past 14 days</u>, how many days did you experience any day with <u>NO</u> day-time or night-time symptoms of asthma (including no wheezing, no cough, no chest tightness, or no shortness of breath)? ___ ___ day(s) (1040)

Remember: Question #4 + Question #5 = 14. If the sum of Question #4 and Question #5 is not 14, please review the responses with the participant.

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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

Childhood Asthma Research & Education
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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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PACT
TERMINATION OF STUDY PARTICIPATION

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of study participation.

1. Has the participant completed the study? ❑1 Yes ❑0 No (1010)

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

2. ***(Pre-randomization)***
   Has the participant been deemed ineligible prior to randomization? ❑1 Yes ❑0 No (1020)

   If ***YES***, indicate the **primary** reason.
   - ❑1 too much asthma (1025)
   - ❑2 too little asthma
   - ❑3 insufficient adherence with study drugs
   - ❑4 inability to demonstrate adherence with study diary
   - ❑6 cold/URI
   - ❑7 FEV_1 % predicted < 80%
   - ❑8 unable to swallow study capsule
   - ❑5 other _____

3. Has the participant been withdrawn from the study due to pregnancy? ❑1 Yes ❑0 No ❑9 N/A (1030)

   (Check N/A if the participant is male, or is female and has not started menses.)

   ➜ If ***YES***, please have the participant initial and date the source documentation box.

   Participant's Initials ___ ___ ___ (1040)
   Date: ___ ___/ ___ ___/ ___ ___ ___ ___ (1050)

4. Has the participant been lost to follow up? ❑1 Yes ❑0 No (1090)

5. Has the participant experienced a serious adverse event? ❑1 Yes ❑0 No (1100)

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

6. Did a physician initiate the termination of study participation? ❑1 Yes ❑0 No (1110)
   If ***YES***, reason _____

7. Is there any other reason why the participant is being terminated from the study? ❑1 Yes ❑0 No (1070)

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

- ❑1 parent withdrew consent (1080)
- ❑2 participant withdrew assent
- ❑3 no longer interested in participating
- ❑4 no longer willing to follow protocol
- ❑5 difficult access to clinic (location, transportation, parking)
- ❑6 unable to make visits during clinic hours
- ❑7 moving out of the area
- ❑8 unable to continue due to personal constraints
- ❑9 dissatisfied with asthma control
- ❑10 unable to continue due to medical condition unrelated to asthma
- ❑11 side effects of study medications
- ❑12 other _____

SIGNATURES

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

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

_____ (1120) ___ ___ / ___ ___ / ___ ___ ___ ___ (1130)
Clinic Coordinator's Signature — month / day / year

_____ (1140) ___ ___ / ___ ___ / ___ ___ ___ ___ (1150)
Principal Investigator's Signature — month / day / year

Childhood Asthma Research & Education
NIH / NHLBI

PACT
TREATMENT FAILURE

Subject ID: 0 3 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant been hospitalized for asthma? ☐ 1 Yes ☐ 0 No (1010)

2. Has the participant had a hypoxic seizure due to asthma? ☐ 1 Yes ☐ 0 No (1020)

3. Has the participant required intubation for asthma? ☐ 1 Yes ☐ 0 No (1030)

4. Has the participant received a third burst of prednisone for an asthma exacerbation? ☐ 1 Yes ☐ 0 No (1040)

5. Has the participant had a Serious Adverse Event related to use of a study medication? ☐ 1 Yes ☐ 0 No (1050)

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

6. Is the participant a treatment failure? ***If any of the shaded boxes are selected, the participant is a treatment failure.*** ☐ 1 Yes ☐ 0 No (1070)

7. Date treatment failure occurred ___ ___ / ___ ___ / ___ ___ ___ ___ (1080) (month / day / year)

Physician/CC signature: _____ (1090)
Date: __ __ / __ __ / __ __ __ __ (1100)

Note: The participant should return to the CARE center following resolution of the exacerbation. Study medications should be stopped and participants should be treated with open-label controller therapy, according to the discretion of the study investigator or primary physician.