Childhood Asthma Research & Education
NIH/NHLBI

CLINICAL ADVERSE EVENTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___

(Clinic Coordinator completed)

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

❑0 None

(1020) DESCRIPTION OF ADVERSE EVENT	(1030) 1. ICD9 CODE	(1040) 2. DATE STARTED (Top Line) / (1050) 3. DATE STOPPED (Bottom Line) MONTH / DAY / YEAR	(1060) 4. ONGOING at current contact	(1080) 5. TYPE 1 - INTERMITTENT 2 - CONTINUOUS	(1090) 6. SEVERITY 1 - MILD 2 - MODERATE 3 - SEVERE	(1100) 7.SERIOUS 1- YES * 0 - NO	(1110) 8. LIKELIHOOD OF RELATIONSHIP TO STUDY DRUG 1 - NONE 2 - UNLIKELY (REMOTE) 3 - POSSIBLE 4 - PROBABLE 5 - HIGHLY PROBABLE	(1120) 9. CHANGE IN STUDY MEDICATIONS 1 - DISCONTINUED 2 - REDUCED 3 - INTERRUPTED, BUT RESUMED AT CURRENT DOSE 4 - UNCHANGED 5 - INCREASED	(1130) 10. OUTCOME *(Skip if #4 or #12 is checked.)* 1 - COMPLETELY RECOVERED 2 - RECOVERED, BUT WITH LASTING EFFECTS 3 - DEATH *	(1140) 11. TREATMENT REQUIRED 1 - NONE 2 - MEDICATION ** 3 - HOSPITALIZATION * 4 - OTHER	(1150) 12. ONGOING at final contact
__ __	___ . __	__ / __ / ____ __ / __ / ____	❑1								❑1
__ __	___ . __	__ / __ / ____ __ / __ / ____	❑1								❑1
__ __	___ . __	__ / __ / ____ __ / __ / ____	❑1								❑1
__ __	___ . __	__ / __ / ____ __ / __ / ____	❑1								❑1

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

Childhood Asthma Research & Education
NIH/NHLBI

ASTHMA SYMPTOMS

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

(Parent/Legal Guardian or Participant Completed)

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

ASTHMA SYMPTOMS AND RESCUE MEDICINE

2. On average, during the past MONTH, how often has the participant had a cough, wheeze, shortness of breath, or chest tightness? **(1010)**
   - ❑ 1 2 days or less per week
   - ❑ 2 3 - 6 days per week
   - ❑ 3 Daily
   - ❑ 4 More than once a day

3. On average, during the past MONTH, how often has the participant had cough, wheeze, shortness of breath, or chest tightness while exercising or playing? **(1020)**
   - ❑ 1 2 days or less per week
   - ❑ 2 3 - 6 days per week
   - ❑ 3 Daily
   - ❑ 4 More than once a day

4. On average, during the past MONTH, how often does asthma keep the participant from doing what he/she wants? **(1030)**
   - ❑ 1 2 days or less per week
   - ❑ 2 3 - 6 days per week
   - ❑ 3 Daily
   - ❑ 4 More than once a day

5. On average, during the past MONTH, how often was the participant awakened from sleep because of coughing, wheezing, shortness of breath, or chest tightness? **(1040)**
   - ❑ 1 2 nights or less per month
   - ❑ 2 3 - 4 nights per month
   - ❑ 3 5 - 9 nights per month
   - ❑ 4 10 or more nights per month

6. In general, during the past MONTH, how bothered was the participant by his/her asthma? **(1050)**

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

7. On average, during the past MONTH, how many days per week did the participant use an albuterol inhaler or nebulizer? **(1060)** ___ days/week

Clinic Coordinator Completed

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

CAP/FEIA RESULTS

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

(Clinic Coordinator Completed)

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education

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CONCOMITANT MEDICATIONS for ASTHMA/ALLERGY-RELATED DRUGS

Subject ID: ___ ___ - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

(Clinic Coordinator completed)

First visit: Please list all concomitant medications used to treat **asthma** and **allergies,** that the participant has taken since signing the informed consent. If the concomitant medication was used for an adverse event, record the corresponding AECLIN event number. If the concomitant medication was taken to treat asthma/allergies and was unrelated to an adverse event, please check the N/A box. Refer to Section 7.12 of the CARE General MOP for applicable drug codes (Q1010). Check the "None" box if the participant has not taken any **asthma** or **allergy** concomitant medications since signing the informed consent.

Subsequent visits: Please list all concomitant medications used to treat **asthma** and **allergies,** that the participant has started taking since the last visit. Check the "None" box if the participant has not started taking any **asthma** or **allergy** concomitant medications since the last visit. **Refer to the CARE Protocol MOP for possible additional medications that must be recorded.**

❑$_0$ None

NAME OF MEDICATION (1010)	CODE (1000)	RELATED EVENT (1020)	(1030)	START DATE (MM/DD/YYYY) (1060)	STOP DATE (MM/DD/YYYY) (1090)	ONGOING AT CURRENT CONTACT (1100)	ONGOING AT FINAL CONTACT (1110)
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$
___ ___		Event ___ ___	❑$_1$ N/A	___ / ___ / _____	___ / ___ / _____	❑$_1$	❑$_1$

Childhood Asthma Research & Education
NIH/NHLBI

MARS COMPLIANCE CHECKLIST

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)
Check the following adherence criteria at Visits 0a through 7 and 99 (Treatment Failure Visit).

1. **Diskus® (Visits 0a - 7 and 99)**

Dose counter number on each Diskus® device distributed to the participant at current and last visits:

	A. Last visit	B. Current visit	C. Last visit - Current visit (A - B)
Diskus® #1	___ ___ doses	___ ___ doses	___ ___ doses
Diskus® #2	___ ___ doses	___ ___ doses	___ ___ doses
Diskus® #3	___ ___ doses	___ ___ doses	___ ___ doses

D. Used doses = sum of column C in the gray box = ___ ___ ___ doses

1a. Number of scheduled inhalations **(1000)** ___ ___ ___ doses

1b. Total number of Used Doses (D from the gray box) **(1010)** ___ ___ ___ doses

1c. Percent adherence = $\frac{\textit{Question \#1b}}{\textit{Question \#1a}}$ x *100* **(1020)** ___ ___ ___ . ___%

2. **eDEM™ Monitor(s)**

The information for Question #2a - Question #2c is obtained from the eDEM™ Monitor Report for eDEM™ #1 (<u>Capsule</u> Vial) (Visits 3 - 7 and 99).

2a. Number of monitored days **(1030)** ___ ___ ___ days

2b. Number of doses taken **(1040)** ___ ___ ___ doses

2c. % Prescribed number of doses taken **(1050)** ___ ___ ___ . ___%

The information for Question #2d - Question #2f is obtained from the eDEM™ Monitor Report for eDEM™ #2 (<u>Tablet</u> Vial) (Visits 3 - 7 and 99).

2d. Number of monitored days **(1060)** ___ ___ ___ days

2e. Number of doses taken **(1070)** ___ ___ ___ doses

2f. % Prescribed number of doses taken **(1080)** ___ ___ ___ . ___%

3. **Capsule count (Visits 1a - 7 and 99).**

3a. Number of scheduled capsules for Capsule Vial **(1090)** ___ ___ ___ capsules

3b. Number of capsules dispensed in Capsule Vial **(1100)** ___ ___ ___ capsules

3c. Number of capsules returned in Capsule Vial **(1110)** ___ ___ ___ capsules

3d. Actual number of capsules taken (Question #3b - Question #3c) **(1120)** ___ ___ ___ capsules

3e. Percent adherence = $\frac{\textit{Question \#3d}}{\textit{Question \#3a}}$ x *100* **(1130)** ___ ___ ___ . ___%

➔ ***At Visit 2, if otherwise eligible according to P5_ELIG2, then complete Question #5 on page 2.***

4. **Tablet count (Visits 3 - 7 and 99).**

4a.	Number of scheduled tablets for Tablet Vial	**(1140)**	___ ___ ___ tablets
4b.	Number of tablets dispensed in Tablet Vial	**(1150)**	___ ___ ___ tablets
4c.	Number of tablets returned in Tablet Vial	**(1160)**	___ ___ ___ tablets
4d.	Actual number of tablets taken (Question #4b - Question #4c)	**(1170)**	___ ___ ___ tablets
4e.	Percent adherence = $\frac{\textit{Question \#4d}}{\textit{Question \#4a}}$ x *100*	**(1180)**	___ ___ ___ . ___%

5. Pulmicort Turbuhaler Compliance (Visit 2 only if otherwise eligible according to P5_ELIG2)

Clinic Use Only
1. Number of inhalations left on each Turbuhaler distributed to the subject at the previous visit:

___ ___ ___ inhalations ___ ___ ___ inhalations ___ ___ ___ inhalations

2. Used inhalations = sum of #1 in the gray box = ___ ___ ___ inhalations
3. Total possible inhalations 205 x the number of Turbuhalers distributed = ___ ___ ___ inhalations

5a.	Number of scheduled inhalations	**(1190)**	___ ___ ___ inhalations
5b.	Number of unused inhalations (#2 from the gray box)	**(1200)**	___ ___ ___ inhalations
5c.	Number of used inhalations (#3 from the gray box - Question #5b)	**(1210)**	___ ___ ___ total inhalations
5d.	Percent adherence = $\frac{\textit{Question \#5c}}{\textit{Question \#5a}}$ x *100*	**(1220)**	___ ___ ___ . ___%

➔ For Visits 3-7, if the percent adherence for the eDEM™ monitor, the Capsule count, or the Diskus® is less than 80%, re-emphasize the importance of maintaining the daily dosing schedule.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS TREATMENT PHASE CONTROL ASSESSMENT

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since the last study visit has the participant required the use of an oral or injectable corticosteroid for asthma (except one prednisone tablet given without physician instruction; see MOP)? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***YES***, ***STOP HERE***. Record the start date on the CMED_AS form, then go to the Treatment Failure Visit Procedure Checklist (P5_VISITTF). Schedule a follow up call within one week.

Symptom History Assessment

2. In the past 2 weeks (or since the last study visit, if < 2 weeks since the last study visit), on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms? **(1010)** ___ ___ days

   2a. Is Question #2 > 6? **(1020)** ❑1 Yes ❑0 No

3. In the past 2 weeks (or since the last study visit, if < 2 weeks since the last study visit), during how many nights has the participant woken up to use albuterol for asthma? **(1030)** ___ ___ nights

   3a. Is Question #3 ≥ 2? **(1040)** ❑1 Yes ❑0 No

4. Is the participant controlled by history? **(1050)** ❑1 Yes, Controlled by history ❑2 No, Uncontrolled by history

   ➔ ***If Question #2a or #3a is answered 'Yes', the participant is not controlled by history.***

Diary Card Assessment

Verify or complete Question #21 on the Diary Card and use the program provided to determine whether the participant's asthma is controlled according to the Diary Card.

5. Is the participant controlled according to the Diary Card? **(1060)** ❑1 Yes, Controlled by Diary Card ❑2 No, Uncontrolled by Diary Card ❑3 Diary Card(s) not available at the time of control assessment

   5a. If ***YES***, ***Controlled by Diary Card***, are there at least 11 days of usable diary data in the past 14 days since the last study visit (or since the last study visit, if < 2 weeks since the last study visit)? (A usable day has at least one of the colored questions completed on the Diary Card.) **(1070)** ❑*1 Yes ❑0 No

If there is a discrepancy in the answers to Q4 and Q5, a physician must be consulted. However, if Q5 = 'Yes, Controlled' and Q5a = 'No' then a physician consultation is not needed.

6. Is the participant controlled by physician consultation? **(1080)** ❑*1 Yes, Controlled ❑2 No, Uncontrolled ❑3 Physician consultation not needed

7. Is the participant controlled? **(1090)**
   - ❑ 1 Yes, Controlled
   - ❑ 2 No, Uncontrolled

   If either of the shaded boxes is selected, the participant is not controlled.

   Otherwise, if either starred box is selected (but no shaded box), the participant is controlled.

   Otherwise, the control status is the response to Question #4.

   ➔ ***If No, Uncontrolled, skip to Question #9.***

FEV_1 assessment

8. Is the participant's pre-bronchodilator FEV_1 value ≥ 80% of the best pre-bronchodilator pre-randomization value? **(1100)** ❑ 1 Yes ❑ 0 No
   (Check the reference box on the participant's flowchart)

9. Is the participant controlled by Diary Card and FEV_1? **(1110)**
   - ❑ 1 Yes, Controlled
   - ❑ 2 No, Uncontrolled
   - ❑ 3 Participant needs to repeat spirometry in 1 - 4 days to determine control status

If Question #7 is...	and Question #8 is...	then answer Question #9
Yes, Controlled	Yes	Yes, Controlled
Yes, Controlled	No	Participant needs to repeat spirometry in 1 - 4 days to determine control status
No, Uncontrolled		No, Uncontrolled

➔ If the participant is **Controlled**, follow the procedures to STEP DOWN according to the MARS Budesonide Dosing (P5_BUD) form.

➔ If the participant is **Uncontrolled**, go to the Treatment Failure Visit Procedure Checklist (P5_VISITTF). Schedule a follow-up call within one week.

➔ If the **Participant needs to repeat spirometry in 1 - 4 days to determine control status**, stop the visit. Administer 4 puffs of albuterol to assess reversibility. Consult a physician with these values. With physician consent, the participant may continue in the study if he/she can return for a follow up visit in 1 - 4 days. Call the patient tomorrow to assess his/her condition. At the follow up visit, please use the P5_VISITFUP Checklist.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS CONTROL ASSESSMENT BY PHONE

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Caregiver or Participant Interview completed)

Clinic Coordinator completed - *Do not ask the caregiver/participant*

1. What type of phone call took place? **(1100)** ❑1 Scheduled
   ❑2 Unscheduled
   ❑3 No contact made

   ➔ **If *No contact made*, STOP HERE.**

2. Since the last study visit, has there been any hospitalization for asthma? **(1110)** ❑1 Yes ❑0 No

   ➔ **If *YES*, STOP HERE. Complete a Serious Adverse Event (SERIOUS) form.**

3. Since the last study visit, has an oral or injectable corticosteroid been used for asthma, <u>other than for Step Up</u> through a CARE physician at a study visit? (Run-In: see MOP discussion on prednisone if the course took place within 10 days of the end of the pervious course. Treatment Phase: except one prednisone tablet given without physician instructions; see MOP). **(1000)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Question #4.
   ➔ If ***YES***, record the start date on the CMED_AS form, and complete Question #3a.

   3a. If ***YES***, was this corticosteroid course considered by the CARE physician to be consistent with poor control or an asthma exacerbation? **(1010)** ❑1 Yes ❑0 No

   ➔ ***STOP HERE***.
   Run-In: If ***No***, the participant is ineligible. Please complete the P5_TERM form.
   If ***Yes***, Step Up the budesonide dose over the phone and schedule a STEP UP Visit immediately.
   Treatment Phase: The participant is a treatment failure. Schedule a Treatment Failure Visit.

The following questions ask about the participant's asthma symptoms in the past 14 days or since the last study visit if this call is placed within 14 days of the last visit. Write the appropriate date in the statement below.

Please use the Diary Cards since ___ ___ / ___ ___ / ___ ___ ___ ___ to help answer the following questions.

4. During how many nights has the participant woken up to use albuterol for asthma (Question #1 on Diary Card is 'Yes')? **(1020)** ___ ___ nights

Nighttime awakenings - *Do not ask the caregiver/participant*

5. Is Question #4 ≥ 2 nights? **(1030)** ❑1 Yes ❑0 No

6. On how many days has the participant had Diary Card Question #21 answered 'YES'? **(1040)** ___ ___ days

   [That is, at least one of the following:

   - coughing or wheezing symptoms (Diary Questions #15 and #16)
   - albuterol use (not counting albuterol used before exercise) (Diary Question #18), or
   - peak flow values in the Yellow or Red Zone (Diary Questions #3 and #9)]

Minimum Asthma Calculation - *Do not ask the caregiver/participant*

7. Is Question #6 > 6? **(1050)** ☐ 1 Yes ☐ 0 No

8. Do you have any questions that I can help to answer?
   Comments _____

   _____

Control Assessment - *Do not ask the caregiver/participant*

9. Is the participant controlled? **(1090)** ☐ 1 Yes, Controlled
   ☐ 2 No, Uncontrolled

   If any of the shaded boxes are selected, the participant is NOT controlled.

   ➔ **If Yes, Controlled, confirm next study visit**

   ➔ **If No, Uncontrolled:**

   Run-In: Please refer to the participant's Run-In Flowchart to determine the next step.

   Treatment Phase: Please bring the participant into the clinic immediately for a Treatment Failure Visit.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS RUN-IN CONTROL ASSESSMENT

Subject ID: 0 5 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

1. Since the last study visit has the participant required the use of an oral or injectable corticosteroid for asthma, other than for Step Up through a CARE physician at a study visit (See MOP discussion on prednisone if the course took place within 10 days of the end of the previous course)? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***NO***, skip to Question #2.

   ➔ If ***YES***, record the start date on the CMED_AS form and continue with Question #1a.

   1a. If ***YES***, was this corticosteroid course considered by the CARE physician to be consistent with poor control or an asthma exacerbation? **(1010)** ❑1 Yes ❑0 No

   ➔ If ***NO, STOP HERE***. The participant is ineligible, please complete the P5_TERM form.

   ➔ If ***YES***, skip to Question #8 and check the "No, Uncontrolled" box.

Diary Card Assessment
If the Diary Cards were forgotten, the visit must be rescheduled. See MOP for safety concerns.

2. Number of diary days with usable data in the past 14 days (or since the last study visit if < 2 weeks since the last study visit). Usable diary days are days with at least one of P5_DIARY Questions #1, 3, 9, 15, 16, or 18 completed (including the current visit date, but excluding the previous visit date). **(1015)** __ __ days

   ➔ If Question #2 < 7 days, count the number of nighttime awakenings in the past 14 days. If there were at least 2 nighttime awakenings, continue. If not, STOP HERE and reschedule the visit; the participant needs more days of completed diary data to assess control.

3. Nighttime awakenings
   3a. Number of nights with awakenings requiring albuterol in the past 14 days (or since the last study visit if < 2 weeks since the last study visit) (P5_DIARY Question #1) (including the morning of the current visit date)? **(1020)** __ __ nights

   3b. Is Question #3a ≥ 2 nights? **(1030)** ❑1 Yes ❑0 No

4. Minimum Asthma Calculation
   4a. Number of days with asthma signs or symptoms, albuterol use (do not include albuterol use prior to exercise), or peak flow values in the Yellow or Red Zone in the past 14 days since the last study visit (or since the last study visit, if < 2 weeks since the last study visit). (P5_DIARY Question #21) ***If peak flow zones were updated at the current visit, use the newly calculated zones.*** Do not count any day more than once. If P5_DIARY Q15, Q16, or Q18 is greater than '0', count that day. If Q3 or Q9 is in the Yellow or Red Zone, count that day. Total days should not exceed 14. **(1040)** __ __ days

   4b. Is Question #4a > 6? **(1050)** ❑1 Yes ❑0 No

5. Is the participant controlled by the Diary Card? **(1060)** ❑1 Yes, Controlled by Diary Card ❑2 No, Uncontrolled by Diary Card

   If any shaded box is selected, the participant is NOT controlled.
   ➔ ***If No, Uncontrolled by Diary Card, skip to Question #8.***

Childhood Asthma Research & Education
NIH/NHLBI

MARS RUN-IN CONTROL ASSESSMENT

Subject ID: 0 5 - ___ - ___ ___ ___

Visit Number: ___ ___

See Visit Procedure Checklist for appropriate visit procedures before proceeding.

FEV_1 Assessment

6. Is the participant's FEV_1 value from today's spirometry measurement ≥ 80% of the participant's personal best FEV_1 during the Run-In?
(Check the reference box on the participant's flowchart)

(1070) ☐ 1 Yes, Controlled by FEV_1
☐ 0 No, Uncontrolled by FEV_1

Physician Assessment

7. Is the participant controlled by physician consultation?

(1080) ☐ 1 Yes, Controlled
☐ 2 No, Uncontrolled
☐ 3 Physician not consulted

8. Is the participant controlled?

If any shaded box is selected, the participant is NOT controlled.

(1090) ☐ 1 Yes
☐ 2 No, Uncontrolled

8a. If ***YES***, is Question #2 ≥ 11 days?

➔ *If **NO**, please **STOP HERE** and reschedule the visit. The participant needs more diary days to verify control. Emphasize the importance of completing the Diary Card.*

(1095) ☐ 1 Yes, Controlled
☐ 0 No

Eligibility Criteria

9. Is the participant uncontrolled on > 1600 mcg budesonide + salmeterol?

(1100) ☐ 1 Yes ☐ 0 No

10. Is the participant controlled on 400 mcg budesonide + salmeterol?

(1110) ☐ 1 Yes ☐ 0 No

10a. If ***YES***, has the participant completed the 4-week holding pattern?

(1120) ☐ 1 Yes ☐ 0 No

11. Is the participant eligible?

(1130) ☐ 1 Yes ☐ 0 No

If either of the shaded boxes in Questions #9 - #10a is selected, the participant is ineligible.

➔ **If NO, please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

➔ **If YES, please follow the instructions on the participant's Flowchart form for Step Up or Step Down instructions and for scheduling the next appointment.**

COMMENTS

(6000): _____

_____

_____

Subject ID: 0 5 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

MARS DIARY CARD

Return Visit Number: ___ ___

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

Personal Peak Flow Reference Value	_____ Best	Below _____ Red Zone	_____ to _____ Yellow Zone	_____ or above Green Zone

Complete with blue or black ink	Day 1:_____	Day 2:_____	Day 3:_____	Day 4:_____	Day 5:_____	Day 6:_____	Day 7:_____
Date (month/day)	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___
Complete at Wake Up							
1. Awakened at night to use albuterol for asthma? (1000)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
2. Time of Wake Up Peak Flow (1010)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. Wake Up Peak Flow (Best of 3 tries) (1020)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Albuterol used in the two hours before Wake Up Peak Flow? (1030)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
5. One salmeterol inhalation taken at Wake Up? (1040)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
6. ____ budesonide inhalation(s) taken at Wake Up? (1050)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
7. Coordinator Completed Wake Up FEV$_1$ (liters) (1060)	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __
Complete at Bedtime							
8. Time of Bedtime Peak Flow (1070)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
9. Bedtime Peak Flow (Best of 3 tries) (1080)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
10. Albuterol used in the two hours before Bedtime Peak Flow? (1090)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
11. One salmeterol inhalation taken at bed-time? (1100)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
12. ____ budesonide inhalation(s) taken at bedtime? (1110)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
13. Both study tablet and capsule(s) taken at bedtime? (1120)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
14. Coordinator Completed Bedtime FEV$_1$ (liters) (1130)	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __

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 led to inability to sleep or perform daily activities)

Complete at Bedtime for the Past 24 Hours

15. Rate your coughing from asthma during the past 24 hours. (1140)	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
16. Rate your wheezing during the past 24 hours. (1150)	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
17. Number of puffs of albuterol taken **before exercise** in the past 24 hours. (1160)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
18. Number of puffs of albuterol taken for **asthma symptoms or low peak flow** in the past 24 hours.	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
19. Absent from school or work for asthma symptoms? (1170)	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$	Yes$_1$ No$_0$ N/A$_9$
20. Contacted healthcare provider for asthma symptoms? (1180)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
21. Did you have either... (1190) • #3 or #9 in the Yellow or Red Zones **or** • #15, #16, or #18 more than 0?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

Childhood Asthma Research & Education
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MARS ELIGIBILITY CHECKLIST 1 Visit 0

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Informed Consent and Subject Assent

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

   1a. If ***YES***, record the date the form was signed **(1010)** ___ ___ / ___ ___ / ___ ___ ___ ___ *Month Day Year*

2. 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? **(1020)** ☐1 Yes ☐0 No

   2a. If ***YES***, record the date the assent was signed or verbally given **(1030)** ___ ___ / ___ ___ / ___ ___ ___ ___ *Month Day Year*

Study Medicines

3. Is the participant able to swallow the study capsules? **(1040)** ☐1 Yes ☐0 No

4. Is the participant currently intolerant of or allergic to Serevent (salmeterol), Pulmicort (budesonide), Singulair (montelukast), Zithromax (azithromycin) or any of their ingredients? **(1050)** ☐1 Yes ☐0 No ☐9 Don't know

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

If the participant is female answer Questions #6 - #6b.

6. Has the participant had her first period? **(1070)** ☐1 Yes ☐0 No
   If ***YES***, please complete Questions #6a and #6b.

   6a. Is the participant currently pregnant or nursing? **(1080)** ☐1 Yes ☐0 No

   6b. Does the participant agree to avoid pregnancy during the study? **(1090)** ☐1 Yes ☐0 No

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

   ➔ **If NO, please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

Medical History Criteria

8. Is the participant 6 to <18 years old? **(1110)** ☐1 Yes ☐0 No

9. Is the participant's weight ≥ 25 kg (55 lbs)? **(1120)** ☐1 Yes ☐0 No

10. Has the participant had physician-diagnosed asthma for at least one year? **(1130)** ☐1 Yes ☐0 No

11. Has the participant been treated with an inhaled corticosteroid for the past 6 consecutive weeks? **(1140)** ☐1 Yes ☐0 No

12.	Has the participant smoked 11 or more cigarettes or any other substance in the past year?	**(1150)**	☐ 1 Yes	☐ 0 No
13.	Has the participant used smokeless tobacco products (chew, snuff) 11 or more times in the past year?	**(1160)**	☐ 1 Yes	☐ 0 No
14.	Has the participant ever had chicken pox or received the chicken pox vaccine? (*Refer to MOP for discussion on immunization records*)	**(1170)**	☐ 1 Yes	☐ 0 No
15.	Has the participant been hospitalized for 4 or more wheezing illnesses within the past 12 months?	**(1180)**	☐ 1 Yes	☐ 0 No
16.	Has the participant used an oral or systemic corticosteroid in the past 4 weeks?	**(1190)**	☐ 1 Yes	☐ 0 No
17.	Has the participant had an asthma exacerbation resulting in intubation and mechanical ventilation for asthma within the past year?	**(1210)**	☐ 1 Yes	☐ 0 No
18.	Is the participant receiving allergy shots?	**(1220)**	☐ 1 Yes	☐ 0 No
	18a. If ***YES***, has the dose been changed in the past 3 months?	**(1230)**	☐ 1 Yes	☐ 0 No
19.	Does the participant have a history of severe sinusitis that required sinus surgery within the past 12 months?	**(1240)**	☐ 1 Yes	☐ 0 No
20.	Is the participant currently being treated with antibiotics for diagnosed sinus disease?	**(1250)**	☐ 1 Yes	☐ 0 No
21.	Does the participant use maintenance oral or systemic antibiotics for treatment of an ongoing condition?	**(1260)**	☐ 1 Yes	☐ 0 No
22.	Has the participant used macrolide antibiotics [erythromycin, Zithromax (azithromycin), Biaxin (clarithromycin), Pediazole, Pediamycin, Ketek (telithromycin)] within the past 6 weeks?	**(1270)**	☐ 1 Yes	☐ 0 No
23.	Does the participant have concurrent medical problems other than asthma that are likely to require a systemic corticosteroid during the study (for example, severe eczema, inflammatory bowel disease, rheumatoid arthritis, lupus)?	**(1280)**	☐ 1 Yes	☐ 0 No
24.	Does the participant have any active or chronic lung disease other than asthma?	**(1290)**	☐ 1 Yes	☐ 0 No
25.	Does the participant have a significant medical illness other than asthma [e.g. cardiac (including arrhythmias), liver, gastrointestinal, endocrine, seizures, immunodeficiency disorders, myasthenia gravis, active urinary tract obstruction]?	**(1300)**	☐ 1 Yes	☐ 0 No
26.	Does the participant have a history of gastroesophageal reflux symptoms not controlled by standard medical therapy?	**(1310)**	☐ 1 Yes	☐ 0 No

27. Is the participant currently using digoxin (Lanoxin), ergotamine (Ergomar, Ergostat, Cafergot, Ercaf), dihydroergotamine (D.H.E.45), triazolam (Halcion), carbamazepine (Tegretol, Epitol), cyclosporine (Neoral, Sandimmune), hexobarbital (Hexenal, Hexobarbitone), phenytoin (Dilantin), or similar classes of medication (inotropic/antiarrhythmic, anticonvulsants/sedatives, or immunosuppressants)? **(1315)** ☐ 1 Yes ☐ 0 No

28. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P5_EXCLDRUG) during the designated washout period? **(1320)** ☐ 1 Yes ☐ 0 No

Other Criteria

29. Has the participant been involved in another investigational drug study within the past month? **(1330)** ☐ 1 Yes ☐ 0 No

30. Does the participant's family have plans to move out of the area within the next 12 months? **(1340)** ☐ 1 Yes ☐ 0 No

31. Is there any other reason for which this participant should not be included in this study? **(1350)** ☐ 1 Yes ☐ 0 No

➔ If ***YES***, please describe: _____

32. Is the participant eligible? **(1360)** ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If NO, please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

Budesonide Initial Dose Determination

33. Which inhaled corticosteroid was the participant taking most recently? **(1370)**
☐ 1 QVAR (beclomethasone HFA)
☐ 2 Pulmicort (budesonide)
☐ 3 Aerobid (flunisolide)
☐ 4 Flovent (fluticasone MDI)
☐ 5 Flovent (fluticasone DPI)
☐ 6 Azmacort (triamcinolone)
☐ 7 Azmanex (mometasone)
☐ 8 Advair (fluticasone dose)
☐ 9 Symbicort (budesonide dose)

34. What was the most recent dose of inhaled corticosteroid? (P5_BUDTABLE) **(1380)** ___ ___ ___ ___ mcg/day

35. What is the pre-enrollment budesonide dose equivalent according to the Budesonide Equivalence Table (P5_BUDTABLE)? **(1390)**
☐ 1 400 mcg/day
☐ 2 800 mcg/day
☐ 3 1600 mcg/day

Control Assessment

36. Has the participant used an oral or systemic corticosteroid in the past 8 weeks? **(1395)** ☐ 1 Yes ☒* 0 No

37. On how many days during the past 2 weeks has the participant had asthma signs or symptoms, albuterol use for symptoms or low peak flow, or peak flow values < 80% of personal best? **(1400)** ___ ___ days

38. Is Question #37 ≤ 6? **(1405)** ☒* 1 Yes ☐ 0 No

39. On how many nights during the past 2 weeks has the participant had nighttime awakenings due to asthma? **(1410)** ___ ___ nights

40. Is Question #39 < 2? **(1420)** ☒* 1 Yes ☐ 0 No

Pulmonary Function Criteria

41. What is the participant's pre-bronchodilator FEV_1 % predicted? (*Result of best effort)* **(1430)** ☐ 1 < 50% ☐ 2 50 - 79% ☒* 3 ≥ 80%

➔ ***If < 50%, skip to Question #43. The participant is ineligible.***

42. Is the participant controlled by both symptom history and pulmonary function testing? (See * above. If Question #36 = 'No', Question #38 = 'YES', Question #40 = 'YES', and Question #41 = '≥ 80%', the participant is controlled, otherwise the participant is uncontrolled.) **(1440)** ☐ 1 Yes, Controlled ☐ 0 No, Uncontrolled

42a. If ***YES, Controlled***, is the pre-enrollment budesonide dose equivalent (Question #35) 400 mcg/day? **(1450)** ☐ 1 Yes ☐ 0 No

42b. If ***NO, Uncontrolled***, is the pre-enrollment budesonide dose equivalent (Question #35) > 1600 mcg/day? **(1460)** ☐ 1 Yes ☐ 0 No

43. Is the participant eligible? **(1470)** ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO,* please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

➔ If ***YES*** and the participant is ***Controlled*** by symptom history, pulmonary function testing, and systemic corticosteroid use (Question #42 = 'YES'), follow the procedure to STEP DOWN. Place the participant on half the budesonide dose indicated in Question #36, plus salmeterol. Schedule a 2-week phone contact.

➔ If ***YES*** and the participant is ***Uncontrolled*** by symptom history, pulmonary function testing, or systemic corticosteroid use (Question #42 = 'NO'), give the participant budesonide at the dose indicated in Question #36, plus salmeterol. Schedule a 2-week visit or phone contact according to the appropriate flowchart.

COMMENTS
(6000):_____

Childhood Asthma Research & Education
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MARS ELIGIBILITY CHECKLIST 2
Visits 0a, 0b, 1, 1a, 2

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant received oral or systemic corticosteroid treatment for a reason <u>other than</u> asthma since the last study visit? **(1000)** ☐1 Yes ☐0 No

2. Has the participant used macrolide antibiotics [erythromycin, Zithromax (azithromycin), Biaxin (clarithromycin), Pediazole, Pediamycin, Ketek (telithromycin)] since the last study visit? **(1003)** ☐1 Yes ☐0 No

3. Has the participant been able to swallow the oral study medications? **(1005)** ☐1 Yes ☐0 No

Adherence criteria

4. Number of days since the last study visit (not including study visit days) **(1010)** ___ ___ days

5. Diary and peak flow adherence

   5a. Number of complete measurements in the defined interval (measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measurements, coughing and wheezing symptoms, and rescue albuterol use for asthma symptoms or low peak flow (Questions #1, 3, 9, 15, 16, and 18))? **(1020)** ___ ___ ___ measurements

   5b. Percent adherence = $\frac{\textit{Question \#5a}}{\textit{(Question \#4 x 6)}}$ x *100* **(1030)** ___ ___ ___. ___ %

   5c. Categorize Question #5b. **(1040)** ☐1 < 60%
   ☐2 60 - 74%
   ☐3 ≥ 75%

   ➔ If ***60 - 74%***, re-emphasize the importance of completing the diary card.
   (75% adherence is needed prior to randomization at visit 2.)

Medication use criteria

6. **Visits 1a and 2 only:** Has the participant shown evidence of adherence (≥ 80%) with the study capsules? **(1050)** ☐1 Yes ☐0 No

7. Has the participant shown evidence of adherence (≥ 80%) with the Serevent® Diskus®? **(1060)** ☐1 Yes ☐0 No

8. Is there any other reason for which this participant should not be included in this study? **(1070)** ☐1 Yes ☐0 No

   ➔ If ***YES***, please describe: _____

9. **Visit 2 only,** if no shaded boxes have been selected: Has the participant shown evidence of adherence (≥ 80%) with the Pulmicort Turbuhaler? **(1075)** ☐1 Yes ☐0 No

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MARS ELIGIBILITY CHECKLIST 2
Visits 0a, 0b, 1, 1a, 2

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

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

➔ **If *NO,* please STOP HERE and complete the MARS Termination of the Study Participation (P5_TERM) form.**

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
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MARS ELIGIBILITY CHECKLIST 3 Visit 1

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Was the participant able to demonstrate reversible airflow obstruction at Visit 0 (≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with 4 puffs albuterol)? *(Check the reference box on the participant's flowchart.)* **(1000)** ☐ 1 Yes ☐ 0 No

   ➔ If ***YES***, skip to Question #2.

   1a. Is the participant ineligible for a methacholine challenge at this visit? (Choose "Yes" if a physician has decided that reversibility testing is preferable to a methacholine challenge at this visit.) **(1010)** ☐ 1 Yes ☐ 0 No

      1ai. If ***NO***, is the participant's methacholine PC_{20} ≤ 12.5 mg/ml? **(1020)** ☐ 1 Yes ☐ 0 No

      1aii. If ***YES***, was the participant able to demonstrate reversible airflow obstruction at the current visit (≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with 4 puffs albuterol)? **(1030)** ☐ 1 Yes ☐ 0 No

Clinic Use Only

Visit 1 Reversal

$$\frac{\textit{SPIRO\_POST Question \#3b - SPIRO\_PRE Question \#2b}}{\textit{SPIRO\_PRE Question \#2b}} \times 100 = \_\_\_\_\_ . \_\_\_ \%$$

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

   ➔ **If *NO*, please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
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MARS ELIGIBILITY CHECKLIST 4 Visit 2

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant demonstrated **control after Step Up** on either 800 mcg or 1600 mcg budesonide daily dose according to today's updated participant flowchart and today's P5_CONTROL_RUNIN Question #8a? **(1000)** ☐1 Yes ☐0 No

2. Has the participant demonstrated ≥ 75% adherence with the diary since the last study visit (P5_ELIG2, Question #5c)? **(1010)** ☐1 Yes ☐0 No

3. Were the participant's Visit 1 liver enzyme test results (SGPT/ALT and SGOT/AST) within normal range? **(1020)** ☐1 Yes ☐0 No

4. Did the EKG show signs of significant abnormalities that would preclude continuation in the study? **(1025)** ☐1 Yes ☐0 No

(1026) Participant's Initials: ___ ___ ___

(1027) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

5. Is the participant eligible? **(1035)** ☐1 Yes ☐0 No

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

➔ **If *NO,* please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

6. Was the participant able to demonstrate either ≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with 4 puffs albuterol at Visit 0 or 1 **OR** methacholine $PC_{20} \leq 12.5$ mg/ml at Visit 1? The Visit 2 Methacholine Challenge must still be performed. **(1028)** ☐1 Yes ☐0 No

6a. If ***NO***, was the participant able to demonstrate either ≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with 4 puffs albuterol **OR** methacholine $PC_{20} \leq 12.5$ mg/ml in another CARE study within the past year? **(1090)** ☐1 Yes ☐0 No

6ai. If ***NO***, is the participant's methacholine $PC_{20} \leq 12.5$ mg/ml at the current visit? **(1029)** ☐1 Yes ☐0 No

7. Is the participant eligible? **(1030)** ☐1 Yes ☐0 No

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

➔ **If *NO,* please STOP HERE and complete the MARS Termination of Study Participation (P5_TERM) form.**

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

8. **Drug Packet Number (record on P5_LOG)** ___ - ___ ___ ___ - ___ ___ ___ **(1040) (1050) (1060)**

COMMENTS

(6000): _____

_____

(1070) Physician/CC signature: _____

(1080) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Childhood Asthma Research & Education
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EXHALED NITRIC OXIDE

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

(Technician Completed) Supervisor ID: ___ ___ ___ ___ ___

Complete the eNO testing only if the participant is eligible according to both the Pulmonary Procedure Checklist (PFT_CHK) form and the Exhaled Nitric Oxide Checklist (ENO_CHK) form.

1. Time eNO started *(based on a 24-hour clock)* **(1000)** ___ ___ ___ ___

Measured FENO

2. ENO Measurement #1 **(1010)** ___ ___ ___ . ___ ppb
3. ENO Measurement #2 **(1020)** ___ ___ ___ . ___ ppb
4. ENO Measurement #3 **(1030)** ___ ___ ___ . ___ ppb
5. Average FE_{NO} **(1040)** ___ ___ ___ . ___ ppb
6. Average V_{NO} **(1050)** ___ ___ ___ . ___ nl/min
7. Test Profile **(1060)**
   - ❑1 10 sec ATS
   - ❑2 6 sec ATS
   - ❑3 6 sec Non-ATS
   - ❑4 Modified by user - Only 2 ATS acceptable
   - ❑5 Modified by user - Other

7a. If Question #7 is answered 'Modified by user - Other,' please explain in the comment section below.

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

EXHALED NITRIC OXIDE CHECKLIST

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

(Clinic Coordinator/Parent/Guardian/Participant Interview Completed)

Complete this form only if the participant is eligible according to the Pulmonary Procedure Checklist (PFT_CHK) form.

EXCLUSIONS AND CONFOUNDERS

1. Has the participant smoked cigarettes or any other substance in the past month? **(1000)** ❑1 Yes ❑0 No

   ➔ ***If NO, skip to Question 2.***

   1a. Has the participant smoked cigarettes or any other substance within the past hour? **(1010)** ❑1 Yes ❑0 No

2. Is there any other reason the participant should not proceed with the exhaled nitric oxide procedure? **(1020)** ❑1 Yes ❑0 No

   If ***YES***, explain_____

3. Did the participant eat or drink in the past hour? **(1030)** ❑1 Yes ❑0 No

4. Is the participant eligible to proceed with exhaled nitric oxide testing? **(1040)** ❑1 Yes ❑0 No

   If any of the shaded boxes are filled in, the participant is NOT eligible for eNO Testing.

   ➔ ***If NO, STOP HERE.***
   If this is a regular protocol visit, the eNO procedure should be rescheduled within the visit window.

Proceed to the Exhaled Nitric Oxide (ENO) form.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

HOME ENVIRONMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant Completed)

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

GENERAL HOUSE CHARACTERISTICS

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

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

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

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

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

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

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

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

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

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

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

9. Which rooms use a window unit?

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

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

(1150) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

12. Which rooms use a window unit?

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

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

(1220) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

15. Which rooms use a humidifier?

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

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

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

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

18. Which rooms use a dehumidifier?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1640) ___ ___ years

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

(1650) ❑ 1 Yes ❑ 0 No

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

(1660) ❑ 1 Yes ■ 0 No

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

(1670) ❑ 1 Yes ❑ 0 No

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

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

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

(1690) ___ ___ years

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

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

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

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

ANIMALS

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

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

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

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

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

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

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

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

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

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

Clinic Coordinator Completed

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS SERUM IgE (VISIT 1)

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Was the IgE result obtained? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***YES***, skip to Question #2.

   1a. If ***NO***, why was the result not obtained? **(1010)** ❑1 Blood not drawn
   ❑2 Insufficient blood
   ❑3 Sample lost
   ❑4 Lab result lost

2. IgE: Complete the exact value, **OR** if the IgE value is below the limit of detection, complete the lower limit of detection (e.g. < 2.0 kU/L).

   Complete only <u>one</u> of the following:

   2a. Exact value **(1020)** ___ ___ ___ ___ ___ . ___ kU/L

   2b. Lower limit of detection **(1030)** < ___ . ___ kU/L

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PRE-BRONCHODILATOR IOS

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

(Technician Completed) Supervisor ID: ___ ___ ___ ___ ___

Complete IOS testing only if the participant is eligible according to the Pulmonary Procedure Checklist (PFT_CHK) form.

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING

1. Time IOS started *(based on a 24-hour clock)* **(1010)** ___ ___ ___ ___

2. Results of first effort
   - 2a. R_5 **(1020)** ___ ___ . ___ ___ kPa/l/s
   - 2b. R_{10} **(1030)** ___ ___ . ___ ___ kPa/l/s
   - 2c. R_{15} **(1040)** ___ ___ . ___ ___ kPa/l/s
   - 2d. R_{35} **(1050)** ___ ___ . ___ ___ kPa/l/s
   - 2e. X_5 **(1060)** ___ ___ . ___ ___ kPa/l/s
   - 2f. Resonant Frequency **(1070)** ___ ___ . ___ ___ Hz
   - 2g. Area X_A **(1080)** ___ ___ . ___ ___ kPa/l

3. Results of second effort
   - 3a. R_5 **(1090)** ___ ___ . ___ ___ kPa/l/s
   - 3b. R_{10} **(1100)** ___ ___ . ___ ___ kPa/l/s
   - 3c. R_{15} **(1110)** ___ ___ . ___ ___ kPa/l/s
   - 3d. R_{35} **(1120)** ___ ___ . ___ ___ kPa/l/s
   - 3e. X_5 **(1130)** ___ ___ . ___ ___ kPa/l/s
   - 3f. Resonant Frequency **(1140)** ___ ___ . ___ ___ Hz
   - 3g. Area X_A **(1150)** ___ ___ . ___ ___ kPa/l

4. Results of third effort
   - 4a. R_5 **(1160)** ___ ___ . ___ ___ kPa/l/s
   - 4b. R_{10} **(1170)** ___ ___ . ___ ___ kPa/l/s
   - 4c. R_{15} **(1180)** ___ ___ . ___ ___ kPa/l/s
   - 4d. R_{35} **(1190)** ___ ___ . ___ ___ kPa/l/s
   - 4e. X_5 **(1200)** ___ ___ . ___ ___ kPa/l/s
   - 4f. Resonant Frequency **(1210)** ___ ___ . ___ ___ Hz
   - 4g. Area X_A **(1220)** ___ ___ . ___ ___ kPa/l

5. In your judgement, was the participant's pre-bronchodilator technique acceptable? **(1230)** ☐1 Yes ☐0 No

5a. If ***NO***, why was it unacceptable

5ai. Coherence < 0.80 (for R_{10}) **(1240)** ☐1 Yes ☐0 No

5aii. Poor repeatability (R_{10} values vary by more than 20%) **(1250)** ☐1 Yes ☐0 No

5aiii. Fewer than 3 good tests **(1260)** ☐1 Yes ☐0 No

5aiv. Inconsistent tidal breathing **(1270)** ☐1 Yes ☐0 No

5av. Participant refusal during test **(1280)** ☐1 Yes ☐0 No

5avi. Other (specify) _____ **(1290)** ☐1 Yes ☐0 No

5b. If ***YES***, grade the participant's technique **(1300)**
☐1 Acceptable, good effort
☐2 Acceptable, questionable effort

IOS STANDARDS

6. How was the participant positioned? **(1310)**
☐1 Sitting on a chair
☐2 Sitting on lap
☐3 Standing
☐4 Other

7. Were the participant's cheeks held? **(1320)** ☐1 Yes ☐0 No

7a. If ***YES***, how were the participant's cheeks held? **(1330)**
☐1 Parent/guardian held the cheeks
☐2 Technician held the cheeks
☐3 Participant held his/her own cheeks
☐4 Other

8. Were nose clips used? **(1340)** ☐1 Yes ☐0 No

8a. If ***YES***, how effective were the nose clips? **(1350)**
☐1 The nose clips sealed the nostrils completely
☐2 The nose clips sealed the nostrils partially
☐3 The nose clips came off during the procedure
☐4 Other

8b. If ***NO***, was the nose occluded? **(1360)** ❑ 1 Yes ❑ 0 No

8bi. If ***YES***, how was the nose occluded? **(1370)**

❑ 1 Parent/guardian occluded the nose
❑ 2 Technician occluded the nose
❑ 3 Participant occluded the nose
❑ 4 Other

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

COMMENTS

(6000): _____

_____

_____

_____

_____

_____

_____

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.)

1. Who is completing the questionnaire? **(1000)**
   - ☐ 1 Participant
   - ☐ 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? **(1010)**
   - ☐ 0 Never
   - ☐ 1 Hardly ever
   - ☐ 2 A few times
   - ☐ 3 Several times
   - ☐ 4 Many times
   - ☐ 5 A great many times
   - ☐ 6 Unable to sleep because of asthma

3. On average, during the past week, how bad were your asthma symptoms when you woke up in the morning? **(1020)**
   - ☐ 0 No symptoms
   - ☐ 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? **(1030)**
   - ☐ 0 Not limited at all
   - ☐ 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? **(1040)**
   - ☐ 0 None
   - ☐ 1 A very little
   - ☐ 2 A little
   - ☐ 3 A moderate amount
   - ☐ 4 Quite a lot
   - ☐ 5 A great deal
   - ☐ 6 A very great deal

JUNIPER ASTHMA CONTROL QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

6. In general, during the past week, how much of the time did you wheeze? **(1050)**

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

7. On average, during the past week, how many puffs of short-acting bronchodilator (e.g., Ventolin) have you used each day? **(1060)**

- ☐ 0 None
- ☐ 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_PRE))? **(1070)** ☐ 1 Yes ☐ 0 No

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS LABORATORY TESTS

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

If your center does not perform a given procedure as noted in Questions #7, 10, and 11, skip the question. The following Questions should be completed as listed:

Visit 0: Question #1
Visit 1: Questions #1 - 7
Visit 2: Questions #1, #8 - 11
Visit 3: Question #1
Visit 4: Question #1
Visit 5: Questions #1, #2 - 3, #9 - 10
Visit 6: Question #1
Visit 7: Questions #9 - 10
Visit 99 (Trtmt Failure): Questions #9 - 10

URINE PREGNANCY TEST (Visits 0, 1, 2 - 6 and unscheduled pregnancy tests)

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

(1000) ❑1 Positive ❑0 Negative ❑9 N/A

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

➔ ***If pregnancy test results are positive, the participant must be terminated from study participation. Complete a Termination of Study Participation (P5_TERM) form and follow study termination procedures.***

CHEMISTRY PANEL (Visits 1 and 5)

2. SGPT/ALT **(1030)** ___ ___ ___ IU/L

3. SGOT/AST **(1040)** ___ ___ ___ IU/L

➔ ***If liver function values are elevated, the lab tests may be repeated at the discretion of the physician if a cause is known. If liver function values are elevated and cause is not known, the participant must be terminated from study participation. Complete a Termination of Study Participation (P5_TERM) form and follow study termination procedures.***

BLOOD TESTS (Visit 1)

4. Total WBC **(1060)** ___ ___ ___ ___ ___ /cu. mm

5. Eosinophils **(1070)** ___ ___ . ___ %

6. Was blood obtained for the serum save? **(1080)** ❑1 Yes ❑0 No

7. **(Denver and St. Louis sites only)**
Was blood obtained for superantigen analysis? **(1090)** ❑1 Yes ❑0 No

OTHER TESTS

8. **(Visit 2)**
Was a urine sample collected for cotinine measurement? **(1100)** ❑1 Yes ❑0 No

9. **(Visits 2, 5, 7, and after Treatment Failure (Visit 99))**
Was a nasal washing completed and a sample collected? **(1110)** ❑1 Yes ❑0 No

10. **(Visits 2, 5, 7, and after of Treatment Failure (Visit 99), St. Louis site only)**
Was a nasal swab collected for antibiotic resistance? **(1120)** ❑1 Yes ❑0 No

11. **(Visit 2, Denver and St. Louis sites only)**
Was a nasal swab collected for a superantigen culture? **(1130)** ❑1 Yes ❑0 No

COMMENTS (6000):_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS SCHEDULED MEDICATIONS

Subject ID: 0 5 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ __ __
Month Day Year
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

1. What type of visit is this?

(1000)
- ❑ 1 Scheduled visit
- ❑ 2 Unscheduled visit

2. What is the budesonide dose prescribed at this visit? (Remember to write/update the dose on the turbuhaler and the diary card.)

(1010)
- ❑ 1 200 mcg/day (1 puff/day)
- ❑ 2 400 mcg/day (1 puff BID)
- ❑ 3 600 mcg/day (1 puff AM, 2 puffs PM)
- ❑ 4 800 mcg/day (2 puffs BID)
- ❑ 5 1200 mcg/day (3 puffs BID)
- ❑ 6 1600 mcg/day (4 puffs BID)

MEDICATION LABEL - *Complete for randomized participants*

Affix the new drug label below:

Copy the drug label number below:

5 - __ __ __ **-** __ __ __
(1020) **(1030)** **(1040)**

Coordinator
(1050) Signature: _____

(1060) Date: __ __ / __ __ / __ __ __ __

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.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

BASELINE MEDICAL HISTORY

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

(Parent/Legal Guardian Interview or Participant Interview Completed)

PARENT/GUARDIAN IDENTIFICATION

1. What is your relationship to the child? (*Check one box only.*) **(1000)**
   - ❑ 1 Participant
   - ❑ 2 Mother
   - ❑ 3 Father
   - ❑ 4 Stepparent
   - ❑ 5 Grandparent
   - ❑ 6 Legal Guardian (but not parent)
   - ❑ 7 Other_____

ASTHMA AND ALLERGY HISTORY

ASTHMA HISTORY

2. How old was the participant when chest symptoms suggesting asthma first began? ___ ___ years **(1010)** ___ ___ months **(1020)**

3. Has a physician diagnosed the participant with asthma? **(1030)** ❑ 1 Yes ❑ 0 No

   3a. If ***YES***, how old was the participant when a doctor first said he or she had asthma? ___ ___ years **(1040)** ___ ___ months **(1050)**

ASTHMA TREATMENT

4. Has the participant ever been hospitalized overnight for asthma? **(1060)** ❑ 1 Yes ❑ 0 No

   ➔ ***If NO, skip to Question #5.***

   4a. During the past 12 months, how many times has the participant been hospitalized overnight for asthma? *(Enter '00' if none.*) **(1070)** ___ ___ times

   4b. Has the participant ever been admitted to an intensive care unit for asthma? **(1080)** ❑ 1 Yes ❑ 0 No

   ➔ ***If NO, skip to Question #5.***

   4bi. During the past 12 months, how many times has the participant been admitted to an intensive care unit for asthma? *(Enter '00' if none.*) **(1090)** ___ ___ times

5. During the past 12 months, how many: *(Enter '00' if none.*)

   5a. Times has the participant been seen in an emergency department for asthma? **(1100)** ___ ___ times

   5b. Times has the participant been seen at a doctor's office for worsening of asthma symptoms? **(1110)** ___ ___ times

   5c. Days of work or school did the participant miss because of asthma symptoms? *(Enter '999' if not applicable.)* **(1120)** ___ ___ ___ days

5d. Days of work did you or another caretaker miss because of the participant's asthma symptoms? *(Enter '999' if not applicable.)* **(1130)** ___ ___ ___ days

SENSITIVITIES
(Check only one response for each question below.)

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

ALLERGY HISTORY

18. Has the participant ever had hay fever? (i.e., itchy eyes, runny nose, or sneezing recurring **over several weeks in a particular season**) **(1260)** ❑ 1 Yes ❑ 0 No

➔ ***If NO, skip to Question #19.***

18a. At what age did the participant FIRST have hay fever? ___ ___ years **(1270)** ___ ___ months **(1280)**

18b. Has the participant ever seen a doctor or other health practitioner because of hay fever? **(1290)** ❑ 1 Yes ❑ 0 No

18c. During the past 12 months, how would you generally describe the participant's hay fever? **(1300)** ❑1 None ❑2 Mild ❑3 Moderate ❑4 Severe

19. Has the participant ever had atopic dermatitis (eczema)? **(1310)** ❑1 Yes ❑0 No
➔ ***If NO, skip to Question #20.***

19a. At what age did the participant FIRST have atopic dermatitis (eczema)? ___ ___ years **(1320)** ___ ___ months **(1330)**

19b. Has the participant ever seen a doctor or other health practitioner because of atopic dermatitis (eczema)? **(1340)** ❑1 Yes ❑0 No

19c. During the past 12 months, how would you generally describe the participant's atopic dermatitis (eczema)? **(1350)** ❑1 None ❑2 Mild ❑3 Moderate ❑4 Severe

➔ ***If NONE, skip to Question #20.***

19d. Which parts of the participant's body were ever affected by eczema in the past 12 months?

19di. Head **(1360)** ❑1 Yes ❑0 No

19dii. Arms/Hands **(1370)** ❑1 Yes ❑0 No

19diii. Trunk (mid-section or torso) **(1380)** ❑1 Yes ❑0 No

19div. Legs/Feet **(1390)** ❑1 Yes ❑0 No

19dv. Other_____ **(1400)** ❑1 Yes ❑0 No

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

20a. Medicines **(1410)** ❑1 Yes ❑0 No
If ***YES***, please list:_____
_____

20b. Foods **(1420)** ❑1 Yes ❑0 No
If ***YES***, please list:_____
_____

20c. Things you breathe in or inhale (e.g., dust, pollens, molds, animal fur, or dander) **(1430)** ❑1 Yes ❑0 No

20d. Stinging insects such as bees or wasps **(1440)** ❑1 Yes ❑0 No

21. Do you have any concerns about allergies that doctors have not yet diagnosed? If yes, explain:_____
_____
_____
(Do not data enter Question #21)

MEDICAL AND FAMILY HISTORY
NOSE/EYE/SINUS SYMPTOMS

22. During the past 12 months, how would you describe any symptoms that have affected the participant's nose, eyes, or sinuses? **(1450)**
➔ ***If NONE, skip to Question #29.***
❑ 1 None
❑ 2 Mild
❑ 3 Moderate
❑ 4 Severe

23. During the past 12 months, how many months did the participant use antihistamines and/or decongestants to treat nose, eye, and sinus symptoms (prescription or over the counter)? *(Enter '00' if none.)* **(1460)** ___ ___ months

24. During the past 12 months, how many months did the participant use a steroid nasal spray [beclomethasone (Beconase, Vancenase), budesonide (Rhinocort), flunisolide (Nasalide, Nasarel), fluticasone (Flonase), mometasone (Nasonex), triamcinolone (Nasacort, Tri-Nasal)] to treat nose, eye, or sinus symptoms? *(Enter '00' if none.)* **(1470)** ___ ___ months

25. During the past 12 months, how many times have you contacted or visited a doctor because of problems with the participant's nose, eyes, or sinuses? *(Enter '00' if none.)* **(1480)** ___ ___ times

26. During the past 12 months, how many times has the participant had a sinus infection that required treatment with antibiotics? *(Enter '00' if none.)* **(1490)** ___ ___ times

27. During the past 12 months, how many times has the participant had a sinus infection that required treatment with steroids by mouth or by injection (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol)? *(Enter '00' if none.)* **(1500)** ___ ___ times

28. During the past 12 months, how many times has the participant had pneumonia? **(1510)** ___ ___ times

29. Has the participant ever had sinus surgery for sinusitis or polyps? **(1520)** ❑ 1 Yes ❑ 0 No

FAMILY HISTORY

30. Has a doctor ever said that the [BIOLOGICAL] father of the participant had:

30a. Asthma?	**(1530)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
30b. Hay fever, eczema, or other atopic disorder?	**(1540)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
30c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?	**(1550)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know

31. Has a doctor ever said that the [BIOLOGICAL] mother of the participant had:

31a. Asthma?	**(1560)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
31b. Hay fever, eczema, or other atopic disorder?	**(1570)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
31c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?	**(1580)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know

32. Does the participant have any [BIOLOGICAL] siblings? (Include half siblings) **(1590)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

➔ ***If NO or DON'T KNOW, skip to Question #34.***

33. Has a doctor ever said that any [BIOLOGICAL] sibling of the participant had:

33a. Asthma?	**(1600)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
33b. Hay fever, eczema, or other atopic disorder?	**(1610)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
33c. Chronic bronchitis, emphysema, chronic obstructive lung disease, or cystic fibrosis?	**(1620)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know

PASSIVE SMOKING EXPOSURE

34. Did the participant's mother smoke while she was pregnant with the participant? **(1630)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

➔ ***If NO or DON'T KNOW, skip to Question #36.***

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

35a. First 3 months	**(1640)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
35b. Middle 3 months	**(1650)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know
35c. Last 3 months	**(1660)**	❑ 1 Yes	❑ 0 No	❑ 9 Don't know

36. Between the time the participant was born and he/she turned 5 years of age:

36a. Did the participant's mother (or stepmother or female guardian) smoke? **(1670)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

36b. Did the participant's father (or stepfather or male guardian) smoke? **(1680)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

36c. Were there any other smokers in the household? *(Include visitors, such as grandparents or baby-sitters, who visited at least once weekly.)* **(1690)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

37. At the present time:

➔ ***If the participant is under 5 years of age, do not complete Question #37a - #37c***

37a. Does the participant's mother (or stepmother or female guardian) smoke? **(1700)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

37b. Does the participant's father (or stepfather or male guardian) smoke? **(1710)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

37c. Are there any other smokers in the household? *(Include visitors, such as grandparents or baby-sitters, who visited at least once weekly.)* **(1720)** ❑ 1 Yes ❑ 0 No ❑ 9 Don't know

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

Complete Methacholine Challenge Testing only if the participant is eligible according to the Pulmonary Procedure Checklist (PFT_CHK) form and the Methacholine Challenge Checklist (METHA_CHK) form.

METHACHOLINE CHALLENGE TEST

1. Was baseline (pre-diluent) spirometry completed? **(1000)** ❑$_1$ Yes ❑$_0$ No

Clinic Use Only

Use the pre-bronchodilator FEV_1 from the SPIRO_PRE 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**

2. Earliest expiration date of all 10 methacholine solutions **(1010)** ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

3. FEV_1 and FVC for serial challenges (leave concentrations not administered blank)

		FEV_1	FVC
3a.	Solution 0 (diluent)	**(1020)** ___ . ___ ___ L	**(1030)** ___ . ___ ___ L
	3ai. Solution 0 (diluent 2)	**(1040)** ___ . ___ ___ L	**(1050)** ___ . ___ ___ L

➔ **If Solution 0 causes a ≥ 20% drop from the baseline (pre-diluent) FEV_1 value, proceed to Question #4 answer it 'Yes,' and record the PC_{20} as zero.**

3b.	Solution 1 (0.098 mg/ml)	**(1060)** ___ . ___ ___ L	**(1070)** ___ . ___ ___ L
3c.	Solution 2 (0.195 mg/ml)	**(1080)** ___ . ___ ___ L	**(1090)** ___ . ___ ___ L
3d.	Solution 3 (0.391 mg/ml)	**(1100)** ___ . ___ ___ L	**(1110)** ___ . ___ ___ L
3e.	Solution 4 (0.781 mg/ml)	**(1120)** ___ . ___ ___ L	**(1130)** ___ . ___ ___ L
3f.	Solution 5 (1.563 mg/ml)	**(1140)** ___ . ___ ___ L	**(1150)** ___ . ___ ___ L
3g.	Solution 6 (3.125 mg/ml)	**(1160)** ___ . ___ ___ L	**(1170)** ___ . ___ ___ L
3h.	Solution 7 (6.25 mg/ml)	**(1180)** ___ . ___ ___ L	**(1190)** ___ . ___ ___ L
3i.	Solution 8 (12.5 mg/ml)	**(1200)** ___ . ___ ___ L	**(1210)** ___ . ___ ___ L
3j.	Solution 9 (25 mg/ml)	**(1220)** ___ . ___ ___ L	**(1230)** ___ . ___ ___ L

4. Did the participant drop ≥ 20% of the *post-diluent (Solution 0) FEV_1* value? (If the participant dropped after administration of Solution 1, contact the Scientific Coordinator at the DCC (717-531-1090) for PC_{20} calculation.) **(1240)** ❑$_1$ Yes ❑$_0$ No

   4a. If ***YES***, record PC_{20} **(1250)** ___ ___ . ___ ___ ___

   4b. If ***NO***, was the methacholine challenge stopped for safety reasons? **(1260)** ❑$_1$ Yes ❑$_0$ No

   ➔ If ***YES*** to Question #4b, proceed to Question #6.

5. Time methacholine challenge was completed (*based on 24-hour clock*) **(1270)** ___ ___ ___ ___

6. Time albuterol administered (*based on 24-hour clock*) **(1280)** ___ ___ ___ ___
   (All participants must receive the standard reversal.)

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

   7a. FEV_1 **(1300)** ___ . ___ ___ L

   7b. Time of FEV_1 in Question #7a *(based on 24-hour clock)* **(1310)** ___ ___ ___ ___

   7c. Was the FEV_1 from Question #7a ≥ the Methacholine Reversal Reference Value in the gray box on page 1 of this form? **(1320)** ❑$_1$ Yes ❑$_0$ No

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

   ➔ ***If NO, call physician for recommendations, and proceed to the Additional Treatment for Methacholine Challenge Testing (METHA_ADD_TRT) form.***

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

ADDITIONAL TREATMENT FOR METHACHOLINE CHALLENGE TESTING

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

(Technician Completed) Supervisor ID: ___ ___ ___ ___ ___

1. Was additional treatment used in the first hour? **(1000)** ❑1 Yes ❑0 No

➔ ***If NO, proceed to Question #3.***

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

1a. Additional albuterol by MDI **(1010)** ❑1 Yes ❑0 No
➔ ***If NO, proceed to Question #1b.***

1ai. Number of additional puffs of albuterol administered **(1020)** ❑1 two ❑2 four ❑3 > four

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

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

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

1e. Other (specify) _____ **(1060)** ❑1 Yes ❑0 No

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

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

2b. Time of FEV_1 in Question #2a *(based on a 24-hour clock)* **(1080)** ___ ___ ___ ___

2c. Was the FEV_1 from Question #2a $\geq$ the Methacholine Reversal Reference Value in the gray box on the Methacholine Challenge Testing (METHA) form? **(1090)** ❑1 Yes ❑0 No

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

➔ ***If NO, proceed to Question #3.***

3. Was additional treatment used after one hour? **(1100)** ❑1 Yes ❑0 No

➔ ***If NO, proceed to Question #4.***

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

3a. Additional albuterol by MDI **(1110)** ❑1 Yes ❑0 No
➔ ***If NO, proceed to Question #3b.***

3ai. Number of additional puffs of albuterol administered **(1120)** ❑1 two ❑2 four ❑3 > four

3b. Nebulized beta-agonist **(1130)** ❑1 Yes ❑0 No

3c. Subcutaneous epinephrine **(1140)** ❑1 Yes ❑0 No

3d. Implementation of clinic emergency protocol or algorithm **(1150)** ❑1 Yes ❑0 No

3e. Treatment in the emergency room **(1160)** ❑1 Yes ❑0 No

ADDITIONAL TREATMENT FOR METHACHOLINE CHALLENGE TESTING

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

3f. Overnight hospitalization **(1170)** ❑$_1$ Yes ❑$_0$ No

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

3g. Other (specify) _____ **(1180)** ❑$_1$ Yes ❑$_0$ No

4. Participant's final FEV_1 after additional treatment

4a. FEV_1 **(1190)** ___ . ___ ___ L

4b. Time of FEV_1 in Question #4a *(based on a 24-hour clock)* **(1200)** ___ ___ ___ ___

4c. Was the FEV_1 from Question #4a $\geq$ the Methacholine Reversal Reference Value in the gray box on the Methacholine Challenge Testing (METHA) form? **(1210)** ❑$_1$ Yes ❑$_0$ No

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

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

Physician Source Documentation

(1310) Physician/CC Signature: _____

(1320) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

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

(Clinic Coordinator/Parent/Guardian/Participant Interview Completed)

Complete this form only if the participant is eligible according to the Pulmonary Procedure Checklist (PFT_CHK) form.

EXCLUSIONS AND CONFOUNDERS

1. During the past 4 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1000)** ☐1 Yes ☐0 No

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

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

   3a. If ***YES***, has the participant received permission from the supervising physician to proceed with the methacholine challenge testing? **(1030)** ☐1 Yes ☐0 No

   Name of physician _____

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

5. Has the participant used any asthma medication other than study medication(s) in the past month? **(1050)** ☐1 Yes ☐0 No

   5a. If ***YES***, indicate which classes and date of last use. *(Check all that apply.)*

Class	Date Last Used
(1060) ☐1 Inhaled Corticosteroid	**(1070)** ___ ___ / ___ ___ / ___ ___ ___ ___
(1080) ☐1 Cromolyn/nedocromil	**(1090)** ___ ___ / ___ ___ / ___ ___ ___ ___
(1100) ☐1 Leukotriene receptor antagonists	**(1110)** ___ ___ / ___ ___ / ___ ___ ___ ___
(1120) ☐1 Long-acting beta-agonist	**(1130)** ___ ___ / ___ ___ / ___ ___ ___ ___

6. Does the participant have a baseline (pre-diluent) FEV_1 less than 70% of predicted FEV_1? **(1140)** ☐1 Yes ☐0 No

7. Pregnancy test results *(Check N/A if the participant is male, or is female and has not started menses.)* **(1150)** ☐1 Positive ☐0 Negative ☐9 N/A

METHACHOLINE CHALLENGE TESTING CHECKLIST

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

8. Is there any other reason you should not proceed with the methacholine challenge? **(1160)** ☐ 1 Yes ☐ 0 No

   If ***YES***, explain _____

9. Is the participant eligible to proceed with the diluent (Solution #0) pulmonary function testing for the Methacholine Challenge? **(1170)** ☐ 1 Yes ☐ 0 No

   If any of the shaded boxes are filled in, the participant is NOT eligible for Methacholine Challenge Testing.

   ➔ ***If NO, STOP HERE.***
   If possible, the baseline pulmonary function testing and Methacholine Challenge should be rescheduled within the visit window.

10. Was the Methacholine Challenge started? **(1180)** ☐ 1 Yes ☐ 0 No

    10a. If ***NO***, indicate the primary reason **(1190)**
    ☐ 1 Participant/Parent refused
    ☐ 2 Equipment failure
    ☐ 3 Other _____

Proceed to the Methacholine Challenge (METHA) form.

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA CAREGIVER'S QUALITY OF LIFE QUESTIONNAIRE

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

(Guardian Completed)

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

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

DURING THE PAST WEEK, **HOW OFTEN:**		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
2. Did you feel helpless or frightened when your child experienced cough, wheeze, or breathlessness?	**(1010)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
3. Did your family need to change plans because of your child's asthma?	**(1020)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
4. Did you feel frustrated or impatient because your child was irritable due to asthma?	**(1030)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
5. Did your child's asthma interfere with your job or work around the house?	**(1040)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
6. Did you feel upset because of your child's cough, wheeze, or breathlessness?	**(1050)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
7. Did you have sleepless nights because of your child's asthma?	**(1060)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
8. Were you bothered because your child's asthma interfered with family relationships?	**(1070)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
9. Were you awakened during the night because of your child's asthma?	**(1080)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA CAREGIVER'S QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
10. Did you feel angry that your child has asthma?	**(1090)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

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

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

Clinic Coordinator Completed

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

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

(Participant completed)

Please complete **all** questions by checking the box under the response that best describes how you have been during the **past week as a result of your asthma**.

HOW **BOTHERED** HAVE YOU BEEN DURING THE LAST WEEK DOING:

			Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
1.	PHYSICAL ACTIVITIES (such as running, swimming, sports, walking uphill/upstairs and bicycling)?	**(1000)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
2.	BEING WITH ANIMALS (such as playing with pets and looking after animals)?	**(1010)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
3.	ACTIVITIES WITH FAMILY AND FRIENDS (such as playing at recess and doing things with your friends and family)?	**(1020)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
4.	COUGHING	**(1030)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

			All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
5.	Feel FRUSTRATED because of your asthma?	**(1040)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
6.	Feel TIRED because of your asthma?	**(1050)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7
7.	Feel WORRIED, CONCERNED OR TROUBLED because of your asthma?	**(1060)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

HOW **BOTHERED** HAVE YOU BEEN DURING THE LAST WEEK BY:

		Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
8. ASTHMA ATTACKS?	**(1070)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
9. Feel **ANGRY** because of your asthma?	**(1080)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

HOW **BOTHERED** HAVE YOU BEEN DURING THE LAST WEEK BY:

		Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
10. WHEEZING?	**(109**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
11. Feel **IRRITABLE** (cranky, grouchy) because of your asthma?	**(11**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

HOW **BOTHERED** HAVE YOU BEEN DURING THE LAST WEEK BY:

		Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
12. TIGHTNESS IN YOUR CHEST?	**(1110)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

	All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
13. Feel DIFFERENT OR LEFT OUT because of your asthma? **(1120)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

HOW **BOTHERED** HAVE YOU BEEN DURING THE LAST WEEK BY:

	Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
14. SHORTNESS OF BREATH? **(1130)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

	All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
15. Feel FRUSTRATED BECAUSE YOU COULDN'T KEEP UP WITH OTHERS? **(1140)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7
16. WAKE UP DURING THE NIGHT because of your asthma? **(1150)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7
17. Feel UNCOMFORTABLE because of your asthma? **(1160)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7
18. Feel OUT OF BREATH because of your asthma? **(1170)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7
19. Feel YOU COULDN'T KEEP UP WITH OTHERS because of your asthma? **(1180)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
20. Have trouble SLEEPING AT NIGHT because of asthma?	**(1190)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7
21. Feel FRIGHTENED BY AN ASTHMA ATTACK?	**(1200)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

THINK ABOUT ALL THE ACTIVITIES THAT YOU DID IN THE PAST WEEK:

		Extremely Bothered	Very Bothered	Quite Bothered	Somewhat Bothered	Bothered A Bit	Hardly Bothered At All	Not Bothered
22. How much were you bothered by your asthma during these activities?	**(1210)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

IN GENERAL, **HOW OFTEN** DURING THE LAST WEEK DID YOU:

		All of the Time	Most of the Time	Quite Often	Some of the Time	Once in a While	Hardly Any of the Time	None of the Time
23. Have difficulty taking a DEEP BREATH?	**(1220)**	❑1	❑2	❑3	❑4	❑5	❑6	❑7

Clinic Coordinator Completed

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS PEAK FLOW REFERENCE VALUE DETERMINATION

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Determining Peak Flow Reference Value

At Visit 0, skip to Question #10

1. Reference Value determined at previous visit **(1000)** ___ ___ ___ l/min

   Pool of Values - Reference Value 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. Exclude PEFR values obtained within 2 weeks of prednisone use.

   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. Highest Peak Flow from Pool **(1010)** ___ ___ ___ l/min

3. 2nd highest Peak Flow from Pool **(1020)** ___ ___ ___ l/min

4. 3rd highest Peak Flow from Pool **(1030)** ___ ___ ___ l/min

5. Is the highest Peak Flow from the Pool (Question #2) equal to the participant's Reference Value from the last visit (Question #1)? **(1040)** ❑1 Yes ❑0 No

   ➔ ***If YES, skip to Question #10. The Reference Value is Question #1.***

6. *Question #3* / *Question #2* **(1050)** ___ . ___ ___

7. Is Question #6 greater than 0.9? **(1060)** ❑1 Yes ❑0 No

   ➔ ***If YES, skip to Question #10. The Reference Value is Question #2.***

8. *Question #4* / *Question #3* **(1070)** ___ . ___ ___

9. Is Question #8 greater than 0.9? **(1080)** ❑1 Yes ❑0 No

   ➔ ***If YES, the Reference Value is Question #3.***

   ➔ ***If NO, the Reference Value is Question #1.***

10. Reference Value **(1090)** ___ ___ ___ l/min

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PULMONARY PROCEDURE CHECKLIST

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

(Clinic Coordinator/Parent/Guardian/Participant Interview Completed)

CONFOUNDERS

1. During the past 48 hours, has the participant used any oral decongestants or cold remedies? **(1000)** ❑1 Yes ❑0 No

2. During the past 4 hours, has the participant consumed caffeine? **(1010)** ❑1 Yes ❑0 No
   Examples: *Caffeinated colas (Pepsi, Coke), Coffee, Mello-Yello Mountain Dew, Tea, Barq's Rootbeer*

3. During the past 8 hours, has the participant used medications with caffeine? **(1020)** ❑1 Yes ❑0 No
   Examples: *Anacin, Darvon compound, Esgic, Exedrin Fiorinal, Fioricet, No Doz, Norgestic, Vivarin*

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

5. During the past 24 hours, has the participant taken the study medication? **(1040)** ❑1 Yes ❑0 No ❑9 N/A

   5a. If ***YES***, indicate the delivery device and number of hours since the last dose.

Delivery Device	Hours Since Last Dose
(1050) ❑1 Tablet/Capsule	**(1055)** ___ ___ Hours
(1060) ❑1 Diskus	**(1065)** ___ ___ Hours
(1070) ❑1 MDI	**(1075)** ___ ___ Hours
(1080) ❑1 Nebulizer	**(1085)** ___ ___ Hours
(1090) ❑1 Other	**(1095)** ___ ___ Hours

EXCLUSIONS

6. During the past 24 hours, has the participant used sustained-release theophylline (i.e., Slo-bid, Theo-dur, Slo-Phyllin)? **(1100)** ❑1 Yes ❑0 No

7. During the past 12 hours, has the participant used a long-acting bronchodilator (i.e., salmeterol, Serevent, formoterol, Foradil, Advair)? **(1110)** ❑1 Yes ❑0 No

8. During the past 4 hours, has the participant used a short-acting bronchodilator (i.e., epinephrine, Primatene Mist, Bronkaid Mist, Duo-Medihaler, Medihaler Epi, albuterol, perbuterol)? **(1120)** ❑1 Yes ❑0 No

9. Is there any other reason the participant should not proceed with pulmonary function testing? **(1130)** ❑1 Yes ❑0 No

   If ***YES***, explain _____

PULMONARY PROCEDURE CHECKLIST

Subject ID: ___ ___ - ___ - ___ ___ ___
Visit Number: ___ ___

10. Is the participant eligible to proceed with pulmonary function testing? **(1140)** ☐1 Yes ☐0 No

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.

11. Standing height *(barefoot or thin socks):* **(1150)** ___ ___ ___ . ___ cm

For Questions #12a - #12h, if the procedure is not performed at this visit, check N/A.

12. Was the procedure performed?

➔***If NO, indicate the primary reason***

12a. Exhaled Nitric Oxide Testing **(1160)** ☐1 Yes ☐0 No ☐9 N/A

12ai. If ***NO***, indicate the reason **(1170)** ☐1 Participant/Parent refused
☐2 Equipment failure
☐9 Other _____

12b. Pre-Bronchodilator IOS Testing **(1200)** ☐1 Yes ☐0 No ☐9 N/A

12bi. If ***NO***, indicate the reason **(1210)** ☐1 Participant/Parent refused
☐2 Equipment failure
☐9 Other _____

12c. Post-Bronchodilator IOS Testing **(1220)** ☐1 Yes ☐0 No ☐9 N/A

12ci. If ***NO***, indicate the reason **(1230)** ☐1 Participant/Parent refused
☐2 Equipment failure
☐3 Pre-Bronchodilator IOS not performed
☐9 Other _____

12d. Pre-Bronchodilator Spirometry **(1240)** ☐1 Yes ☐0 No ☐9 N/A

12di. If ***NO***, indicate the reason **(1250)** ☐1 Participant/Parent refused
☐2 Equipment failure
☐9 Other _____

12e. Post-Bronchodilator Spirometry **(1260)** ❑1 Yes ❑0 No ❑9 N/A

12ei. If ***NO***, indicate the reason **(1270)**
- ❑1 Participant/Parent refused
- ❑2 Equipment failure
- ❑3 Pre-Bronchodilator Spirometry not performed
- ❑9 Other _____

12f. Maximal Bronchodilator Testing **(1280)** ❑1 Yes ❑0 No ❑9 N/A

12fi. If ***NO***, indicate the reason **(1290)**
- ❑1 Participant/Parent refused
- ❑2 Equipment failure
- ❑3 Baseline Spirometry not performed
- ❑9 Other _____

12g. Methacholine Challenge Testing **(1300)** ❑1 Yes ❑0 No ❑9 N/A

12gi. If ***NO***, indicate the reason **(1310)**
- ❑1 Participant/Parent refused
- ❑2 Equipment failure
- ❑3 Baseline Spirometry not performed
- ❑9 Other _____

If eNO is performed at this visit, please complete the ENO_CHK form.
If Methacholine Challenge Testing is performed at this visit, please complete the METHA_CHK form.

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PHYSICAL EXAMINATION

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

(Clinic Coordinator Completed)

MEASUREMENTS

1. Time measurements started *(based on a 24-hour clock)* **(1000)** ___ ___ ___ ___

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

   2a. First measurement **(1010)** ___ ___ ___ . ___ cm

   2b. Second measurement **(1020)** ___ ___ ___ . ___ cm

   2c. Third measurement **(1030)** ___ ___ ___ . ___ cm

   2d. Average height measurement **(1040)** ___ ___ ___ . ___ cm

   ➔ ***If required, plot average height on gender- and age-appropriate growth charts. See study MOP for further details.***

   2e. In your judgement, was the participant's height measurement acceptable? **(1050)** ❑1 Yes ❑0 No

   2ei. If ***NO***, why was it unacceptable?_____

   _____

3. Weight *(shoes off, light clothing)* **(1060)** ___ ___ ___ . ___ kg

PULMONARY AUSCULTATION

4. Is chest auscultation clear? **(1070)** ❑1 Yes ❑0 No

   ➔ ***If YES, skip to Question #5.***

   4a. Slight expiratory wheeze **(1080)** ❑1 Yes ❑0 No

   4b. Loud expiratory wheeze **(1090)** ❑1 Yes ❑0 No

   4c. Inspiratory and expiratory wheeze **(1100)** ❑1 Yes ❑0 No

   4d. Rales **(1110)** ❑1 Yes ❑0 No

   4e. Rhonchi **(1120)** ❑1 Yes ❑0 No

   4f. Crackles **(1130)** ❑1 Yes ❑0 No

   4g. Other_____ **(1140)** ❑1 Yes ❑0 No

5. Does the participant have evidence of oral candidiasis? **(1150)** ❑$_1$ Yes ❑$_0$ No

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

NOSE/EYE/SINUS SYMPTOMS

6. In general, how would you describe the participant's nasal symptoms? **(1160)**
   - ❑$_1$ None
   - ❑$_2$ Mild
   - ❑$_3$ Moderate
   - ❑$_4$ Severe

ECZEMA SYMPTOMS

7. In general, how would you describe the participant's eczema? **(1170)**
   - ❑$_1$ None
   - ❑$_2$ Mild
   - ❑$_3$ Moderate
   - ❑$_4$ Severe

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PRIOR ASTHMA MEDICATION HISTORY

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

(Clinic Coordinator completed)

1. Who is the respondent? **(1000)**
   - ❑ 1 Participant
   - ❑ 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, pirbuterol (Maxair), levalbuterol (Xopenex)]? **(1010)** ❑ 1 Yes ❑ 0 No
   ➔ ***If NO, please STOP HERE.***

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) **(1020)** ___ ___ months

   3b. Inhaled or nebulized corticosteroids [beclomethasone (Beclovent, Vanceril, QVAR), budesonide (Pulmicort), flunisolide (Aerobid), fluticasone (Flovent), triamcinolone (Azmacort), ciclesonide (Alvesco), mometasone (Asmanex)] **(1030)** ___ ___ months

   3c. Leukotriene Modifiers [montelukast (Singulair), zafirlukast (Accolate)] **(1040)** ___ ___ months

   3d. Theophylline (Slo-bid, Theo-dur, Slo-Phyllin) **(1050)** ___ ___ months

   3e. Advair/Symbicort **(1060)** ___ ___ months

   3f. Cromolyn/Nedocromil (Intal, Tilade) **(1070)** ___ ___ months

   3g. Other:_____ **(1080)** ___ ___ months

   3h. Other:_____ **(1090)** ___ ___ months

4. In the ***past 12 months***, how many courses of steroids by mouth or injection (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol) has the participant taken for asthma?

(1100)
- ❑ 0 0 courses
- ❑ 1 1 course
- ❑ 2 2 courses
- ❑ 3 3 courses
- ❑ 4 4 courses
- ❑ 5 5 courses
- ❑ 6 More than 5 courses

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

CARE REGISTRY

Participant's Last Name: _____
Participant's First Name: _____
Participant's Initials: ___ ___ ___
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator/Parent/Guardian/Participant Interview Completed)

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

ADMINISTRATIVE

1. Did the parent/legal guardian sign and date a CARE Protocol Informed Consent and HIPAA Authorization form? **(1000)** ❑1 Yes ❑0 No

   ➔ ***If NO, STOP HERE.*** Data cannot be entered into the CARE Registry.

   1a. If ***YES***, record the signature date. **(1010)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

2. Is participant assent required for the protocol in Question #1? **(1015)** ❑1 Yes ❑0 No

   2a. If ***YES,*** did the participant sign and date a CARE Protocol Informed Assent and HIPAA Authorization form, or if the participant is less than 7 years old, has the participant given verbal assent? **(1020)** ❑1 Yes ❑0 No

   ➔ ***If NO, STOP HERE.*** Data cannot be entered into the CARE Registry.

   2ai. If ***YES***, record the date assent was given. **(1030)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

DEMOGRAPHICS

3. Participant's date of birth **(1040)** ___ ___ / ___ ___ / ___ ___ ___ ___
   (Ask the participant his/her date of birth.) *Month Day Year*

4. Participant's gender **(1050)** ❑1 Male ❑2 Female

5. Participant's ethnic background **(1060)** ❑1 Hispanic or Latino ❑2 Not Hispanic or Latino
   (Check one box only.)

6. Participant's racial background
   (Check at least one 'Yes.')

   6a. American Indian or Alaskan Native **(1070)** ❑1 Yes ❑0 No

   6b. Asian **(1080)** ❑1 Yes ❑0 No

   6c. Black or African American **(1090)** ❑1 Yes ❑0 No

   6d. White **(1100)** ❑1 Yes ❑0 No

   6e. Native Hawaiian or Other Pacific Islander **(1110)** ❑1 Yes ❑0 No

7. Participant's primary racial identification (This identification will be used in spirometry testing. Ask the parent/guardian or participant which category best describes him or her, and check only one box.) **(1120)**

- ❑ 1 Black or African American
- ❑ 2 White
- ❑ 3 Hispanic
- ❑ 4 Other

Registry Form Storage Instructions:

Upon printing the participant's Registry Report, print the participant's name on the report. Registry Reports should be stored alphabetically by Participant's last name in the CARE Registry binder.

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

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

S5 SINUS SYMPTOM SCORE

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

(Parent/Legal Guardian completed)

For the following questions, please choose the one answer that best describes how much each problem has bothered the child during the last few days.

			not present	small problem	medium problem	large problem	don't know
1.	Blocked up or stuffy nose	**(1000)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 9
2.	Headaches or face pain	**(1010)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 9
3.	Coughing during the day	**(1020)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 9
4.	Coughing at night	**(1030)**	❑ 1	❑ 2	❑ 3	❑ 4	❑ 9

5. During the last few days, what has been the color of the mucus from your child's nose? **(1040)**

❑ 1 None
❑ 2 Clear
❑ 3 Yellow
❑ 4 Green
❑ 9 Don't know

Clinic Coordinator Completed

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

SERIOUS ADVERSE EVENT REPORTING FORM

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

(Clinic 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 Form (AECLIN), Concomitant Medications Form (CMED_AS), and any relevant source documents.

1. Date of Adverse Event **(1000)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

2. Description of Adverse Event (ICD9 Code) **(1010)** ___ ___ ___ . ___ ___
   Describe: _____

3. Is the participant currently taking study drug? **(1020)** ❑1 Yes ❑0 No
   ➔ ***If NO, proceed to Question #6.***

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

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

6. Why was the event serious?

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

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

   6c. Inpatient hospitalization required **(1070)** ❑1 Yes ❑0 No
   ➔ ***If NO, proceed to Question #6d.***

   6ci. Admission date **(1080)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

   6cii. Discharge date **(1090)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

   6d. Disabling or incapacitating **(1100)** ❑1 Yes ❑0 No

   6e. Overdose **(1110)** ❑1 Yes ❑0 No

   6f. Cancer **(1120)** ❑1 Yes ❑0 No

   6g. Congenital anomaly **(1130)** ❑1 Yes ❑0 No

   6h. Serious laboratory abnormality with clinical symptoms **(1140)** ❑1 Yes ❑0 No

   6i. Height failure **(1150)** ❑1 Yes ❑0 No

   6j. Pregnancy **(1160)** ❑1 Yes ❑0 No ❑9 N/A

   6k. Other _____ **(1170)** ❑1 Yes ❑0 No

7. What in your opinion, caused the event?

7a.	Toxicity of study drug(s)	**(1180)**	❑ 1 Yes	❑ 0 No
7b.	Withdraw of study drug(s)	**(1190)**	❑ 1 Yes	❑ 0 No
7c.	Concurrent medication	**(1200)**	❑ 1 Yes	❑ 0 No
	If ***YES***, describe _____			
7d.	Other condition or event	**(1210)**	❑ 1 Yes	❑ 0 No
	If ***YES***, describe _____			

DO NOT ENTER QUESTIONS #8 - #11: FOR REPORTING PURPOSES ONLY.

8. If participant died, cause of death:_____
_____

9. Was an autopsy performed? ❑ 1 Yes ❑ 0 No
If YES, attach report or send as soon as possible.

REPORTING INVESTIGATOR:

10. Name: _____
Address: _____
_____
_____
Signature:_____
Date: ___ ___ / ___ ___ / ___ ___ ___ ___

11. 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.

COMMENTS

(6000):_____
_____
_____

Childhood Asthma Research & Education
NIH/NHLBI

ALLERGY SKIN TEST RESULTS

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

(Clinic Coordinator Completed)

1. Has the participant had a previous skin test using CARE procedures within the approved time limit? **(1000)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***(Protocol-specific time limits for reusing the SKIN form can be found in the Manual of Operations for each protocol.)***

   ➔ ***If NO, proceed to Question #2.***

   1a. Date of previous skin test **(1010)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

   1a. ID of coordinator who performed the skin test **(1020)** ___ ___ ___ ___ ___

2. Has the participant used any of the medications, listed in the skin test section of the CARE MOP within the exclusionary periods? **(1030)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If YES, STOP HERE, reschedule the skin testing procedure.***

3. Has the participant ever had a severe systemic reaction to allergy skin testing? **(1040)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If YES, STOP HERE. Complete CAP/FEIA tests for all allergens and record the results on the CAP/FEIA form.***

4. Has the participant ever had an anaphylactic reaction to egg? **(1050)** ❑$_1$ Yes ❑$_0$ No

5. Has the participant ever had an anaphylactic reaction to peanut? **(1060)** ❑$_1$ Yes ❑$_0$ No

6. Has the participant ever had an anaphylactic reaction to milk? **(1070)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***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.***

7. Time test sites **pricked** (*based on a 24-hour clock*) **(1080)** ___ ___ ___ ___

8. Time test sites **evaluated** (*based on a 24-hour clock*) **(1090)** ___ ___ ___ ___

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

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Visit Number: ___ ___

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.

9. $\frac{(\text{Histamine: Largest Wheal}) + (\text{Histamine: Perpendicular Wheal})}{2}$ = **(1100)** ___ ___ ___ . ___ mm

9a. Is Question #9 < 3mm? **(1110)** ❑1 Yes ❑0 No

➔ ***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.***

10. $\frac{(\text{Saline: Largest Wheal}) + (\text{Saline: Perpendicular Wheal})}{2}$ = **(1120)** ___ ___ ___ . ___ mm

10a. Question #9 - Question #10 = **(1130)** ___ ___ ___ . ___ mm

10b. Is Question #10a < 3 mm? **(1140)** ❑1 Yes ❑0 No

➔ ***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.***

11. Question #10 + 3 mm = **(1150)** ___ ___ ___ . ___ mm

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 ≥ Question #11.

COMMENTS

(6000):_____

_____

_____

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Visit Number: ___ ___

1. Histamine (A1)	Was there a reaction? **(1160)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1170)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1180)** ___ ___ ___ mm	2. Mite Mix (A2)	Was there a reaction? **(1190)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1200)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1210)** ___ ___ ___ mm
3. Roach Mix (A3)	Was there a reaction? **(1220)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1230)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1240)** ___ ___ ___ mm	4. Cat (A4)	Was there a reaction? **(1250)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1260)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1270)** ___ ___ ___ mm
5. Dog (A5)	Was there a reaction? **(1280)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1290)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1300)** ___ ___ ___ mm	6. Mold Mix (A6)	Was there a reaction? **(1310)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1320)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1330)** ___ ___ ___ mm
7. Grass Mix (A7)	Was there a reaction? **(1340)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1350)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1360)** ___ ___ ___ mm	8. Saline (A8)	Was there a reaction? **(1370)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1380)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1390)** ___ ___ ___ mm

ALLERGY SKIN TEST RESULTS

Subject ID: ___ ___ - ___ - ___ ___ ___
Visit Number: ___ ___

9. Tree Mix (B1)	Was there a reaction? **(1400)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1410)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1420)** ___ ___ ___ mm	10. Weed Mix (B2)	Was there a reaction? **(1430)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1440)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1450)** ___ ___ ___ mm
11. Milk (B3)	Was there a reaction? **(1460)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1470)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1480)** ___ ___ ___ mm	12. Egg (B4)	Was there a reaction? **(1490)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1500)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1510)** ___ ___ ___ mm
13. Peanut (B5)	Was there a reaction? **(1520)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1530)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1540)** ___ ___ ___ mm	14. Other _____ (B6)	Was there a reaction? **(1550)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1560)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1570)** ___ ___ ___ mm
15. Other _____ (B7)	Was there a reaction? **(1580)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1590)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1600)** ___ ___ ___ mm	16. Other _____ (B8)	Was there a reaction? **(1610)** ❑1 Yes ❑0 No Largest Wheal Diameter: **(1620)** ___ ___ ___ mm Perpendicular Wheal Diameter: **(1630)** ___ ___ ___ mm

Childhood Asthma Research & Education
NIH/NHLBI

SINUS AND NASAL QUALITY OF LIFE SURVEY

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

(Parent/Legal Guardian Completed)

Instructions: Please help us understand the impact of sinus and/or nasal problems on your child's quality of life by checking one box [X] for each question below. Thank you.

1. <u>SINUS INFECTION:</u> Nasal discharge, bad breath, daytime cough, post-nasal drip, headache, facial pain or head banging. How often was this a problem for your child during the past 4 weeks?

(1000)
- ❑ 1 None of the time
- ❑ 2 Hardly any time at all
- ❑ 3 A small part of the time
- ❑ 4 Some of the time
- ❑ 5 A good part of the time
- ❑ 6 Most of the time
- ❑ 7 All of the time

2. <u>NASAL OBSTRUCTION:</u> Stuffy or blocked nose, nasal congestion, reduced sense of smell, trouble breathing with mouth closed. How often was this a problem for your child during the past 4 weeks?

(1010)
- ❑ 1 None of the time
- ❑ 2 Hardly any time at all
- ❑ 3 A small part of the time
- ❑ 4 Some of the time
- ❑ 5 A good part of the time
- ❑ 6 Most of the time
- ❑ 7 All of the time

3. <u>ALLERGY SYMPTOMS:</u> Sneezing, itchy nose/eyes, need to rub nose/eyes, or watery eyes. How often was this a problem for your child during the past 4 weeks?

(1020)
- ❑ 1 None of the time
- ❑ 2 Hardly any time at all
- ❑ 3 A small part of the time
- ❑ 4 Some of the time
- ❑ 5 A good part of the time
- ❑ 6 Most of the time
- ❑ 7 All of the time

4. <u>EMOTIONAL DISTRESS:</u> Irritable, frustrated, sad, restless, or trouble sleeping. How often was this a problem for your child during the past 4 weeks because of nose or sinus illness?

(1030)
- ❑ 1 None of the time
- ❑ 2 Hardly any time at all
- ❑ 3 A small part of the time
- ❑ 4 Some of the time
- ❑ 5 A good part of the time
- ❑ 6 Most of the time
- ❑ 7 All of the time

SINUS AND NASAL QUALITY OF LIFE SURVEY

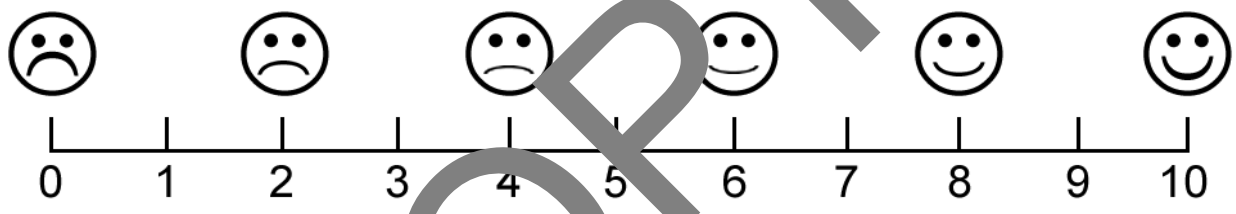
Subject ID: ___ ___ - ___ - ___ ___ ___
Visit Number: ___ ___

5. ACTIVITY LIMITATIONS: Missed school/daycare, lost time with family/friends, unable to do projects. How often was this a problem for your child during the past 4 weeks because of nose or sinus illness?

(1040)
- ❑ 1 None of the time
- ❑ 2 Hardly any time at all
- ❑ 3 A small part of the time
- ❑ 4 Some of the time
- ❑ 5 A good part of the time
- ❑ 6 Most of the time
- ❑ 7 All of the time

---

6. Overall, how would you rate your child's quality of life as a result of nose or sinus problems? **(1050)** (Circle one number)



Worst Possible Quality-of-Life

Half-way Between Worst and Best

Best Possible Quality-of-Life

REMEMBER to circle just one number

DO NOT PLACE A MARK BETWEEN NUMBERS

Clinic Coordinator Completed
COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

POST-BRONCHODILATOR SPIROMETRY TESTING

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

POST-BRONCHODILATOR PULMONARY FUNCTION TESTING

Post-bronchodilator spirometry should be performed 15 minutes after dose is administered.

1. Time bronchodilator given *(based on a 24-hour clock)* **(1000)** ___ ___ ___ ___

2. Time post-bronchodilator spirometry started *(based on a 24-hour clock)* **(1010)** ___ ___ ___ ___

3. Results of best effort
   - 3a. FVC **(1020)** ___ . ___ ___ L
   - 3b. FEV_1 **(1030)** ___ . ___ ___ L
   - 3c. FEV_1 (% predicted) **(1040)** ___ ___ ___ % predicted
   - 3d. FEV_1 / FVC **(1050)** ___ ___ ___ %
   - 3e. FEF_{25-75} **(1060)** ___ . ___ ___ liters/sec
   - 3f. ATS Accepted **(1140)** ___ . 0 0
   - 3g. ATS Error Code **(1150)** ___ ___ ___ . 0 0

4. In your judgement, was the participant's post-bronchodilator technique acceptable? **(1160)** ❑ 1 Yes ❑ 0 No
   - 4a. If ***NO***, why was it unacceptable?
     - 4ai. Inadequate start of test, no rapid onset of expiration, large back extrapolation **(1170)** ❑ 1 Yes ❑ 0 No
     - 4aii. Unacceptable peak flow (low, rounded, not clearly determined) **(1180)** ❑ 1 Yes ❑ 0 No
     - 4aiii. Unacceptable FET **(1190)** ❑ 1 Yes ❑ 0 No
     - 4aiv. Cough/Glottic closure during maneuver **(1200)** ❑ 1 Yes ❑ 0 No
     - 4av. Abrupt ending, sharp drop, or cessation in flow (truncation) **(1210)** ❑ 1 Yes ❑ 0 No
     - 4avi. Other (specify) _____ **(1220)** ❑ 1 Yes ❑ 0 No
   - 4b. If ***YES***, grade the participant's technique **(1230)** ❑ 1 Acceptable, good effort
     ❑ 2 Acceptable, questionable effort

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

COMMENTS (6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PRE-BRONCHODILATOR SPIROMETRY TESTING

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

(Technician Completed) Supervisor ID: ___ ___ ___ ___ ___

Complete spirometry testing only if the participant is eligible according to the Pulmonary Procedure Checklist (PFT_CHK) form.

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING

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

2. Results of best effort

   2a. FVC **(1020)** ___ . ___ ___ L

   2b. FEV_1 **(1030)** ___ . ___ ___ L

   2c. FEV_1 (% predicted) **(1040)** ___ ___ ___ % predicted

   2d. FEV_1 / FVC **(1050)** ___ ___ ___ %

   2e. FEF_{25-75} **(1060)** ___ . ___ ___ liters/sec

   2f. FEF_{50} **(1070)** ___ . ___ ___ liters/sec

   2g. FEF_{75} **(1080)** ___ . ___ ___ liters/sec

   2h. PEF (best effort) **(1090)** ___ ___ . ___ ___ liters/sec

   2i. FET **(1100)** ___ ___ . ___ ___ sec

   2j. FET PEF **(1110)** ___ . ___ ___ sec

   2k. V backextrapolation ex **(1120)** ___ . ___ ___ liters

   2l. V backextrapolation % FVC **(1130)** ___ ___ . ___ ___ %

   2m. ATS Accepted **(1140)** ___ . 0 0

   2n. ATS Error Code **(1150)** ___ ___ ___ . 0 0

3. In your judgement, was the participant's pre-bronchodilator technique acceptable? **(1160)** ❑$_1$ Yes ❑$_0$ No

   3a. If ***NO***, why was it unacceptable?

      3ai. Inadequate start of test, no rapid onset of expiration, large back extrapolation **(1170)** ❑$_1$ Yes ❑$_0$ No

      3aii. Unacceptable peak flow (low, rounded, not clearly determined) **(1180)** ❑$_1$ Yes ❑$_0$ No

      3aiii. Unacceptable FET **(1190)** ❑$_1$ Yes ❑$_0$ No

3aiv. Cough/Glottic closure during maneuver **(1200)** ☐ 1 Yes ☐ 0 No

3av. Abrupt ending, sharp drop, or cessation in flow (truncation) **(1210)** ☐ 1 Yes ☐ 0 No

3avi. Other (specify) _____ **(1220)** ☐ 1 Yes ☐ 0 No

3b. If ***YES***, grade the participant's technique **(1230)** ☐ 1 Acceptable, good effort
☐ 2 Acceptable, questionable effort

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS TERMINATION OF STUDY PARTICIPATION

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Please indicate the reason for termination of the study participant

1. Has the participant completed the study? **(1000)** ❑1 Yes ❑0 No
   ➔ ***If YES, skip to the SIGNATURE section on page 2.***

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

   2a. If ***YES***, indicate the **primary** reason. **(1030)**
   - ❑1 insufficient adherence with study drugs
   - ❑2 inability to demonstrate adherence with study diary
   - ❑3 pre-bronchodilator FEV_1 < 50% predicted at Visit 0
   - ❑4 unable to swallow study capsule
   - ❑5 budesonide dose too high
   - ❑6 budesonide dose too low
   - ❑7 abnormal lab value/heart rhythm
   - ❑8 parent withdrew consent
   - ❑9 participant withdrew assent
   - ❑10 FEV_1 reversibility < 12% and PC_{20} > 12.5 mg/ml
   - ❑11 other _____

3. Has the participant been withdrawn from the study due to pregnancy? **(1040)** ❑1 Yes ❑0 No

4. Has the participant been assigned treatment failure status? **(1070)** ❑1 Yes ❑0 No

5. Has the participant been lost to follow up? **(1080)** ❑1 Yes ❑0 No

6. Has the participant experienced a serious adverse event? **(1090)** ❑1 Yes ❑0 No
   ➔ ***If YES, please complete the Serious Adverse Event Reporting (SERIOUS) form.***

7. Did a physician initiate the termination of study participation? **(1100)** ❑1 Yes ❑0 No
   If **YES**, reason _____

8. Is there any other reason why the participant is being terminated from the study? **(1110)** ❑ 1 Yes ❑ 0 No

8a. If **YES**, indicate the **primary** reason. **(1120)**

- ❑ 1 parent withdrew consent
- ❑ 2 participant withdrew assent
- ❑ 3 oral/systemic corticosteroid use other than for asthma
- ❑ 4 no longer interested in participating
- ❑ 5 no longer willing to follow protocol
- ❑ 6 difficult access to clinic (location, transportation, parking)
- ❑ 7 unable to make visits during clinic hours
- ❑ 8 moving out of the area
- ❑ 9 unable to continue due to personal constraints
- ❑ 10 dissatisfied with asthma control
- ❑ 11 unable to continue due to medical condition unrelated to asthma
- ❑ 12 abnormal laboratory value/heart rhythm
- ❑ 13 side effects of study medication
- ❑ 14 other _____

SIGNATURE

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

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

(1130) _____
Clinic Coordinator's Signature

(1140) Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

(1150) _____
Principal Investigator's Signature

(1160) Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

COMMENTS
(6000):_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MARS TREATMENT FAILURE

Subject ID: 0 5 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant met the criteria for inadequate control? **(1000)** ☐1 Yes ☐0 No

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

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

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

5. Has the participant received, or will he/she receive a course of an oral/systemic corticosteroid for an asthma exacerbation? **(1040)** ☐1 Yes ☐0 No

   ➔ If ***NO***, skip to Question #6.

   5a. What was the start date of the oral/systemic corticosteroid? (If prescribed today, put today's date.) **(1045)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

   5b. Why was the course prescribed? **(1050)** ☐1 Physician discretion
   The MARS protocol specifications are to prescribe oral corticosteroids if: ☐2 Protocol specifications
   - The patient uses more than 12 puffs of albuterol in 24 hours (excluding preventive use before exercise) and has a Diary Card symptom rating of 3 or PEF less than 80% of personal best before albuterol use.
   - The participant has symptom rating of 3 for 48 hours or longer, or PEF drops to less than 50% of personal best despite albuterol treatment.

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

   ➔ ***If YES, please complete the MARS Termination of Study Participation (P5_TERM) form.***

7. Date treatment failure occurred **(1070)** ___ ___ / ___ ___ / ___ ___ ___ ___
   (This should be the date the participant met the treatment failure criteria, whether by symptoms or by prednisone use, or some other criteria, whichever occurred first)
   Month Day Year

(1080) Physician/CC signature: _____

(1090) Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

COMMENTS

(6000):_____

_____

_____