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

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
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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

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NIH/NHLBI

MIST COMPLIANCE CHECKLIST

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Check the following adherence criteria at Visits 3 through 9 for used study drug kits.

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

   ➔ ***If 0, skip to Question #3.***

   ➔ ***If > 0, please complete a Respiratory Illness Compliance Checklist (P8_RICOMPLY) for each respiratory illness kit that was used.***

2. Were respiratory illness kits used for all of the above illnesses? **(1010)** ❑1 Yes ❑0 No

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

   _____

3. Daily Medication Adherence

   3a. Number of days since last visit (Count the day of the previous visit, but not today) **(1070)** ___ ___ ___ days

   3b. Number of respules dispensed **(1080)** ___ ___ ___ respules

   3c. Number of respules returned **(1090)** ___ ___ ___ respules

   3d. Number of respules scheduled (Question #3a - (Question #1 x 7)) **(1100)** ___ ___ ___ respules

   3e. Actual number of respules used (Question #3b - Question #3c) **(1110)** ___ ___ ___ respules

   3f. Percent adherence = $\frac{\textit{Question \#3e}}{\textit{Question \#3d}} \times \textit{100}$ **(1120)** ___ ___ ___ . ___%

COMMENTS

(6000):_____

_____

Subject ID: 0 8 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

MIST DIARY CARD

Return Visit Number: ___

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

Complete with blue or black ink	Day 1:___	Day 2:___	Day 3:___	Day 4:___	Day 5:___	Day 6:___	Day 7:___
Date (month/day)	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___
Complete each morning: Covers period of time from when your child went to bed for the night to when he/she awoke this morning.							
1. How much albuterol did your child use since being put to bed? (If none, enter "0".)							
Albuterol Inhaler: number of puffs (1000)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Albuterol by nebulizer: number of treatments (1010)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Complete each night after child goes to bed: Covers period of time since your child awoke this morning for the day.							
2. How severe was your child's cough today? (1020) 0 = No cough 3 = Moderate cough 1 = Very mild cough 4 = Severe cough 2 = Mild cough 5 = Very severe cough	__	__	__	__	__	__	__
3. How severe was your child's wheezing today? (1030) 0 = No wheezing 3 = Moderate wheezing 1 = Very mild wheezing 4 = Severe wheezing 2 = Mild wheezing 5 = Very severe wheezing	__	__	__	__	__	__	__
4. How severe was your child's trouble breathing today? (1040) 0 = No trouble breathing 3 = Moderate trouble breathing 1 = Very mild trouble breathing 4 = Severe trouble breathing 2 = Mild trouble breathing 5 = Very severe trouble breathing	__	__	__	__	__	__	__
5. How much did your child's asthma symptoms interfere with your child's activities today? (1050) 0 = Did not interfere 3 = Moderately interfered 1 = Very mildly interfered 4 = Severely interfered 2 = Mildly interfered 5 = Very severely interfered	__	__	__	__	__	__	__
6a. Visited a doctor? (1060)	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$_0$
6b. Visited an Emergency Room? (1070)	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$_0$
6c. Admitted to the Hospital Overnight? (1080)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
6d. Treated with Prednisone? (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$_0$
7. How much albuterol did your child use since waking up? (If none, enter "0".)							
Albuterol Inhaler: number of puffs (1100)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
Albuterol by nebulizer: number of treatments (1110)	__ __	__ __	__ __	__ __	__ __	__ __	__ __
8. Was your child absent from school or daycare today due to breathing problems? (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$_0$
9. Was a parent unable to go to work or school today due to your child's breathing problems? (1130)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
Daily Respules ***Take every night except when using the respiratory illness medication.***							
10. Did your child take the Daily Respule tonight? (1140)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
Respiratory Illness Medications (7 days) ***If your child starts study medication due to respiratory illness symptoms as per your MIST Action Plan, stop Daily Respules and start using a Respiratory Illness Kit and contact study personnel within 72 hours.***							
11. Did your child take the Respiratory Illness Respule this morning? (1150)	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$	Yes$_1$ No$_0$
12. Did your child take the Respiratory Illness Respule tonight? (1160)	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$_0$

Childhood Asthma Research & Education
NIH/NHLBI

MIST ELIGIBILITY CHECKLIST 1 Visit 1

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

(Clinic Coordinator completed)

Informed Consent

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 parent/legal guardian consented to a genotype evaluation for the participant? **(1020)** ❑1 Yes ❑0 No

   2a. If ***YES***, record the date the form was signed. **(1030)** __ __ / __ __ / __ __ __ __ (*Month / Day / Year*)

3. Will the participant be using Spanish translated materials while enrolled in the MIST study? **(1040)** ❑1 Yes ❑0 No

Study Medicines

4. Does the participant have an intolerance or allergy to budesonide (Pulmicort)? **(1050)** ❑1 Yes ❑0 No ❑9 Unknown

5. Does the participant have an intolerance or allergy to oral corticosteroids (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone)? **(1060)** ❑1 Yes ❑0 No

6. Is the participant able to take albuterol (such as Proventil and Ventolin)? **(1070)** ❑1 Yes ❑0 No

7. 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 MIST Termination of Study Participation *(P8_TERMR) form.***

Medical History Criteria

8. Is the participant 12 to 53 months old? **(1090)** ❑1 Yes ❑0 No

9. Was the participant born before 34 weeks gestation? **(1100)** ❑1 Yes ❑0 No

10. Does the parent report that the participant is up-to-date with immunizations? **(1110)** ❑1 Yes ❑0 No

11. Has the participant ever had chicken pox or received the chicken pox vaccine? **(1120)** ❑1 Yes ❑0 No
    (*Refer to MOP for discussion on immunization records*)

12. Is the participant receiving allergy shots? **(1130)** ❑1 Yes ❑0 No

    12a. If ***YES***, has the dose been changed in the past 3 months? **(1140)** ❑1 Yes ❑0 No

13. Does the participant have any immunodeficiency disorders? **(1150)** ☐1 Yes ☐0 No

14. Is the participant currently on antibiotics for sinus disease? **(1160)** ☐1 Yes ☐0 No

15. Does the participant have uncontrolled gastroesophageal reflux? **(1170)** ☐1 Yes ☐0 No

16. Does the participant have concurrent medical problems other than asthma that are likely to require oral or injectable corticosteroids during the study? **(1180)** ☐1 Yes ☐0 No

17. Does the participant have a chronic or active lung disease other than asthma (cystic fibrosis, BPD, pneumonia, etc.)? **(1190)** ☐1 Yes ☐0 No

18. Does the participant have a significant medical illness other than asthma (refer to P8_EXCLMED)? **(1200)** ☐1 Yes ☐0 No

19. Is the participant eligible? **(1210)** ☐1 Yes ☐0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation *(P8_TERMR) form.***

API Criteria

20. Has either of the participant's biological parents been diagnosed with asthma by a health care provider? **(1212)** ☐1 Yes ☐0 No

21. Has the participant ever been diagnosed with atopic dermatitis (eczema) by a health care provider? **(1214)** ☐1 Yes ☐0 No

22. Has the participant met the API criteria? If either Question #20 or #21 is 'Yes', the participant has met the API criteria. **(1216)** ☐1 Yes ☐0 No

➔ **If *YES*, skin testing and the blood draw can be performed at Visit 2. Skip to Question #28.**

➔ **If *NO*, skin testing must be performed at Visit 1.**

23. Was allergy skin testing performed? **(1222)** ☐1 Yes ☐0 No

➔ **If *NO*, RAST testing is required. Skip to Question #28.**

24. Does the participant possess an allergic sensitization to at least one aeroallergen? **(1223)** ☐1 Yes ☐0 No

➔ **If *YES*, skip to Question #28.**

25. Has the participant experienced any wheezing not associated with colds? **(1224)** ☐*1 Yes ☐0 No

26. Does the participant possess an allergic sensitization to milk, egg, or peanuts? **(1225)** ☐*1 Yes ☐0 No

27. Is the participant eligible? **(1226)** ☐1 Yes ☐0 No

➔ ***If either starred box is selected for Question #25 or #26, the participant is eligible and the blood draw should take place at Visit 1.***

➔ ***If both starred boxes are selected for Questions #25 and #26, the participant is eligible and the blood draw can take place at Visit 2.***

➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation (P8_TERMR) form.**

Wheezing/Other Criteria

28. During the past 12 months, how many wheezing episodes has the participant had? **(1220)** __ __ wheezing episodes

28a. Is Question #28 ≥ 4? **(1230)** ☐1 Yes ☐0 No

➔ ***If NO, skip to Question #28b.***

28ai. If ***YES***, was at least one of the wheezing episodes diagnosed by a health care provider? **(1240)** ☐1 Yes ☐0 No

➔ ***If YES, skip to Question #29.***

28b. Is Question #28 ≥ 3? **(1242)** ☐1 Yes ☐0 No

28bi. If ***YES***, did the participant use an asthma controller medication for at least 3 months during the past year? **(1245)** ☐1 Yes ☐0 No

28bii. If ***YES***, was at least one of the wheezing episodes diagnosed by a health care provider? **(1247)** ☐1 Yes ☐0 No

29. Has the participant had a severe exacerbation requiring systemic corticosteroids, urgent unscheduled or emergent visit or hospitalization within the past 12 months? **(1250)** ☐1 Yes ☐0 No

30. During the past year, how many oral or systemic corticosteroid courses has the participant had? **(1260)** __ __ courses

30a. Is Question #30 ≥ 7? **(1270)** ☐1 Yes ☐0 No

31. Has the participant used an oral or systemic corticosteroid for any reason in the past 2 weeks? **(1280)** ☐1 Yes ☐0 No

32. During the past year, how many times has the participant been hospitalized for wheezing illnesses? **(1290)** __ __ times

32a. Is Question #32 ≥ 3? **(1300)** ☐1 Yes ☐0 No

33. Has the participant had a wheezing episode resulting in mechanical ventilation or resulting in a hypoxic seizure? **(1310)** ☐1 Yes ☐0 No

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

35. Currently, or within the past month, has the participant been involved in an investigational drug trial? **(1330)** ☐1 Yes ☐0 No

36. Does the participant's family have plans to move out of the area before the end of the study? **(1340)** ☐1 Yes ☐0 No

37. 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: _____

Growth Criteria

38. Does the participant have significant developmental delay/failure to thrive? (*If a child plots less than the 10th percentile for age and gender, a growth chart for the previous year will be obtained from the child's primary care provider. If the child has crossed two major percentile lines during the previous year, he/she has significant developmental delay/failure to thrive.*) **(1360)** ☐1 Yes ☐0 No

39. Does the participant have head circumference < 3 percentile or > 97 pecentile? **(1365)** ☐1 Yes ☐0 No

39a. If ***YES*****,** is the head circumference finding clinically relevant? **(1370)** ☐1 Yes ☐0 No

40. Is the participant eligible? **(1380)** ☐1 Yes ☐0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation *(P8_TERMR) form.***

Medication History

41. Has the participant been treated with a controller therapy for at least 4 weeks prior to Visit 1? **(1385)** ☐1 Yes ☐0 No

➔ **If *NO*, STOP HERE.**

42. Which controller therapies was the participant taking during the last 4 weeks? In the following table, complete the Dose and Frequency for each controller therapy the participant has been taking for the past 4 weeks. If the participant has not been taking a medication, select N/A.

Medication		Dose	Frequency	
42a. QVAR (beclomethasone)	**(1390-1410)**	___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42b. Pulmicort (budesonide) Flexhaler or Pulmicort respules (budesonide)	**(1420-1440)**	___ ___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42c. Symbicort (budesonide)	**(1450-1470)**	___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42d. Aerobid (flunisolide)	**(1480-1500)**	___ ___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42e. Flovent (fluticasone)	**(1510-1530)**	___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42f. Azmacort (triamcinolone)	**(1540-1560)**	___ ___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42g. Singulair (montelukast)	**(1570-1590)**	___ ___ ___ mg qd	___ days/wk	❑9 N/A
42h. Accolate (zafirlukast)	**(1600-1620)**	___ ___ ___ mg bid	___ days/wk	❑9 N/A
42i. Uniphyl (theophylline)	**(1630-1650)**	___ ___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42j. Intal (cromolyn) MDI or Intal (cromolyn) solution	**(1660-1680)**	___ ___ ___ times/day	___ days/wk	❑9 N/A
42k. Serevent (salmeterol)	**(1700-1720)**	___ ___ ___ times/bid	___ days/wk	❑9 N/A
42l. Advair (fluticasone/salmeterol)	**(1730-1750)**	___ ___ ___ mcg/day	___ days/wk	❑9 N/A
42m. Asmanex (mometasone)	**(1760-1780)**	___ ___ ___ mcg/day	___ days/wk	❑9 N/A

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
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MIST ELIGIBILITY CHECKLIST 2 Visit 2

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 2
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Asthma Medications

1. Has the participant used any asthma medications other than daily respules and albuterol since Visit 1? **(1000)** ☐ 1 Yes ☐ 0 No

   ➔ **If *YES*, STOP HERE and complete the MIST Termination of Study Participation (P8_TERMR) form.**

API Criteria

2. Was the participant API positive at Visit 1 (P8_ELIG1, Questions #20 - #27)? **(1010)** ☐ 1 Yes ☐ 0 No

   ➔ ***If YES, skip to Question #8.***

3. Does the participant possess an allergic sensitization to at least one aeroallergen? **(1030)** ☐ 1 Yes ☐ 0 No

   ➔ ***If YES, the participant has met the API criteria. Skip to Question #8.***

4. Has the participant experienced any wheezing not associated with colds? **(1050)** ☐* 1 Yes ☐ 0 No

5. Does the participant possess an allergic sensitization to milk, egg, or peanuts? **(1060)** ☐* 1 Yes ☐ 0 No

6. Is the participant's eosinophil count greater than or equal to 4% in circulation? **(1070)** ☐* 1 Yes ☐ 0 No

7. Is the participant eligible? **(1090)** ☐ 1 Yes ☐ 0 No
   If at least two starred boxes in Questions #4, #5, or #6 are selected, the participant is eligible.

   ➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation *(P8_TERMR) form.***

Persistent Symptoms

8. Number of days between Visit 1 and Visit 2 (excluding today and Visit 1 day) **(1100)** ___ ___ days

9. Number of days with albuterol use. Do not count any day more than once. (If P8_DIARY Q1# > 0 or Q#7 > 0, count that day. Total days should not exceed the answer for Question #8.) **(1110)** ___ ___ days

10. Average number of days per week with albuterol use for breathing problems.

    10a. Average = $\frac{\textit{Question \#9}}{\textit{Question \#8}}$ x *7* **(1120)** ___ ___ . ___ days

    10b. Is Question #10a > 3.0? **(1130)** ☐ 1 Yes ☐ 0 No

11. Number of days with night time awakenings requiring albuterol due to asthma? **(1140)** __ __ days

12. Is Question #11 ≥ 2? **(1150)** ☐1 Yes ☐0 No

13. Is the participant eligible? **(1160)** ☐1 Yes ☐0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation *(P8_TERMR) form.***

Diary Adherence

14. Number of complete measurements in the defined interval [Questions that count toward adherence include Questions #1 - #10]? **(1170)** __ __ __ measurements

15. Percent adherence = $\frac{\textit{Question \#14}}{\textit{(Question \#8 x 10)}} \times 100$ **(1180)** __ __ __ . __ %

16. Categorize Question #15. **(1185)** ☐1 < 75%
☐2 ≥ 75%

Medication Adherence

17. Number of respules scheduled (including day of last visit, but not today's visit) **(1190)** __ __ Respules

18. Number of respules dispensed **(1200)** __ __ Respules

19. Number of respules returned **(1210)** __ __ Respules

20. Number of respules used (Question #18 - Question #19) **(1220)** __ __ Respules

21. Percent adherence = $\frac{\textit{Question \#20}}{\textit{Question \#17}} \times 100$ **(1230)** __ __ __ . __ %

22. Categorize Question #21. **(1240)** ☐1 < 75%
☐2 ≥ 75%

23. Is there any other reason for which this participant should not be included in this study? **(1250)** ☐1 Yes ☐0 No

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

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MIST ELIGIBILITY CHECKLIST 2

Subject ID: 0 8 - ___ - ___ ___ ___
Visit Number: 0 2

24. Is the participant eligible? **(1260)** ☐1 Yes ☐0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the MIST Termination of Study Participation (P8_TERMR) form.**

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

25. **Drug Packet Number (record on P8_LOG)** ___ - ___ ___ ___ - ___ ___ ___
(1270) (1280) (1290)

(1300) Physician/CC Signature: _____

(1310) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
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HOME ENVIRONMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant Completed)

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

GENERAL HOUSE CHARACTERISTICS

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

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

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

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

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

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

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

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

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

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

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

9. Which rooms use a window unit?

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

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

(1150) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

12. Which rooms use a window unit?

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

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

(1220) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

15. Which rooms use a humidifier?

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

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

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

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

18. Which rooms use a dehumidifier?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1640) ___ ___ years

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

(1650) ❑ 1 Yes ❑ 0 No

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

(1660) ❑ 1 Yes ■ 0 No

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

(1670) ❑ 1 Yes ❑ 0 No

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

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

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

(1690) ___ ___ years

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

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

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

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

ANIMALS

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

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

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

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

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

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

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

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

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

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

Clinic Coordinator Completed

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
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SERUM IgE

Subject ID: ___ ___ - ___ - ___ ___ ___
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):_____

_____

_____

INFANT AND TODDLER QUALITY OF LIFE QUESTIONNAIRE (ITQOL-97)

PARENT FORM - 97 ENGLISH (U.S.)

PATIENT ID NUMBER

TODAY'S DATE

MONTH / DAY / YEAR

INSTRUCTIONS: This form asks about your child's health and well-being. Your responses will be treated confidentially. There are no right or wrong responses. If you are unsure how to respond to a question, give the best response you can. It is important that you fill in each question. Please use blue or back ink.

Correct Marks: ■ ☒ ☑

SECTION 1: YOUR CHILD'S HEALTH OVERALL

		Excellent	Very good	Good	Fair	Poor
1.1	In general, how would you rate your child's health?	☐	☐	☐	☐	☐

SECTION 2: YOUR CHILD'S PHYSICAL ACTIVITIES

2.1 Considering your child's age and abilities, has he/she been limited in any of the following because of health or learning problems?	Yes, limited a lot	Yes, limited some	Yes, limited a little	No, not limited	Not doing yet
a. Feeding/nursing/eating	☐	☐	☐	☐	☐
b. Sleeping	☐	☐	☐	☐	☐
c. Grasping	☐	☐	☐	☐	☐
d. Reaching	☐	☐	☐	☐	☐
e. Rolling over	☐	☐	☐	☐	☐
f. Sitting up	☐	☐	☐	☐	☐
g. Crawling	☐	☐	☐	☐	☐
h. Playing	☐	☐	☐	☐	☐
i. Taking steps or walking	☐	☐	☐	☐	☐
j. Running	☐	☐	☐	☐	☐

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SECTION 3: SATISFACTION WITH YOUR CHILD'S OVERALL GROWTH AND DEVELOPMENT

3.1 In general, how satisfied are you with your child's:	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
a. Physical growth and development? (such as height or weight)	☐	☐	☐	☐	☐
b. Motor development? (such as reaching or grasing, rolling over, sitting up, or walking)	☐	☐	☐	☐	☐
c. Responsiveness to others? (such as returning a (smile, turning toward the sound of a familiar voice or responding to questions)	☐	☐	☐	☐	☐
d. Language development?	☐	☐	☐	☐	☐
e. Learning abilities or cognitive development?	☐	☐	☐	☐	☐
f. Feeding/nursing/eating habits?	☐	☐	☐	☐	☐
g. Sleep habits?	☐	☐	☐	☐	☐
h. Bowel habits?	☐	☐	☐	☐	☐
i. General temperament?	☐	☐	☐	☐	☐
j. Overall growth and development?	☐	☐	☐	☐	☐

SECTION 4: YOUR CHILD'S DISCOMFORT/PAIN

4.1 During the past 4 weeks, how much bodily pain or discomfort (due to gas, teething, injury, illness) has your child had anywhere in his/her body?

None	Mild	Moderate	Severe	Very Severe
☐	☐	☐	☐	☐

4.2 During the past 4 weeks, how often has your child had discomfort or pain anywhere in his/her body?

None of the time	A few times	Fairly often	Very often	Every day or almost every day
☐	☐	☐	☐	☐

4.3 During the past 4 weeks, how much did discomfort or pain anywhere in your child's body interfere with his/her usual activities (including sleeping, playing or other activities at daycare, school, home or with others)?

None at all	A little bit	Some	Quite a bit	A lot
☐	☐	☐	☐	☐

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SECTION 5: YOUR CHILD'S TEMPERAMENT AND MOODS

5.1 During the past 4 weeks, how much of the time did your child seem:

	All of the time	Most of the time	Some of the time	A little of the	None of the time
a. To have trouble sleeping?	☐	☐	☐	☐	☐
b. To be a picky feeder/nurser/eater?	☐	☐	☐	☐	☐
c. Cranky, fussy, or irritable?	☐	☐	☐	☐	☐
d. Less active than usual?	☐	☐	☐	☐	☐
e. Happy?	☐	☐	☐	☐	☐
f. Difficult to comfort?	☐	☐	☐	☐	☐
g. Interested in activities going on around him/her?	☐	☐	☐	☐	☐
h. More quiet than usual?	☐	☐	☐	☐	☐
i. Bothered or upset?	☐	☐	☐	☐	☐
j. "Just not him/herself"?	☐	☐	☐	☐	☐
k. Responsive to others?	☐	☐	☐	☐	☐
l. Cheerful?	☐	☐	☐	☐	☐
m. Easily upset?	☐	☐	☐	☐	☐
n. Fearful of others?	☐	☐	☐	☐	☐
o. Playful?	☐	☐	☐	☐	☐
p. Alert?	☐	☐	☐	☐	☐
q. To want to be held more often or seem more clingy than usual?	☐	☐	☐	☐	☐
r. To do well with changes in his/her routine?	☐	☐	☐	☐	☐

IS YOUR CHILD AT LEAST 1 YEAR OF AGE OR OLDER?

- **NO (Skip to page 5, section #8)**
- **YES (Continue on next page)**

SECTION 6: YOUR CHILD'S BEHAVIOR OVERALL

6.1 How much do you agree/disagree with each statement for your child?	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
a. My child's behavior is excellent.	☐	☐	☐	☐	☐
b. My child's behavior is sometimes difficult to manage.	☐	☐	☐	☐	☐
c. My child seems to misbehave quite often.	☐	☐	☐	☐	☐
d. My child seems to misbehave more often than other children I know.	☐	☐	☐	☐	☐
e. My child's behavior is rarely very bad.	☐	☐	☐	☐	☐
f. I think my child's behavior will be worse in the future.	☐	☐	☐	☐	☐
g. I rarely worry about my child's behavior.	☐	☐	☐	☐	☐
h. Doctors or other child professionals have suggested that my child's behavior is a problem.	☐	☐	☐	☐	☐
i. I think my child's behavior will not be a problem for him/her in the future.	☐	☐	☐	☐	☐
j. People have complimented me on my child's behavior.	☐	☐	☐	☐	☐
k. I worry about my child's behavior more than other parents worry about their child's behavior.	☐	☐	☐	☐	☐
l. Others have complained about my child's behavior.	☐	☐	☐	☐	☐

6.2 Compared to children of the same age, how would you rate your child's behavior overall?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

IS YOUR CHILD AT LEAST 1 YEAR OF AGE OR OLDER?

- **NO (Skip to page 5, section #8)**
- **YES (Continue on next page)**

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SECTION 7: GETTING ALONG WITH OTHERS

7.1 During the past 4 weeks, how often did your child:	Very often	Fairly often	Sometimes	Almost never	Never
a. Seem to cooperate with others (including adults and children)?	☐	☐	☐	☐	☐
b. Seem unable to sit still for more than a few minutes?	☐	☐	☐	☐	☐
c. Go to sleep or to bed with few problems?	☐	☐	☐	☐	☐
d. Hit, kick, or bite others?	☐	☐	☐	☐	☐
e. Appear sorry after having misbehaved?	☐	☐	☐	☐	☐
f. Have behavior that was difficult to manage?	☐	☐	☐	☐	☐
g. Seem able to adjust to new situations or strangers?	☐	☐	☐	☐	☐
h. Act shy or timid?	☐	☐	☐	☐	☐
i. Get along with other children?	☐	☐	☐	☐	☐
j. Throw tantrums?	☐	☐	☐	☐	☐
k. Respond positively to affection?	☐	☐	☐	☐	☐
l. Act withdrawn?	☐	☐	☐	☐	☐
m. Seem distracted more than other children his/her age?	☐	☐	☐	☐	☐
n. Act his/her age?	☐	☐	☐	☐	☐
o. Listen or follow directions?	☐	☐	☐	☐	☐

SECTION 8: YOUR CHILD'S HEALTH

8.1 How true or false is each statement for your child?	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a. My child's health is excellent.	☐	☐	☐	☐	☐
b. My child was once so sick, I thought he/she might die.	☐	☐	☐	☐	☐
c. My child seems to resist illness very well.	☐	☐	☐	☐	☐
d. My child seems to be less healthy than other children I know.	☐	☐	☐	☐	☐
e. My child has never been seriously ill.	☐	☐	☐	☐	☐
f. When there is something going around my child usually catches it.	☐	☐	☐	☐	☐
g. I think my child's health will be worse in the future than it is now.	☐	☐	☐	☐	
h. I expect my child will have a very healthy life.	☐	☐	☐	☐	☐
i. I rarely worry about my child's health.	☐	☐	☐	☐	☐
j. Doctors say my child is healthy now.	☐	☐	☐	☐	☐
k. I worry about my child's health more than other people worry about their children's health.	☐	☐	☐	☐	☐

IS YOUR CHILD AT LEAST 1 YEAR OF AGE OR OLDER?

- **NO (Skip to section 9, this page)**
- **YES (Continue below)**

8.2 Compared to one year ago, how would you rate your child's health now:

Much better now than 1 year ago	Somewhat better now than 1 year ago	About the same now as 1 year ago	Somewhat worse now than 1 year ago	Much worse now than 1 year ago
☐	☐	☐	☐	☐

SECTION 9: YOUR CHILD'S IMPACT ON YOU

9.1 During the past 4 weeks, how MUCH anxiety or worry did each of the following cause YOU?	None at all	A little bit	Some	Quite a bit	A lot
a. Your child's feeding/eating/sleeping habits	☐	☐	☐	☐	☐
b. Your child's physical health	☐	☐	☐	☐	☐
c. Your child's emotional well-being	☐	☐	☐	☐	☐
d. Your child's learning abilities or cognitive development	☐	☐	☐	☐	☐
e. Your child's ability to interact with others	☐	☐	☐	☐	☐
f. Your child's behavior	☐	☐	☐	☐	☐
g. Your child's temperament	☐	☐	☐	☐	☐

9.2 During the past 4 weeks, were you LIMITED in the amount of time YOU had for your own personal needs due to problems with your child's:	Yes, limited a lot	Yes, limited some	Yes, limited a little	Not limited
a. feeding/eating/sleeping habits?	☐	☐	☐	☐
b. physical health?	☐	☐	☐	☐
c. emotional well-being?	☐	☐	☐	☐
d. learning abilities or cognitive development?	☐	☐	☐	☐
e. ability to interact with others?	☐	☐	☐	☐
f. behavior?	☐	☐	☐	☐
g. temperament?	☐	☐	☐	☐

9.3 Sometimes families may have difficulty getting along with one another. They do not always agree and they may get angry. In general, how would you rate your family's ability to get along with one another?

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

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Childhood Asthma Research & Education
NIH/NHLBI

MIST JUNIPER ASTHMA CONTROL QUESTIONNAIRE

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

(Coordinator or Parent/Legal Guardian Completed)

1. Who is completing the questionnaire? **(1000)**
   - ☐ 1 Mother
   - ☐ 2 Father
   - ☐ 3 Stepparent
   - ☐ 4 Grandparent
   - ☐ 5 Legal Guardian
   - ☐ 6 Other _____

2. On average, during the past week, how often was your child awakened by breathing problems during the night? **(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 child's breathing problems when he/she 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 your child's activities because of breathing problems? **(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 your child experience because of breathing problems? **(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

MIST JUNIPER ASTHMA CONTROL QUESTIONNAIRE

Subject ID: 0 8 - ___ - ___ ___ ___
Visit Number: ___ ___

6. In general, during the past week, how much of the time did your child 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 albuterol has your child used each day? **(1060)**
- ❑ 0 <1 puff most days
- ❑ 1 1 - 2 puffs most days
- ❑ 2 3 - 4 puffs most days
- ❑ 3 5 - 8 puffs most days
- ❑ 4 9 - 12 puffs most days
- ❑ 5 13 - 16 puffs most days
- ❑ 6 More than 16 puffs most days

8. On average, during the past week, how many nebulizer treatments of albuterol has your child used each day? **(1070)**
- ❑ 0 <1 dose most days
- ❑ 1 1 - 2 doses most days
- ❑ 2 3 - 4 doses most days
- ❑ 3 5 - 8 doses most days
- ❑ 4 9 - 12 doses most days
- ❑ 5 13 - 16 doses most days
- ❑ 6 More than 16 doses most days

9. Since the last visit, did the child take any systemic or oral steroids for breathing problems (Decadron, Dexamethasone, Orapred, Prelone, Pediapred, prednisone, Solumedrol)? **(1080)** ❑ 1 Yes ❑ 0 No

9a. If ***YES***, on how many days **(1090)** ___ ___ days

➔ ***If YES, make sure the Coordinator was notified and a Prednisolone Medication Form (P8_PRED) was completed.***

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST LABORATORY TESTS

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

BLOOD TESTS and SPECIMEN COLLECTIONS (Visit 1 or Visit 2)

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

2. Eosinophils **(1010)** ___ ___ . ___ %

3. Was blood obtained for the serum save? **(1020)** ❑1 Yes ❑0 No

NASAL SAMPLING (Visits 2 and 5)

4. Were you able to collect a nasal sample from the participant today? **(1030)** ❑1 Yes ❑0 No

   4a. If ***YES***, which collection technique was used? **(1035)** ❑1 Nasal Blow ❑2 Nasal Swab

Home NASAL SAMPLING (between Visits 2 and 9)

5. Were any nasal samples collected at home between visits? **(1040)** ❑1 Yes ❑0 No

   ➔ ***If NO, STOP HERE.***

6. How many were collected? **(1050)** ___

7. Which collection technique was used? **(1060)** ❑1 Nasal Blow ❑2 Nasal Swab

8. Were the samples thawed? **(1070)** ❑1 Yes ❑0 No

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST SCHEDULED MEDICATIONS

Subject ID: 0 8 - ___ - ___ ___ ___
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

MEDICATION LABEL - *Complete for randomized participants*

Affix the new drug label below:

Copy the drug label number below:

8 - ___ - ___
(1010) **(1020)** **(1030)**

Coordinator
(1040) Signature: _____

(1050) 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.

2. Which of the following devices is the participant using with the study medications?

(1060) ❑ 1 Pari Bubbles II mask
❑ 2 Pari baby face mask
❑ 3 Mouthpiece

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 #28.***
❑ 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

OFFLINE EXHALED NITRIC OXIDE

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

EXCLUSIONS

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

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

3. Is the child eligible to proceed with the ENO testing? **(1020)** ☐ 1 Yes ☐ 0 No
   If any of the shaded boxes are filled in, the child is NOT eligible for ENO testing.
   ➔ ***If NO, STOP HERE.***

CONFOUNDERS

4. Did the child take an oral steroid within the past month? **(1030)** ☐ 1 Yes ☐ 0 No

5. Does the child have a cold presently? **(1040)** ☐ 1 Yes ☐ 0 No

6. During the past 4 hours, has the child used a bronchodilator? **(1070)**
   ☐ 1 Yes
   ☐ 0 No
   ☐ 9 Unknown

7. During the past 12 hours, has the child used a long-acting bronchodilator or salmeterol? **(1075)**
   ☐ 1 Yes
   ☐ 0 No
   ☐ 9 Unknown

8. Has the child been exposed to a smoker in the past 24 hours? **(1080)**
   ☐ 1 Yes
   ☐ 0 No
   ☐ 9 Unknown

9. Did the child eat or drink in the past hour? **(1085)**
   ☐ 1 Yes
   ☐ 0 No
   ☐ 9 Unknown

10. Was the ENO procedure performed? **(1050)** ❑1 Yes ❑0 No

10a. If ***NO***, indicate the primary reason **(1060)** ❑1 Participant/Parent refused
❑2 Equipment failure
❑3 Participant uncooperative
❑9 Other _____

➔ ***If Question #10 is answered NO, STOP HERE.***

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

11. ENO Measurement Bag #1 **(1090)** ___ ___ ___ . ___ ___ ppb

11a. Number of Breaths **(1100)** ___ ___

11b. Was the child fussy? **(1110)** ❑1 Yes ❑0 No

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

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

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

13. ENO Measurement Bag #3 **(1150)** ___ ___ ___ . ___ ___ ppb

13a. Number of Breaths **(1160)** ___ ___

13b. Was the child fussy? **(1170)** ❑1 Yes ❑0 No

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST RESPIRATORY ILLNESS FOLLOW-UP PHONE CONTACT

Subject ID: 0 8 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Coordinator completed)

This form is completed when the parent/guardian calls within 72 hours of beginning the respiratory illness medication.

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

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

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

3. On average, since the start of the illness, how often was your child awakened by breathing problems 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

4. On average, since the start of the illness, how bad were your child's breathing problems when he/she woke up in the morning? **(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

5. In general, since the start of the illness, how limited were your child's activities because of breathing problems? **(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

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

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

8. Have you started the respiratory illness medication? **(1060)** ❑ 1 Yes ❑ 0 No

   ➔ ***If NO, instruct the parent/guardian to start the Respiratory Illness Kit immediately AND skip to Question #10.***

   8a. Date the respiratory illness medication started **(1070)** __ __ / __ __ / __ __ __ __

   8b. Time the respiratory illness medication started *(based on a 24-hour clock)* **(1080)** __ __ __ __

   8c. Have you stopped the Daily Respules? **(1090)** ❑ 1 Yes ❑ 0 No

9. Have you been giving your child the respiratory illness medication in the morning and at night? **(1100)** ❑ 1 Yes ❑ 0 No

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

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

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

    ➔ ***If YES, complete a MIST Prednisolone Medication (P8_PRED) form.***

Childhood Asthma Research & Education
NIH/NHLBI

MIST PREDNISOLONE MEDICATION FORM

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator or Physician completed)

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

1. Initiation of prednisolone due to asthma

1a. Date started on prednisolone **(1000)** ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

1b. Instructions to patient *(dose, frequency)* **(1010)**
- ❑1 Standard Treatment
- ❑2 Other _____

➔ **Standard Treatment: 2 mg/kg/day for 2 days (maximum 60 mg/day) followed by 1 mg/kg/day**

1c. Primary reason for initiation of prednisolone **(1020)**
- ❑1 Symptoms did not improve after 3 albuterol treatments administered every 15 minutes
- ❑2 Albuterol was needed more than 6 nebulization treatments or more than 12 puffs per day for greater than 24 hours
- ❑3 Moderate-severe cough or wheeze occurred for at least 5 of the preceding 7 days
- ❑4 There was an unscheduled visit for acute asthma care requiring repeated doses of albuterol (physician office, urgent care, emergency department)
- ❑5 Hospitalization was needed for asthma
- ❑6 Physician discretion **(If Physician discretion, please explain in the comments section below.)**

2. Method of initiation of prednisolone **(1030)**
- ❑1 Office visit
- ❑2 Phone decision by study doctor
- ❑3 Other _____

COMMENTS

(6000):_____
_____
_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST PREDNISOLONE MEDICATION FOLLOW UP FORM

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator)

Two Week Prednisolone Call Section

1. Since the last course of oral/systemic corticosteriod recorded on the MIST Prednisolone Medication (P8_PRED) form, has your child received an additional corticosteroid course? **(1000)** ❑1 Yes ❑0 No

   ➔ **If *YES*, please STOP HERE and complete another MIST Prednisolone Medication (P8_PRED) form.**

2. In the past 2 weeks, has your child been hospitalized for breathing problems? **(1010)** ❑1 Yes ❑0 No

   ➔ **If *YES*, please STOP HERE and go to the MIST Treatment Failure (P8_TRTFAIL) form.**

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

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

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

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

   ➔ **If *Questions # 3, 4, or 5a* are answered *YES*, complete a new MIST Prednisolone Medication (P8_PRED) form.**

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

Childhood Asthma Research & Education
NIH/NHLBI

PRIOR ASTHMA MEDICATION HISTORY

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

(Clinic Coordinator completed)

1. Who is the respondent? **(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

MIST RESPIRATORY ILLNESS COMPLIANCE CHECKLIST

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

(Clinic Coordinator completed)

Check the following adherence criteria at Visits 3 through 9 for used Respiratory Illness Kits. A separate Checklist should be completed for EACH used Respiratory Illness Kit. If the participant is currently using a Respiratory Illness Kit, complete a Respiratory Illness Compliance Checklist at the next visit for that kit.

1. Respiratory Illness Kit #
   (Use the kit # from the Respiratory Illness Kit) **(1000)** ___ ___

2. Start Date of the Respiratory Illness **(1010)** ___ ___ / ___ ___ / ___ ___ ___ ___ (*Month / Day / Year*)

3. Did the parent bring all of the study medications (daily and illness) to the visit? **(1020)** ❑1 Yes ❑0 No

   ➔ **If *NO*, please complete the remainder of this checklist based on parental report and the Diary Cards.**

4. Respiratory Illness Adherence

   4a. Number of respules returned (or not used if relying on parental report) **(1030)** ___ ___ respules

   4b. Number of respules used (20 - Question #4a) **(1040)** ___ ___ respules

   4c. Percent adherence = $\frac{\textit{Question \#4b}}{\textit{14}} \times \textit{100}$ **(1050)** ___ ___ ___ . ___%

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

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

   ➔ ***STOP HERE, do not complete the rest of the form.***

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. $\frac{\text{(Histamine: Largest Wheal) + (Histamine: Perpendicular Wheal)}}{2}$ = **(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. $\frac{\text{(Saline: Largest Wheal) + (Saline: Perpendicular Wheal)}}{2}$ = **(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

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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

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MIST SYMPTOMS OF RESPIRATORY ILLNESS SURVEY

Subject ID: 0 8 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Coordinator completed)

Please answer the following questions about your child's typical respiratory illness:

1. **What is <u>usually</u> the very first symptom you notice that leads you to believe your child is starting a respiratory illness?** Please choose one of the general categories in blue text from the list provided (P8_SYMPTLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space.)

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

2. **Is there <u>usually</u> a symptom you notice that makes you very certain that the illness will lead to significant breathing problems?** **(1030)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If NO, go to Question #3.***

   2a. **What is <u>usually</u> the most important symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the general categories in blue text from the list provided (P8_SYMPTLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space.)

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

   2b. **Is there <u>usually</u> a second symptom you notice that makes you very certain that the illness will lead to significant breathing problems?** **(1060)** ❑$_1$ Yes ❑$_0$ No

   ➔ ***If NO, go to Question #3.***

   2c. **What is <u>usually</u> the second symptom you notice that makes you feel certain the illness will lead to significant breathing problems?** Please choose one of the general categories in blue text from the list provided (P8_SYMPTLIST). Then choose the symptom in red text from the specific list within that category. (If the very first symptom is not on the list, please indicate the very first symptom in the 'Other' space.)

   (1070) General:_____
   (1080) Specific:_____
   Other:_____

MIST SYMPTOMS OF RESPIRATORY ILLNESS SURVEY

Subject ID: 0 8 - __ - __ __ __
Visit Number: __

3. When your child has a respiratory illness, how important are each of the symptoms?

Category		Not at all Important	Mildly Important	Moderately Important	Very Important	Not Applicable
Appearance Changes	**(1090)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Appetite Changes	**(1100)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Behavior Changes	**(1110)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Breathing Problems	**(1120)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Changes in Sleep Patterns	**(1130)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Cough A	**(1140)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Cough B	**(1150)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Fever	**(1160)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Noisy Breathing	**(1170)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Noisy Chest	**(1180)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Nose Symptoms	**(1190)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Activity Changes	**(1200)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9

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MIST SYMPTOMS OF RESPIRATORY ILLNESS

Subject ID: 0 8 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

This form is completed when the parent/guardian calls within 72 hours of beginning the respiratory illness medication. Instruct the parent/guardian to refer to the Symptoms of Respiratory Illness (P8_SYMP_PARENT) form. Record their responses onto this form using the symptom codes. Each specific symptom in red text corresponds to a general (blue text) symptom code and a specific (red text) symptom code. If the parent/guardian specified an other symptom, be sure to record the general code that the symptom was written under as well as the parent/guardian's description of the other symptom.

1. What was the very first symptom you noticed that led you to believe your child is starting a respiratory illness?

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

2. What was the most important symptom you noticed that made you feel certain this illness would lead to significant breathing problems?

(1020) General:_____
(1030) Specific:_____
Other:_____

3. What were the two most important symptoms present that led you to start the respiratory illness medications?

3a. Symptom:

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

3b. Symptom:

(1060) General:_____
(1070) Specific:_____
Other:_____

MIST
SYMPTOMS OF RESPIRATORY ILLNESS

Subject ID: 0 8 - __ - __ __ __

Visit Number: __

4. For the respiratory illness that your child is currently experiencing, how important are each of the symptoms?

Category		Not at all Important	Mildly Important	Moderately Important	Very Important	Not Applicable
Appearance Changes	**(1090)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Appetite Changes	**(1100)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Behavior Changes	**(1110)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Breathing Problems	**(1120)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Changes in Sleep Patterns	**(1130)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Cough A	**(1140)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Cough B	**(1150)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Fever	**(1160)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Noisy Breathing	**(1170)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Noisy Chest	**(1180)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Nose Symptoms	**(1190)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9
Activity Changes	**(1200)**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 9

Childhood Asthma Research & Education
NIH/NHLBI

MIST
TERMINATION OF STUDY PARTICIPATION
(Treatment Phase)

Subject ID: 0 8 - ___ - ___ ___ ___
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.***

2. Indicate the **primary** reason why the participant is being terminated from the study after randomization. **(1010)**

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

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

** ***Reason*** _____

SIGNATURE

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

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

(1030) _____ **(1040)** Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Clinic Coordinator's Signature Month Day Year

(1050) _____ **(1060)** Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Principal Investigator's Signature Month Day Year

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST TERMINATION OF STUDY PARTICIPATION (Run-In)

Subject ID: 0 8 - __ - __ __ __
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. Indicate the **primary** reason for ineligibility during the Run-In. **(1010)**

- ❑ 1 ineligible at Visit 1
- ❑ 2 insufficient adherence with study drugs
- ❑ 3 inability to demonstrate adherence with study diary
- ❑ 4 too many asthma symptoms during Run-In
- ❑ 5 asthma exacerbation during Run-In
- ❑ 6 negative API status
- ❑ 7 participant required an asthma medication other than albuterol since Visit 1
- ❑ 8 parent withdrew consent
- ❑ 9 participant lost to follow up
- ❑ 10 participant experienced a serious adverse event *
- ❑ 11 physician initiated termination of study participation **
- ❑ 12 other _____

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

** ***Reason*** _____

SIGNATURE

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

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

(1030) _____
Clinic Coordinator's Signature

(1040) Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)

(1050) _____
Principal Investigator's Signature

(1060) Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

MIST TODDLER PHYSICAL EXAMINATION

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

(Clinic Coordinator Completed)

PARENTAL HEIGHT - First study visit only or until both are completed

1. Biological mother's height (complete height or check unknown) **(1000 - 1010)** ___ feet ___ ___ inches
   (1020) ❑ 9 Unknown

2. Biological father's height (complete height or check unknown) **(1030 - 1040)** ___ feet ___ ___ inches
   (1050) ❑ 9 Unknown

PARTICIPANT MEASUREMENTS - Complete at all applicable study visits

3. Time measurements started *(based on a 24-hour clock)* **(1060)** ___ ___ ___ ___

4. Was standing height or length obtained? **(1080)** ❑ 1 Standing Height
   ❑ 2 Length

   4a. First measurement **(1090)** ___ ___ ___ . ___ cm

   4b. Second measurement **(1100)** ___ ___ ___ . ___ cm

   4c. Third measurement **(1110)** ___ ___ ___ . ___ cm

   4d. Average height or length measurement **(1120)** ___ ___ ___ . ___ cm

   ➔ ***Plot average height or length on gender- and age-appropriate growth charts. See study MOP for further details.***

   At Visit 1: Check eligibility requirements. If a child's height plots less than the 10th percentile and has crossed 2 major percentile lines during the last year, he/she is ineligible.

   All other Visits: Check for growth problems. If a child's height crosses 2 major percentile lines, falls below the 3rd percentile, or growth has been less than 1 cm during a four month period, he/she should be evaluated for growth failure.

   4e. In your judgement, was the participant's height or length measurement acceptable? **(1130)** ❑ 1 Yes ❑ 0 No

   4ei. If ***NO***, why was it unacceptable? _____
   _____

5. Weight *(shoes off, light clothing)* **(1150)** ___ ___ ___ . ___ kg

   ➔ ***Plot weight on gender- and age-appropriate growth charts. See study MOP for further details.***

   All Visits except for Visit 1: Check for growth problems. If a child's weight crosses 2 major percentile lines or falls below the 3rd percentile, he/she should be evaluated for growth failure.

6. Head circumference (Visit 1 & 9 only)

6a. First measurement **(1160)** ___ ___ ___ . ___ cm

6b. Second measurement **(1170)** ___ ___ ___ . ___ cm

6c. Third measurement **(1180)** ___ ___ ___ . ___ cm

6d. Average head circumference measurement **(1190)** ___ ___ ___ . ___ cm

➔ ***At Visit 1 & 9, plot head circumference on gender- and age-appropriate growth charts. See study MOP for further details.***

At Visit 1: Check eligibility requirements. If a child's head circumference plots less than the 3rd percentile or greater than the 97th percentile, he/she is only ineligible if the finding is clinically relevant.

6e. In your judgement, was the participant's head circumference measurement acceptable? **(1200)** ❑$_1$ Yes ❑$_0$ No

6ei. If ***NO***, why was it unacceptable? _____

_____

PULMONARY AUSCULTATION

7. Is chest auscultation clear? **(1210)** ❑$_1$ Yes ❑$_0$ No

➔ ***If YES, skip to Question #8.***

7a. Slight expiratory wheeze **(1220)** ❑$_1$ Yes ❑$_0$ No

7b. Loud expiratory wheeze **(1230)** ❑$_1$ Yes ❑$_0$ No

7c. Inspiratory and expiratory wheeze **(1240)** ❑$_1$ Yes ❑$_0$ No

7d. Rales **(1250)** ❑$_1$ Yes ❑$_0$ No

7e. Rhonchi **(1260)** ❑$_1$ Yes ❑$_0$ No

7f. Crackles **(1270)** ❑$_1$ Yes ❑$_0$ No

7g. Other_____ **(1280)** ❑$_1$ Yes ❑$_0$ No

8. Does the participant have evidence of oral candidiasis? **(1290)** ❑$_1$ Yes ❑$_0$ No

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

NOSE/EYE/SINUS SYMPTOMS

9. In general, how would you describe the participant's nasal symptoms? **(1300)**
   - ❑ 1 None
   - ❑ 2 Mild
   - ❑ 3 Moderate
   - ❑ 4 Severe

ECZEMA SYMPTOMS

10. In general, how would you describe the participant's eczema? **(1310)**
   - ❑ 1 None
   - ❑ 2 Mild
   - ❑ 3 Moderate
   - ❑ 4 Severe

VOCAL SYMPTOMS

11. In general, how would you describe the participant's vocal quality (hoarseness/tonation)? **(1320)**
   - ❑ 1 Normal
   - ❑ 2 Abnormal

11a. ***If abnormal,*** categorize the abnormality **(1330)**
   - ❑ 1 Hoarse
   - ❑ 2 Scratchy
   - ❑ 3 Other _____

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
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MIST
TREATMENT FAILURE

Subject ID: 0 8 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant received his/her fourth course of oral corticosteroids? **(1000)** ☐ 1 Yes ☐ 0 No

2. Has the participant been hospitalized for an acute exacerbation of wheezing? **(1010)** ☐ 1 Yes ☐ 0 No

3. Has the participant had an hypoxic seizure during an acute exacerbation of asthma or wheezing? **(1020)** ☐ 1 Yes ☐ 0 No

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

5. Has the participant had a serious adverse event related to a study medication? **(1040)** ☐ 1 Yes ☐ 0 No

6. Has a physician deemed the participant a treatment failure? **(1050)** ☐ 1 Yes ☐ 0 No

   ➔ ***If YES, provide a reason in Comments section***

7. 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

8. Date treatment failure occurred **(1070)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

(1080) Physician/CC Signature: _____

(1090) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS

(6000):_____

_____

_____