Table 2. Forms Completed at each Study Visit

(●=mandatory visit procedure; ❍=completed as needed)

VISIT NOTES: Visit 1 = Enrollment 3 = Randomization *Visit 2 was removed in March 2007. (56 out of 843 subjects had already been enrolled by then.)

	Visit Number								
Form Name	**1**	**2***	**3**	**4**	**5**	**6**	**7**	**8**	**9**
ACT (ages 12+) or C_ACT (ages 4-11)			●	●	●	●	●	●	●
AECLIN	❍	❍	❍	❍	❍	❍	❍	❍	❍
CAP_FEIA (or SKIN)			●						
CMED_AS	❍	❍	❍	❍	❍	❍	❍	❍	❍
P7_COMPLY		●	●	●	●	●	●	●	●
P7_COMPLY_RSC		●	●	●	●	●	●	●	●
P7_DIARY	*Completed by patient at home between every visit*								
P7_ELIG1	●								
P7_ELIG2R	●								
P7_ELIG3	●								

	Visit Number								
Form Name	**1**	**2***	**3**	**4**	**5**	**6**	**7**	**8**	**9**
P7_ELIG4 *(form removed in March 2007)*		●							
P7_ELIG5			●						
ENO	●	●	●	●	●	●	●	●	●
ENO_CHK	●	●	●	●	●	●	●	●	●
HEQ	*Completed at Visit 1, 2, or 3*								
IGE			●						
IOS_PRE	●	●	●	●	●	●	●	●	●
P7_LAB *(Can also be completed for any unscheduled pregnancy tests.)*	●		●			●			●
P7_MED		●	●	●	●	●	●	●	
MEDHX	●								
METHA			●			●			
METHA_ADD_TRT			❍			❍			
METHA_CHK			●			●			
PAQLQ(S)			●	●	●	●	●	●	●

	Visit Number								
Form Name	**1**	**2***	**3**	**4**	**5**	**6**	**7**	**8**	**9**
PEFR	●	●	●						
PFT_CHK	●	●	●	●	●	●	●	●	●
PHY_EXAM	●	●	●	●	●	●	●	●	●
PRIORMED	●								
REGISTRY	●								
SERIOUS	❍	❍	❍	❍	❍	❍	❍	❍	❍
SKIN (or CAP_FEIA)			●						
SPIRO_POST	●				●			●	
SPIRO_PRE	●	●	●	●	●	●	●	●	●
P7_TERM			❍	❍	❍	❍	❍	❍	●
P7_TERMR	❍	❍	❍						
P7_TRTFAIL			❍	❍	❍	❍	❍	❍	●

Childhood Asthma Research & Education
NIH/NHLBI

ASTHMA CONTROL TEST™
For Ages 12+ Years

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

(Participant or Parent/Legal Guardian Completed)

Write the number of each answer in the score box provided. Please answer as honestly as possible. This will help you and your doctor discuss whether your asthma is controlled as well as it could be. **SCORE**

1. In the past **4 weeks**, how much of the time did your **asthma** keep you from getting as much done at work, school or at home?

All of the time 1	Most of the time 2	Some of the time 3	A little of the time 4	None of the time 5

__ **(Q1000)**

2. During the past **4 weeks**, how often have you had shortness of breath?

More than once a day 1	Once a day 2	3 to 6 times a week 3	Once or twice a week 4	Not at all 5

__ **(Q1010)**

3. During the past **4 weeks**, how often did your **asthma** symptoms (wheezing, coughing, shortness of breath, chest tightness, or pain) wake you up at night or earlier than usual in the morning?

4 or more nights a week 1	2 or 3 nights a week 2	Once a week 3	Once or twice 4	Not at all 5

__ **(Q1020)**

4. During the past **4 weeks**, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?

3 or more times per day 1	1 or 2 times per day 2	2 or 3 times per week 3	Once a week or less 4	Not at all 5

__ **(Q1030)**

5. How would you rate your **asthma** control during the **past 4 weeks**?

Not controlled at all 1	Poorly controlled 2	Somewhat controlled 3	Well controlled 4	Completely controlled 5

__ **(Q1040)**

(Clinic Coordinator Completed)

Add the answers from Questions #1 - #5 and write the score in Question #6. If the score is 19 or less, the participant's asthma may not be controlled as well as it could be.

6. Total *(Do not data enter)* __ __

COMMENTS
(6000):_____

_____

_____

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
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ASTHMA CONTROL TEST™ For Children 4 – 11 Years Old

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

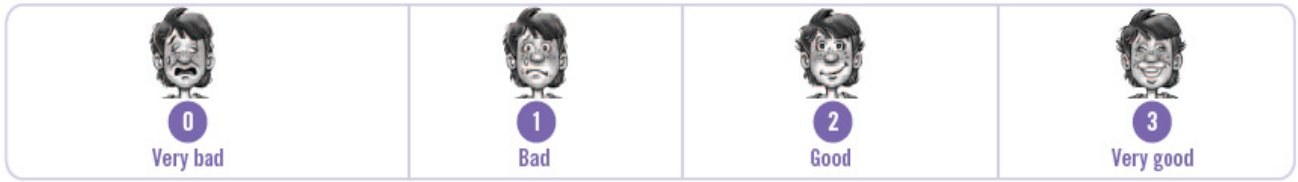
(Participant or Parent/Legal Guardian Completed)

How to take the Childhood Asthma Control Test

Let your child respond to **the first four questions (1 to 4)**. If your child needs help reading or understanding the question, you may help, but let your child select the response. Complete the remaining **three questions (5 to 7)** on your own without letting your child's response influence your answers. There are no right or wrong answers.

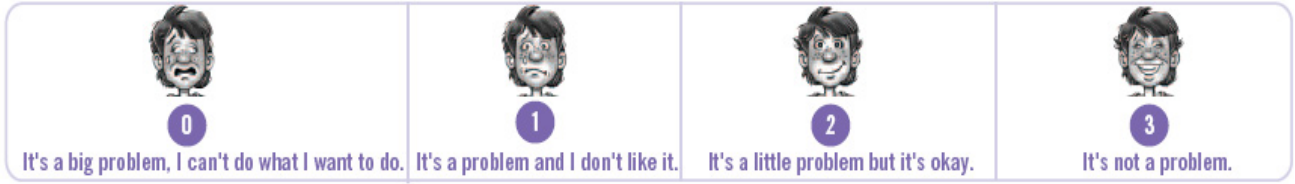
Have your child complete these questions. **SCORE**

1. How is your asthma today?



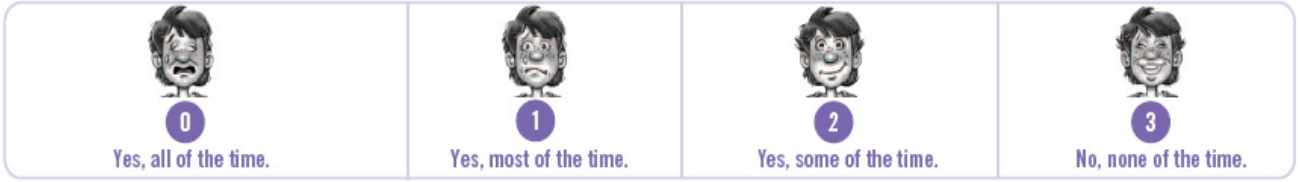
__ (Q1000)

2. How much of a problem is your asthma when you run, exercise, or play sports?



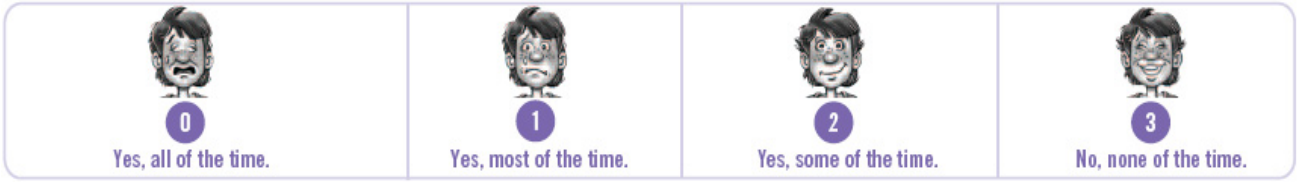
__ (Q1010)

3. Do you cough because of your asthma?



__ (Q1020)

4. Do you wake up during the night because of your asthma?



__ (Q1030)

Please complete the following questions on your own.

5. During the last four weeks, on average, how many days per month did your child have daytime asthma symptoms?

5 Not at all | 4 1-3 days/mo | 3 4-10 days/mo | 2 11-18 days/mo | 1 19-24 days/mo | 0 Everyday

__ (Q1040)

6. During the last 4 weeks, on average, how many days per month did your child wheeze during the day because of asthma?

5 Not at all | 4 1-3 days/mo | 3 4-10 days/mo | 2 11-18 days/mo | 1 19-24 days/mo | 0 Everyday

__ (Q1050)

7. During the last 4 weeks, on average, how many days per month did your child wake up during the night because of asthma?

5 Not at all | 4 1-3 days/mo | 3 4-10 days/mo | 2 11-18 days/mo | 1 19-24 days/mo | 0 Everyday

__ (Q1060)

(Clinic Coordinator Completed)

Add the answers from Questions #1 - #7 and write the score in Question #8. If the score is 19 or less, it may be a sign that the participant's asthma is not controlled as well as it could be.

8. Total *(Do not data enter)* __ __

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

CAP/FEIA RESULTS

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

(Clinic Coordinator Completed)

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education

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CONCOMITANT MEDICATIONS for ASTHMA/ALLERGY-RELATED DRUGS

Subject ID: ___ ___- ___ - ___ ___ ___

Subject Initials: ___ ___ ___

Visit Number: ___ ___

(Clinic Coordinator completed)

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

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

❑$_0$ None

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

Childhood Asthma Research & Education
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TREXA BROWN DAILY INHALER DOSING COMPLIANCE FORM

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

(Clinic Coordinator completed)

Directions: Participant adherence with the brown Daily Inhaler dosing schedule must be assessed at each visit. Complete the table below using the DOSER™ history from the brown Daily Inhaler for all full days between the current and last visit. You may not need to complete all of the days that are included in the table. If the number of puffs taken is at least 2, the participant is considered to be adherent for the given day.

DOSER™ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
# Scheduled puffs for the brown Daily Inhaler	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
# Puffs in DOSER™ history for the brown Daily Inhaler															
Adherent? (✓ if yes)															

DOSER™ Day	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
# Scheduled puffs for the brown Daily Inhaler	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
# Puffs in DOSER™ history for the brown Daily Inhaler															
Adherent? (✓ if yes)															

1. Number of days between current and last visit (or 30, whichever is smaller) **(1000)** ___ ___ days

2. Number of adherent days **(1010)** ___ ___ days

3. Percent adherence $\frac{\textit{Question \#2}}{\textit{Question \#1}}$ *x 100* **(1020)** ___ ___ ___ . ___%

If the percent adherence is < 75%, re-emphasize the importance of maintaining the daily dosing schedule.

Childhood Asthma Research & Education
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TREXA RED ALBUTEROL INHALER AND WHITE RESCUE INHALER DOSING COMPLIANCE FORM

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

(Clinic Coordinator completed) **Directions:** Participant adherence to using the same number of puffs from both the red Albuterol Inhaler and the white Rescue Inhaler for asthma symptoms or low peak flow must be assessed at Visits 2-9. Complete the table below using the red Albuterol Inhaler and white Rescue Inhaler DOSER™ histories for all full days between the current and last visits.

DOSER™ Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
# Puffs in DOSER™ history for the **red Albuterol Inhaler**															
# Puffs albuterol taken before exercise (P7_DIARY Question #14)															
# Puffs in DOSER™ history for the **white Rescue Inhaler**															
DOSER™ histories match? (✓ if yes) (If pre-exercise albuterol accounts for the difference, check that a match occurred. Day 1 = yesterday)															

DOSER™ Day	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
# Puffs in DOSER™ history for the **red Albuterol Inhaler**															
# Puffs albuterol taken before exercise (P7_DIARY Question #14)															
# Puffs in DOSER™ history for the **white Rescue Inhaler**															
DOSER™ histories match? (✓ if yes) (If pre-exercise albuterol accounts for the difference, check that a match occurred. Day 1 = yesterday)															

1. Number of days between current and last visit (or 30, whichever is smaller) **(1000)** ___ ___ days
2. Number of matching days **(1010)** ___ ___ days
3. Percent adherence $\frac{\textit{Question \#2}}{\textit{Question \#1}}$ x 100 **(1020)** ___ ___ ___ . ___%

If the percent adherence is < 75%, re-emphasize the importance of using the same number of puffs from the red Albuterol Inhaler and the white Rescue Inhaler (except pre-treatment before exercise).

Subject ID: 0 7 - ___ - ___ ___ ___

Subject Initials: ___ ___ ___

TREXA DIARY CARD

Return Visit Number: ___ ___

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

Personal Peak Flow Reference Value	_____ *Best*	Below _____ *Red Zone*		_____ to _____ *Yellow Zone*		_____ or above *Green Zone*	
Complete with blue or black ink	Day 1:_____	Day 2:_____	Day 3:_____	Day 4:_____	Day 5:_____	Day 6:_____	Day 7:_____
Date (month/day)	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___	___ / ___
Complete at Wake Up							
1. Awakened at night to use albuterol for asthma? (1000)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
2. Time of Wake Up Peak Flow (1010)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
3. Wake Up Peak Flow (Best of 3 tries) (1020)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
4. Albuterol used in the two hours before Wake Up Peak Flow? (1030)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
5. One inhalation taken from your **brown Daily Inhaler** at Wake Up? (1040)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
6. Coordinator Completed Wake Up FEV_1 (liters) (1050)	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __
Complete at Bedtime							
7. Time of Bedtime Peak Flow (1060)	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __	__ __ : __ __
8. Bedtime Peak Flow (Best of 3 tries) (1070)	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___
9. Albuterol used in the two hours before Bedtime Peak Flow? (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
10. One inhalation taken from your **brown Daily Inhaler** at bedtime? (1090)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
11. Coordinator Completed Bedtime FEV_1 (liters) (1120)	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __	__ . __ __
Symptom Rating Scale 0 = None (No symptoms) 1 = Mild (Awareness of symptoms that were easily tolerated) 2 = Moderate (Symptoms with some discomfort, causing some interference of sleep or daily activities) 3 = Severe (Symptoms which led to inability to sleep or perform daily activities)	**Complete at Bedtime for the Past 24 Hours**						
12. Rate your coughing from asthma during the past 24 hours. (1130)	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
13. Rate your wheezing during the past 24 hours. (1140)	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3
14. Number of puffs from your **red Albuterol Inhaler** taken **before exercise** in the past 24 hours. (1150)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
15. Number of puffs from your **red Albuterol Inhaler** taken for **asthma symptoms or low peak flow** in the past 24 hours. (1160)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
16. Number of puffs from your **white Rescue Inhaler** taken for **asthma symptoms or low peak flow** in the past 24 hours. (1170)	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___	___ ___
17. Absent from school or work for asthma symptoms? (1180)	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9	Yes_1 No_0 N/A_9
18. Seen by a health care provider for asthma symptoms? (1190)	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0	Yes_1 No_0
19. Coordinator Completed (Visit 2 & 3) Did the participant have either... • #3 or #8 in the Yellow or Red Zones **or** • #12, #13, #15, or 16 more than 0?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 1 Visit 1

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

Informed Consent and Participant Assent

1. Has the parent/legal guardian appropriately signed and dated the informed consent? **(1000)** ☐1 Yes ☐0 No
   1a. If ***YES***, record the date the form was signed. **(1010)** __ __ / __ __ / __ __ __ __ (Month / Day / Year)
2. Has the participant appropriately signed and dated the assent form, or if the participant is less than 7 years old, has the participant given verbal assent? **(1020)** ☐1 Yes ☐0 No
   2a. If ***YES***, record the date the assent was signed or verbally given. **(1030)** __ __ / __ __ / __ __ __ __ (Month / Day / Year)
3. Has the participant consented to a genotype evaluation? **(1040)** ☐1 Yes ☐0 No
   3a. If ***YES***, record the date the form was signed. **(1050)** __ __ / __ __ / __ __ __ __ (Month / Day / Year)
4. Will the participant be using Spanish translated materials while enrolled in the TREXA Study? **(1055)** ☐1 Yes ☐0 No

Study Medicines

5. Is the participant currently intolerant of or allergic to QVAR (beclomethasone) or any of its ingredients? **(1070)** ☐1 Yes ☐0 No ☐9 Don't know
6. Is the participant able to take albuterol such as Proventil and Ventolin? **(1080)** ☐1 Yes ☐0 No

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

7. Has the participant had her first period? **(1090)** ☐1 Yes ☐0 No
   If ***YES***, please complete Questions #6a and #6b.
   7a. Is the participant currently pregnant or nursing? **(1100)** ☐1 Yes ☐0 No
   7b. Does the participant agree to avoid pregnancy during the study? **(1110)** ☐1 Yes ☐0 No

8. Is the participant eligible? **(1120)** ☐1 Yes ☐0 No
   If any of the shaded boxes are selected, the participant is ineligible.

   ➔ **If *NO*, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

Medical History Criteria

9.	Is the participant 6 to < 18 years old?	**(1130)**	☐ 1 Yes	☐ 0 No
10.	Has the participant smoked 11 or more cigarettes or any other substance in the past year?	**(1140)**	☐ 1 Yes	☐ 0 No
11.	Has the participant used smokeless tobacco products (chew, snuff) 11 or more times in the past year?	**(1150)**	☐ 1 Yes	☐ 0 No
12.	Has the participant ever had chicken pox or received the chicken pox vaccine? (*Refer to MOP for discussion on immunization records*)	**(1160)**	☐ 1 Yes	☐ 0 No
13.	Is the participant receiving allergy shots?	**(1170)**	☐ 1 Yes	☐ 0 No
	13a. If ***YES***, has the dose been changed in the past 3 months?	**(1180)**	☐ 1 Yes	☐ 0 No
14.	Has the participant ever had oral or systemic corticosteroids for asthma?	**(1185)**	☐ 1 Yes	☐ 0 No

➔ ***If NO, skip to Question #17***

15.	What is the approximate date of the participant's last course of oral or systemic corticosteroids for asthma? *(Please complete the month and year **OR** select Don't Know. If only the year is known, leave the month blank)*	**(1190 - 1191)**	__ __ / __ __ __ __ *Month* *Year*
		(1192)	☐ 9 Don't Know
16.	Has the participant had more than 2 asthma exacerbations during the past year or any during the past 3 months?	**(1205)**	☐ 1 Yes ☐ 0 No
17.	Has the participant been hospitalized for asthma during the past year?	**(1208)**	☐ 1 Yes ☐ 0 No
18.	Has the participant ever had an asthma exacerbation resulting in intubation, mechanical ventilation or resulting in a hypoxic seizure?	**(1210)**	☐ 1 Yes ☐ 0 No
19.	Has the participant used an oral, injectable or systemic corticosteroid for any non-asthmatic reason in the past 2 weeks?	**(1230)**	☐ 1 Yes ☐ 0 No
20.	Does the participant have concurrent medical problems other than asthma that are likely to require a systemic corticosteroid during the study (for example, severe eczema, inflammatory bowel disease, rheumatoid arthritis, lupus)?	**(1240)**	☐ 1 Yes ☐ 0 No
21.	Does the participant have any active or chronic lung disease other than asthma?	**(1250)**	☐ 1 Yes ☐ 0 No

22. Does the participant have a significant medical illness other than asthma [e.g. cardiac (including arrhythmias), liver, gastrointestinal, endocrine, seizures, immunodeficiency disorders, myasthenia gravis, active urinary tract obstruction, thyroid disease, diabetes mellitus, Cushing's disease, Addison's disease]? **(1260)** ☐1 Yes ☐0 No

23. Does the participant have a history of gastroesophageal reflux symptoms not controlled by standard medical therapy? **(1270)** ☐1 Yes ☐0 No

24. Does the participant have a history of cataracts, glaucoma, or any other medical disorder associated with an adverse effect to corticosteroids? **(1280)** ☐1 Yes ☐0 No

25. During the past 2 weeks, has the participant used any medications known to significantly interact with corticosteroid disposition including but not limited to carbomazepine, erythromycin or other macrolide antibiotics, phenobarbital, phenytoin, rifampin or ketoconazole? **(1290)** ☐1 Yes ☐0 No

26. Has the participant used any of the drugs listed on the Exclusionary Drugs reference card (P7_EXCLDRUG) during the designated washout periods? **(1300)** ☐1 Yes ☐0 No

27. Has the participant been involved in another investigational drug study within the past month (except for the CARE Network BADGER trial)? **(1310)** ☐1 Yes ☐0 No

Other Criteria

28. Does the participant's family have plans to move out of the area within the next 12 months? **(1320)** ☐1 Yes ☐0 No

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

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

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

➔ **If *NO*, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 2 Visit 1

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

1. In the past 4 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms? (Do not include pre-exercise albuterol use.) **(1000)** __ __ days

   1a. Is Question #1 > 8? **(1010)** ☐1 Yes ☐0 No

2. In the past 4 weeks, during how many nights has the participant woken up to use albuterol for asthma? **(1020)** __ __ nights

   2a. Is Question #2 > 2? **(1030)** ☐1 Yes ☐0 No

3. Has the participant received combination therapy treatment with an inhaled corticosteroid for the past 8 consecutive weeks? **(1035)** ☐1 Yes ☐0 No

   ➔ If ***YES,* STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

4. In the past year, has the participant had evidence of mild persistent asthma (at some time during the past year symptoms or albuterol use for symptoms on average > 2 days/week or > 2 nighttime awakenings/month) OR has the participant been on monotherapy treatment with an inhaled corticosteroid regularly? **(1037)** ☐1 Yes ☐0 No

5. Has the participant received monotherapy treatment with an inhaled corticosteroid for the past 8 consecutive weeks? **(1040)** ☐1 Yes ☐0 No

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

   5a. If ***YES***, which inhaled corticosteroid was the participant taking most recently? **(1050)**
   - ☐1 QVAR (beclomethasone HFA)
   - ☐2 Pulmicort (budesonide)
   - ☐3 Aerobid (flunisolide)
   - ☐4 Flovent (fluticasone MDI)
   - ☐5 Flovent (fluticasone DPI)
   - ☐6 Azmacort (triamcinolone)
   - ☐7 Asmanex (mometasone)

   5b. What was the most recent dose of inhaled corticosteroid? **(1060)** __ __ __ __ mcg/day

   5c. What is the pre-enrollment beclomethasone dose equivalent according to the Beclomethasone Equivalence Table (P7_ICSTABLE)? **(1070)**
   - ☐1 ≤ 160 mcg/day
   - ☐2 > 160 mcg/day

   ➔ **SKIP to Question #7.**

TREXA ELIGIBILITY CHECKLIST 2 Visit 1

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

6. Has the participant had 1 - 2 exacerbations in the past year? **(1075)** ☐ 1 Yes ☐ 0 No

   6a. If ***YES***, has the participant had an exacerbation in the past 6 months? **(1080)** ☐ 1 Yes ☐ 0 No

Exacerbation is defined as an emergency room visit related to asthma/wheezing, 3 albuterol treatments in a physician's office, or a systemic corticosteroid burst for asthma.

7. Is the participant eligible? **(1110)** ☐ 1 Yes ☐ 0 No
   If any of the shaded boxes are selected, the participant is ineligible.

   ➔ **If NO, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

   ➔ **If YES, the participant's beclomethasone dose should be 80 mcg/day.**

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 2 Visit 1

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. In the past 4 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms? (Do not include pre-exercise albuterol use.) **(1000)** ___ ___ days

   1a. Is Question #1 > 8? **(1010)** ☐ 1 Yes ☐ 0 No

2. In the past 4 weeks, during how many nights has the participant woken up to use albuterol for asthma? **(1020)** ___ ___ nights

   2a. Is Question #2 > 2? **(1030)** ☐ 1 Yes ☐ 0 No

3. Has the participant received combination therapy treatment with an inhaled corticosteroid for the past 8 consecutive weeks? **(1035)** ☐ 1 Yes ☐ 0 No

   ➔ If ***YES,* STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

4. Has the participant received monotherapy treatment with either an inhaled corticosteroid or an age-appropriate dose of a leukotriene receptor antagonist (LTRA) for the past 8 consecutive weeks? **(1040)** ☐ 1 Yes ☐ 0 No

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

   4a. If ***YES***, which medication was the participant taking most recently? **(1050)**
   - ☐ 1 QVAR (beclomethasone HFA)
   - ☐ 2 Pulmicort (budesonide)
   - ☐ 3 Aerobid (flunisolide)
   - ☐ 4 Flovent (fluticasone MDI)
   - ☐ 5 Flovent (fluticasone DPI)
   - ☐ 6 Azmacort (triamcinolone)
   - ☐ 7 Asmanex (mometasone)
   - ☐ 8 an LTRA (montelukast or zafirlukast)

   ➔ If ***an LTRA***, SKIP to Question #4d.

   4b. What was the most recent dose of inhaled corticosteroid? **(1060)** ___ ___ ___ ___ mcg/day

   4c. What is the pre-enrollment beclomethasone dose equivalent according to the Beclomethasone Equivalence Table (P7_ICSTABLE)? **(1070)**
   - ☐ 1 ≤ 160 mcg/day
   - ☐ 2 > 160 mcg/day

   4d. Has the participant received treatment with either an inhaled corticosteroid or an age-appropriate dose of a leukotriene recepter antagonist (LTRA) for the past year? **(1071)** ☐ 1 Yes ☐ 0 No

   ➔ **If *YES*, SKIP to Question #6.**

TREXA ELIGIBILITY CHECKLIST 2 Visit 1

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

4e. In the past year, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month)? **(1072)** ❑1 Yes ❑0 No

➔ **SKIP to Question #6.**

5. Has the participant had 1 - 2 exacerbations in the past year? **(1075)** ❑1 Yes ❑0 No

5a. If ***YES***, has the participant had an exacerbation in the past 3 months? **(1080)** ❑1 Yes ❑0 No

5b. In the past 2 years, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month)? **(1090)** ❑1 Yes ❑0 No

Exacerbation is defined as an emergency room visit related to asthma/wheezing, 3 albuterol treatments in a physician's office, or a systemic corticosteroid burst for asthma.

6. Is the participant eligible? **(1110)** ❑1 Yes ❑0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If NO, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

➔ **If YES, the participant's beclomethasone dose should be 80 mcg/day.**

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 2 Visit 1 Revised

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: 0 1
Visit Date: __ __ / __ __ / __ __ __ __ (Month / Day / Year)
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

1. Has the participant received combination therapy treatment with an inhaled corticosteroid for the past 8 consecutive weeks? **(1035)** ☐1 Yes ☐0 No

   ➔ If ***YES,*** **STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

2. In the past 4 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms? (Do not include pre-exercise albuterol use.) **(1000)** __ __ days

3. In the past 4 weeks, during how many nights has the participant woken up to use albuterol for asthma? **(1020)** __ __ nights

4. Has the participant received monotherapy treatment with either an inhaled corticosteroid or an age-appropriate dose of a leukotriene receptor antagonist (LTRA) or other non-ICS controller (i.e., salmeterol, formoterol, theophylline, cromolyn or nedocromil) for the past 8 consecutive weeks? **(1040)** ☐1 Yes ☐0 No

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

   4a. If ***YES***, which medication was the participant taking most recently? **(1050)**
   - ☐1 QVAR (beclomethasone HFA)
   - ☐2 Pulmicort (budesonide)
   - ☐3 Aerobid (flunisolide)
   - ☐4 Flovent (fluticasone MDI)
   - ☐5 Flovent (fluticasone DPI)
   - ☐6 Azmacort (triamcinolone)
   - ☐7 Asmanex (mometasone)
   - ☐8 an LTRA (montelukast or zafirlukast)
   - ☐9 Salmeterol or formoterol
   - ☐10 Theophylline
   - ☐11 Cromolyn/nedocromil

   ➔ **If *8, 9, 10, 11*, SKIP to Question #4d.**

   4b. What was the most recent dose of inhaled corticosteroid? **(1060)** __ __ __ __ mcg/day

   4c. What is the pre-enrollment beclomethasone dose equivalent according to the Beclomethasone Equivalence Table (P7_ICSTABLE)? **(1070)**
   - ☐1 < 160 mcg/day
   - ☐2 > 160 mcg/day
   - ☐3 = 160 mcg/day

   ➔ **If the gray box is selected, SKIP to Question #6.**

4ci. If **the starred box is selected**, in the past 8 weeks, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month)? **(1120)** ☐ 1 Yes ☐ 0 No

➔ **If YES, SKIP to Question #6.**

4d. In the past 2 years, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month) OR the need to use daily controller therapy to remain well controlled? **(1072)** ☐ 1 Yes ☐ 0 No

➔ **SKIP to Question #6.**

5. Has the participant had 1 - 2 exacerbations in the past year? **(1075)** ☐ 1 Yes ☐ 0 No

5a. If ***YES***, has the participant had an exacerbation in the past 3 months? **(1080)** ☐ 1 Yes ☐ 0 No

5b. In the past 2 years, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month)? **(1090)** ☐ 1 Yes ☐ 0 No

Exacerbation is defined as an emergency room visit related to asthma/wheezing, 3 albuterol treatments in a physician's office, or a systemic corticosteroid burst for asthma.

6. Is the participant eligible? **(1110)** ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If NO, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 2 Visit 1 Revised

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant received combination therapy treatment with an inhaled corticosteroid for the past 8 consecutive weeks? **(1035)** ☐1 Yes ☐0 No

   ➔ If ***YES,* STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

2. In the past 4 weeks, on how many days has the participant had coughing or wheezing from asthma or used albuterol for asthma symptoms? (Do not include pre-exercise albuterol use.) **(1000)** ___ ___ days

3. In the past 4 weeks, during how many nights has the participant woken up to use albuterol for asthma? **(1020)** ___ ___ nights

4. Has the participant received monotherapy treatment with either an inhaled corticosteroid or an age-appropriate dose of a leukotriene receptor antagonist (LTRA) or other non-ICS controller (i.e., salmeterol, formoterol, theophylline, cromolyn or nedocromil) for the past 8 consecutive weeks? **(1040)** ☐1 Yes ☐0 No

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

   4a. If ***YES***, which medication was the participant taking most recently? **(1050)**
   - ☐1 QVAR (beclomethasone HFA)
   - ☐2 Pulmicort (budesonide)
   - ☐3 Aerobid (flunisolide)
   - ☐4 Flovent (fluticasone MDI)
   - ☐5 Flovent (fluticasone DPI)
   - ☐6 Azmacort (triamcinolone)
   - ☐7 Asmanex (mometasone)
   - ☐8 an LTRA (montelukast or zafirlukast)
   - ☐9 Salmeterol or formoterol
   - ☐10 Theophylline
   - ☐11 Cromolyn/nedocromil

   ➔ **If *8, 9, 10, 11*, SKIP to Question #6.**

   4b. What was the most recent dose of inhaled corticosteroid? **(1060)** ___ ___ ___ ___ mcg/day

   4c. What is the pre-enrollment beclomethasone dose equivalent according to the Beclomethasone Equivalence Table (P7_ICSTABLE)? **(1070)**
   - ☐1 < 160 mcg/day
   - ☐2 > 160 mcg/day
   - ☒3 = 160 mcg/day

   ➔ **If 1 or 2 is selected, SKIP to Question #6.**

4ci. If **the starred box is selected**, in the past 8 weeks, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month)? **(1120)** ☐ 1 Yes ☐ 0 No

➔ **SKIP to Question #6.**

5. Has the participant had 1 - 2 exacerbations in the past year? **(1075)** ☐ 1 Yes ☐ 0 No

5a. If ***YES***, has the participant had an exacerbation in the past 3 months? **(1080)** ☐ 1 Yes ☐ 0 No

5b. Sometime in the past 2 years, has the participant needed to use daily controller therapy over at least a 1 month period in order to remain well controlled? **(1085)** ☐ 1 Yes ☐ 0 No

➔ **If *YES*, SKIP to Question #6.**

5c. Sometime in the past 2 years, has the participant had a history of mild persistent asthma (symptoms or albuterol use for symptoms on average > 2 days per week or > 2 nighttime awakenings per month) over at least a 1 month period? **(1088)** ☐ 1 Yes ☐ 0 No

Exacerbation is defined as an emergency room visit related to asthma/wheezing, 3 albuterol treatments in a physician's office, or a systemic corticosteroid burst for asthma.

6. Is the participant eligible? **(1110)** ☐ 1 Yes ☐ 0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If NO, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

COMMENTS
(6000):_____

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_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 3 Visit 1

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 1
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

Pulmonary Function Criteria (Visit 1)

1. Is the participant's pre-bronchodilator FEV_1 % predicted ≥ 60%? **(1000)** ❑ 1 Yes ❑ 0 No

2. Is the participant able to perform reproducible Spirometry according to ATS criteria? **(1010)** ❑ 1 Yes ❑ 0 No

3. Did the participant meet the reversibility requirement of ≥ 12% improvement in FEV_1 following bronchodilator administration (4 puffs)? **(1020)** ❑ 1 Yes ❑ 0 No

Clinic Use Only

Visit 1 Reversal

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

4. Is the participant eligible? **(1030)** ❑ 1 Yes ❑ 0 No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 5 Visit 3

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 3
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since the last study visit, has the participant used an oral or injectable corticosteroid for any reason? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***YES,* STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

Adherence Criteria

2. Is the participant able to perform the study procedures? **(1070)** ❑1 Yes ❑0 No

3. Number of days since the last study visit (not including study visit days) **(1080)** ___ ___ days

4. Diary and peak flow adherence

   4a. Number of complete measurements in the defined interval [measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measurements, coughing and wheezing symptoms, and red Albuterol Inhaler and white Rescue Inhaler use for asthma symptoms or low peak flow (Diary Questions #1, 3, 8, 12, 13, 15, and 16)]? **(1090)** ___ ___ ___ measurements

   4b. Percent adherence = $\frac{\textit{Question \#4a}}{\textit{(Question \#3x 7)}}$ x *100* **(1100)** ___ ___ ___ . ___%

5. Is the percent adherence ≥ 75%? **(1110)** ❑1 Yes ❑0 No

6. Has the participant shown evidence of adherence (≥ 75%) with the brown Daily Inhaler? **(1120)** ❑1 Yes ❑0 No

7. Has the participant shown evidence of adherence (≥ 75%) with the red Albuterol Inhaler and white Rescue Inhaler? **(1125)** ❑1 Yes ❑0 No

Asthma Control Check

Complete the last question on the Diary Cards, and use the BADGER/TREXA Asthma Control Verification program along with all Run-In Diary Cards to determine whether the participant's asthma has been controlled since Visit 1. (Use the zones calculated at Visit 1 to classify the peak flow values since the last visit.)

8. Has the participant's asthma been controlled since Visit 1? **(1130)** ❑1 Yes ❑0 No

9. 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 TREXA Termination of Study Participation (P7_TERMR) form.**

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 5 Visit 3

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 3
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

Pulmonary Function Criteria

10. Is the participant's pre-bronchodilator FEV_1 % predicted ≥ 80%? **(1135)** ☐ 1 Yes ☐ 0 No

    ➔ ***If NO,* SKIP to Question #16.**

11. Was the participant able to demonstrate ≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with 4 puffs albuterol at Visit 1? **(1140)** ☐* 1 Yes ☐ 0 No

    11a. If ***NO***, was the participant able to demonstrate ≥ 12% improvement in FEV_1 following the post-bronchodilator testing procedure with a maximum of 4 puffs albuterol during a CARE center PI-approved procedure in the past 2 years? (The Visit 3 Methacholine Challenge must still be performed.) **(1142)** ☐* 1 Yes ☐ 0 No

    ➔ **If *YES*, send a copy of the source documentation report to the DCC with the Visit 3 packet.**

12. Is the participant able to demonstrate either a methacholine PC_{20} ≤ 12.5 mg/ml OR a ≥ 12% improvement in FEV_1 following bronchodilator administration with 4 puffs albuterol? **(1145)** ☐* 1 Yes ☐ 0 No

    ➔ **If *YES*, skip to Question #14.**

13. Was the participant able to demonstrate methacholine PC_{20} ≤ 12.5 mg/ml in another CARE study within the past 2 years? **(1147)** ☐* 1 Yes ☐ 0 No

14. Is at least one of the starred boxes selected in Questions #11 - #13? **(1148)** ☐ 1 Yes ☐ 0 No

15. Did the participant provide (or previously provide) a blood sample for genetics? **(1150)** ☐ 1 Yes ☐ 0 No

16. Is there any other reason for which this participant should not be included in this study? **(1155)** ☐ 1 Yes ☐ 0 No

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

17. Is the participant eligible? **(1165)** ☐ 1 Yes ☐ 0 No
    If any of the shaded boxes are selected, the participant is ineligible.

    ➔ **If *NO*, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

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

18. **Drug Packet Number (record on P7_LOG)** ___ - ___ ___ ___ - ___ ___ ___
    (1170) (1180) (1190)

(1200) Physician/CC Signature: _____

(1210) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS
(6000):_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 5 Visit 3

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 3
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Since the last study visit, has the participant used an oral or injectable corticosteroid for any reason? **(1000)** ❑1 Yes ❑0 No

   ➔ If ***YES,* STOP HERE.** The participant is ineligible, please complete the P7_TERMR form.

Adherence Criteria

2. Is the participant able to perform the study procedures? **(1070)** ❑1 Yes ❑0 No

3. Number of days since the last study visit (not including study visit days) **(1080)** ___ ___ days

4. Diary and peak flow adherence

   4a. Number of complete measurements in the defined interval [measurements that count toward adherence include nighttime awakenings, AM and PM peak flow measurements, coughing and wheezing symptoms, and red Albuterol Inhaler and white Rescue Inhaler use for asthma symptoms or low peak flow (Diary Questions #1, 3, 8, 12, 13, 15, and 16)]? **(1090)** ___ ___ ___ measurements

   4b. Percent adherence = $\frac{\textit{Question \#4a}}{\textit{(Question \#3x 7)}}$ x *100* **(1100)** ___ ___ ___ . ___%

5. Is the percent adherence ≥ 75%? **(1110)** ❑1 Yes ❑0 No

6. Has the participant shown evidence of adherence (≥ 75%) with the brown Daily Inhaler? **(1120)** ❑1 Yes ❑0 No

7. Has the participant shown evidence of adherence (≥ 75%) with the red Albuterol Inhaler and white Rescue Inhaler? **(1125)** ❑1 Yes ❑0 No

Asthma Control Check

Complete the last question on the Diary Cards, and use the BADGER/TREXA Asthma Control Verification program along with all Run-In Diary Cards to determine whether the participant's asthma has been controlled since Visit 1. (Use the zones calculated at Visit 1 to classify the peak flow values since the last visit.)

8. Has the participant's asthma been controlled since Visit 1? **(1130)** ❑1 Yes ❑0 No

9. 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 TREXA Termination of Study Participation (P7_TERMR) form.**

Childhood Asthma Research & Education
NIH/NHLBI

TREXA ELIGIBILITY CHECKLIST 5 Visit 3

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: 0 3
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

Pulmonary Function Criteria

10. Is the participant's pre-bronchodilator FEV_1 % predicted ≥ 80%? **(1135)** ❑$_1$ Yes ❑$_0$ No

➔ ***If NO,* SKIP to Question #13.**

11. Did the participant provide (or previously provide) a blood sample for genetics? **(1150)** ❑$_1$ Yes ❑$_0$ No

12. Is there any other reason for which this participant should not be included in this study? **(1155)** ❑$_1$ Yes ❑$_0$ No

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

13. Is the participant eligible? **(1165)** ❑$_1$ Yes ❑$_0$ No
If any of the shaded boxes are selected, the participant is ineligible.

➔ **If *NO*, please STOP HERE and complete the TREXA Termination of Study Participation (P7_TERMR) form.**

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

14. **Drug Packet Number (record on P7_LOG)** ___ - ___ ___ ___ - ___ ___ ___
(1170) (1180) (1190)

(1200) Physician/CC Signature: _____

(1210) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

EXHALED NITRIC OXIDE

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

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

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

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

Measured FENO

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

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

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

EXHALED NITRIC OXIDE CHECKLIST

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

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

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

EXCLUSIONS AND CONFOUNDERS

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

   ➔ ***If NO, skip to Question 2.***

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

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

   If ***YES***, explain_____

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

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

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

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

Proceed to the Exhaled Nitric Oxide (ENO) form.

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

HOME ENVIRONMENT QUESTIONNAIRE

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

(Parent/Legal Guardian or Participant Completed)

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

GENERAL HOUSE CHARACTERISTICS

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

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

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

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

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

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

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

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

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

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

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

9. Which rooms use a window unit?

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

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

(1150) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

12. Which rooms use a window unit?

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

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

(1220) ☐ 1 Yes ☐ 0 No ☐ 9 Don't know

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

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

15. Which rooms use a humidifier?

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

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

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

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

18. Which rooms use a dehumidifier?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1640) ___ ___ years

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

(1650) ❑ 1 Yes ❑ 0 No

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

(1660) ❑ 1 Yes ■ 0 No

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

(1670) ❑ 1 Yes ❑ 0 No

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

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

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

(1690) ___ ___ years

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

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

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

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

ANIMALS

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

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

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

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

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

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

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

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

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

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

Clinic Coordinator Completed

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

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):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PRE-BRONCHODILATOR IOS

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

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

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

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING

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

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

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

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

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

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

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

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

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

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

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

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

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

IOS STANDARDS

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

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

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

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

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

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

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

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

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

COMMENTS

(6000): _____

_____

_____

_____

_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA LABORATORY TESTS

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

URINE PREGNANCY TEST (Visits 1, 3, 6, 9, and unscheduled pregnancy tests)

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

(1000) ☞1 Positive
☐0 Negative
☐9 N/A

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

➔ ***If pregnancy test results are positive, the participant must be terminated from study participation. Complete a Termination of Study Participation (P7_TERMR for Run-In participants and P7_TERM for Treatment Phase participants) form and follow study termination procedures.***

BLOOD TESTS and SPECIMEN COLLECTIONS (Visit 3)

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

3. Eosinophils **(1040)** ___ ___ . ___ %

4. Was blood obtained for the serum save? **(1050)** ☐1 Yes ☐0 No

5. Was urine obtained for the urine save? **(1060)** ☐1 Yes ☐0 No

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

TREXA SCHEDULED MEDICATIONS

Subject ID: 0 7 - __ - __ __ __
Subject Initials: __ __ __
Visit Number: __ __
Visit Date: __ __ / __ __ / __ __ __ __
Month Day Year
Coordinator ID: __ __ __ __ __

(Clinic Coordinator completed)

1. What type of visit is this? **(1000)**
   - ☐ 1 Scheduled visit
   - ☐ 2 Unscheduled visit

2. Since the last study visit, which inhalation technique did the participant use most often with the following inhalers?

   2a. Brown Daily Inhaler **(1010)**
   - ☐ 1 Open-mouth technique
   - ☐ 2 Closed-mouth technique

   2b. White Rescue Inhaler **(1020)**
   - ☐ 1 Open-mouth technique
   - ☐ 2 Closed-mouth technique

   2c. Red Albuterol Inhaler **(1030)**
   - ☐ 1 Open-mouth technique
   - ☐ 2 Closed-mouth technique
   - ☐ 3 Spacer

MEDICATION LABEL - *Complete for randomized participants*

Affix the new drug labels below:

Brown Daily Inhaler carton label	White Rescue Inhaler carton label

Copy the drug label number below:

7 - __ __ __ - __ __ __
(1040) **(1050)** **(1060)**

Coordinator
(1070) Signature: _____

(1080) Date: __ __ / __ __ / __ __ __ __

By signing in the source documentation box you are:

1) Confirming that the label on the dispensed medications matches the number on the outside of the carton 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.

Reference Peak Flow - Complete only at Scheduled Visit 3 for randomized subjects

3. Reference Peak Flow % predicted calculated from Excel Spreadsheet at Visit 3 (Does not change during study) **(1085)** ___ ___ ___ . ___ %

Reference Peak Flow - Complete only at Scheduled Visits 4 - 8

Clinic Use Only

A. Reference Peak Flow % Predicted from P7_MED Question #3 at Visit 3 (Does not change during study) ___ ___ ___ . ___ %

B. Predicted Peak Flow from the current visit (Calculated from Excel Spreadsheet) ___ ___ ___ L/min

C. Reference Peak Flow (Question A/100) x Question B ___ ___ ___ L/min

D. Previous Reference Peak Flow (from last scheduled visit) ___ ___ ___ L/min

4. Reference Peak Flow (larger of C and D) **(1090)** ___ ___ ___ L/min

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

BASELINE MEDICAL HISTORY

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

(Parent/Legal Guardian Interview or Participant Interview Completed)

PARENT/GUARDIAN IDENTIFICATION

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

ASTHMA AND ALLERGY HISTORY

ASTHMA HISTORY

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

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

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

ASTHMA TREATMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

ALLERGY HISTORY

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

➔ ***If NO, skip to Question #19.***

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

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

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

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

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

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

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

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

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

19di. Head **(1360)** ❑ 1 Yes ❑ 0 No

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

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

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

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

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

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

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

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

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

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

MEDICAL AND FAMILY HISTORY
NOSE/EYE/SINUS SYMPTOMS

22. During the past 12 months, how would you describe any symptoms that have affected the participant's nose, eyes, or sinuses? **(1450)**
➔ ***If NONE, skip to Question #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

METHACHOLINE CHALLENGE TESTING

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

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

METHACHOLINE CHALLENGE TEST

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

Clinic Use Only

Use the pre-bronchodilator FEV_1 from the SPIRO_PRE form as the baseline (pre-diluent) value.

A. FEV_1 ___ . ___ ___ L

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

ADDITIONAL TREATMENT FOR METHACHOLINE CHALLENGE TESTING

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Participant's final FEV_1 after additional treatment

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

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

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

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

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

Physician Source Documentation

(1310) Physician/CC Signature: _____

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

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

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

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

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

EXCLUSIONS AND CONFOUNDERS

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

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

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

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

   Name of physician _____

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

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

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

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

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

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

METHACHOLINE CHALLENGE TESTING CHECKLIST

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

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

   If ***YES***, explain _____

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

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

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

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

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

Proceed to the Methacholine Challenge (METHA) form.

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

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

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

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

EXCLUSIONS AND CONFOUNDERS

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

   1a. If ***YES***, during the past 2 weeks, has the participant had any respiratory infections, colds, or bronchitis (see the Methacholine MOP)? **(1005)** ☐ 1 Yes ☐ 0 No

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

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

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

   Name of physician _____

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

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

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

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

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

Childhood Asthma Research & Education
NIH/NHLBI

METHACHOLINE CHALLENGE TESTING CHECKLIST

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

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

- ☐ 1 Positive
- ☐ 0 Negative
- ☐ 9 N/A

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

If ***YES***, explain _____

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

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

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

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

10a. If ***NO***, indicate the primary reason **(1190)**

- ☐ 1 Participant/Parent refused
- ☐ 2 Equipment failure
- ☐ 3 Other _____

Proceed to the Methacholine Challenge (METHA) form.

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

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

(Participant completed)

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

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

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

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

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

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

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

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

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

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

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

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

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

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

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

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

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

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

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

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

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

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

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

Childhood Asthma Research & Education
NIH/NHLBI

PEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE

Subject ID: ___ ___ - ___ - ___ ___ ___

Visit Number: ___ ___

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

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

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

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

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

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

Clinic Coordinator Completed

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PEAK FLOW REFERENCE VALUE DETERMINATION

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

(Clinic Coordinator completed)

Determining Peak Flow Reference Value

At the first study visit, skip to Question #10

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

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

   Clinic Use Only
   A. List the 3 **acceptable** Peak Flow Values from the AM1® Device performed during this Visit.

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

   B. Question #1 x 1.2 = ___ ___ ___ l/min

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

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

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

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

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

6. $\frac{\textit{Question \#3}}{\textit{Question \#2}}$ **(1050)** ___ . ___ ___

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

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

8. $\frac{\textit{Question \#4}}{\textit{Question \#3}}$ **(1070)** ___ . ___ ___

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

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

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

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

COMMENTS
(6000):_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PULMONARY PROCEDURE CHECKLIST

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

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

CONFOUNDERS

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

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

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

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

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

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

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

EXCLUSIONS

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

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

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

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

   If ***YES***, explain _____

PULMONARY PROCEDURE CHECKLIST

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

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

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

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

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

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

12. Was the procedure performed?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS

(6000): _____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PHYSICAL EXAMINATION

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

(Clinic Coordinator Completed)

MEASUREMENTS

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

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

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

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

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

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

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

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

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

   _____

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

PULMONARY AUSCULTATION

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

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

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

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

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

   4d. Rales **(1110)** ❑1 Yes ❑0 No

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

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

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

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

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

NOSE/EYE/SINUS SYMPTOMS

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

ECZEMA SYMPTOMS

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

PRIOR ASTHMA MEDICATION HISTORY

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

(Clinic Coordinator completed)

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

2. In the ***past 12 months***, has the participant used any asthma medication(s) other than albuterol [Proventil, Ventolin, pirbuterol (Maxair), levalbuterol (Xopenex)]? **(1010)** ❑ 1 Yes ❑ 0 No
   ➔ ***If NO, please STOP HERE.***

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

   3a. Salmeterol (Serevent) or formoterol (Foradil) **(1020)** ___ ___ months

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

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

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

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

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

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

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

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

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

COMMENTS

(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

CARE REGISTRY

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

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

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

ADMINISTRATIVE

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

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

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

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

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

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

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

DEMOGRAPHICS

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

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

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

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

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

   6b. Asian **(1080)** ❑1 Yes ❑0 No

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

   6d. White **(1100)** ❑1 Yes ❑0 No

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

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

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

Registry Form Storage Instructions:

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

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

COMMENTS
(6000):_____

_____

_____

Childhood Asthma Research & Education
NIH/NHLBI

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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POST-BRONCHODILATOR SPIROMETRY TESTING

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

(Technician Completed)

Supervisor ID: ___ ___ ___ ___ ___

POST-BRONCHODILATOR PULMONARY FUNCTION TESTING

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

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

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

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

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

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

COMMENTS (6000):_____

_____

_____

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PRE-BRONCHODILATOR SPIROMETRY TESTING

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

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

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

PRE-BRONCHODILATOR PULMONARY FUNCTION TESTING

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

2. Results of best effort

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMENTS

(6000):_____

_____

_____

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TREXA TERMINATION OF STUDY PARTICIPATION (Treatment Phase)

Subject ID: 0 7 - ___ - ___ ___ ___
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 participant withdrew assent
- ❑3 no longer interested in participating
- ❑4 no longer willing to follow protocol
- ❑5 difficult access to clinic (location, transportation, parking)
- ❑6 unable to make visits during clinic hours
- ❑7 moving out of the area
- ❑8 unable to continue due to personal constraints
- ❑9 dissatisfied with asthma control
- ❑10 unable to continue due to medical condition unrelated to asthma
- ❑11 side effects of study medication
- ❑12 participant withdrew due to pregnancy
- ❑13 participant lost to follow up
- ❑14 participant experienced a serious adverse event *
- ❑15 physician initiated termination of study participation **
- ❑16 treatment failure
- ❑17 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 TREXA 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 TREXA Protocol.

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

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

COMMENTS

(6000):_____

_____

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TREXA TERMINATION OF STUDY PARTICIPATION (Run-In)

Subject ID: 0 7 - ___ - ___ ___ ___
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 insufficient adherence with study drugs
- ❑ 2 inability to demonstrate adherence with study diary
- ❑ 3 pre-bronchodilator FEV_1 < 60% predicted at Visit 1
- ❑ 14 pre-bronchodilator FEV1 < 80% predicted at Visit 2 or Visit 3
- ❑ 4 FEV_1 reversibility < 12%, PC_{20} > 12.5 mg/ml, and no source doc
- ❑ 5 too many asthma symptoms during Run-In
- ❑ 6 asthma exacerbation during Run-In period
- ❑ 7 parent withdrew consent
- ❑ 8 participant withdrew assent
- ❑ 9 participant withdrew due to pregnancy
- ❑ 10 participant lost to follow up
- ❑ 11 participant experienced a serious adverse event *
- ❑ 12 physician initiated termination of study participation **
- ❑ 13 other _____
- ❑ 15 ineligible at Visit 1

* ***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 TREXA 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 TREXA Protocol.

(1030) _____ Clinic Coordinator's Signature

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

(1050) _____ Principal Investigator's Signature

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

COMMENTS

(6000):_____

_____

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TREXA
TREATMENT FAILURE

Subject ID: 0 7 - ___ - ___ ___ ___
Subject Initials: ___ ___ ___
Visit Number: ___ ___
Visit Date: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year
Coordinator ID: ___ ___ ___ ___ ___

(Clinic Coordinator completed)

1. Has the participant been hospitalized for asthma? **(1000)** ☐ 1 Yes ☐ 0 No

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

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

4. Has the participant received his/her second course of an oral/systemic corticosteroid for an asthma exacerbation within any 6-month period? **(1030)** ☐ 1 Yes ☐ 0 No

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

   ➔ ***If YES, please complete the TREXA Termination of Study Participation (P7_TERM) form.***

6. Date treatment failure occurred **(1050)** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month Day Year

(1060) Physician/CC Signature: _____

(1070) Date: ___ ___ / ___ ___ / ___ ___ ___ ___

COMMENTS

(6000):_____

_____

_____