Baseline Asthma and Medical History

Purpose: To collect baseline information concerning participant's asthma and medical history.

When: V1.

Instructions: Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 1

6. Form version date:

3 1 – M A Y – 1 2
day mon year

B. Demographic information

7. Gender *(check only one):*

Male (1)
Female (2)

8. Ethnicity *(check only one):*

Hispanic/Latino/Spanish (1)
Not Hispanic/Latino/Spanish (2)

9. Race *(check only one):*

White (1)
Black or African American (2)
Asian (3)
American Indian or Alaskan Native (4)
Hawaiian or other Pacific Islander (5)
Other *(specify)* (6)

_____
race

10. Date of birth:

____ ____ – ____ ____ ____ – ____ ____
day mon year

11. Age: ____ ____ years

C. Asthma history

12. Age of onset of asthma symptoms *(years; if onset before first birthday, record as "01"):*

____ ____ years

13. In the past 12 months, how many times have you had to visit a doctor, emergency department, or hospital because of an asthma attack:

____ ____

14. In the past 12 months, how many times have you required a course of prednisone (or other systemic steroid) for treatment of an asthma attack:

____ ____

15. Do you have allergies that make your asthma worse:

Yes (1) No (2)

D. Emergency care

16. When were you last seen by a doctor because of breathing problems *(check only one):*

Never (1)
Within the last year (2)
Greater than one year ago (3)

17. When did you last visit a hospital emergency room or urgent care facility because of breathing problems *(check only one):*

Never (1)
Within the last year (2)
Greater than one year ago (3)

18. When did you last spend a night in the hospital because of breathing problems *(check only one):*

Never (1)
Within the last year (2)
Greater than one year ago (3)

19. When did you last have an Intensive Care Unit (ICU) admission because of an asthma attack *(check only one):*

Never (1)
Within the last year (2)
Greater than one year ago (3)

E. Asthma triggers

Do any of the following make your asthma worse:

20. Respiratory infections *(eg, cold):*

Yes (1)
No (2)
Not sure (3)

21. Irritants *(eg, smoke, chemicals):*

Yes (1)
No (2)
Not sure (3)

22. Emotions *(eg, crying, anger, etc):*

Yes (1)
No (2)
Not sure (3)

23. Drugs *(eg, aspirin, NSAIDs, beta-blockers, ACE-inhibitors):*

Yes (1)
No (2)
Not sure (3)

24. Food additives:

Yes (1)
No (2)
Not sure (3)

25. Weather changes:

Yes (1)
No (2)
Not sure (3)

26. Exercise:

Yes (1)
No (2)
Not sure (3)

27. Cleaning supplies:

Yes (1)
No (2)
Not sure (3)

28. Exposure to animals *(check all that apply)*

a. Cat: (1)
b. Dog: (1)
c. Rodent: (1)
d. Other *(specify):* (1)

_____
animal

e. None: (1)

29. A particular season *(check all that apply)*

a. Winter: (1)
b. Spring: (1)
c. Summer: (1)
d. Fall: (1)
e. None: (1)

If male, skip to item 32.

30. Menstruation *(premenstruation or during menses):*

Yes (1)
No (2)
Not sure (3)
Affected in the past (4)
Not yet menstruating (5)

31. Pregnancy:

Yes (1)
No (2)
Not sure (3)
Never pregnant (4)

F. Symptoms

32. In general, over the last 3 months, how often did you have the following symptoms:

	Never	Once a month	1-2 times per week	3-6 times per week	Daily	Twice a day or more
a. Cough - deep, chest, chronic:	(1)	(2)	(3)	(4)	(5)	(6)
b. Sputum - phlegm or mucus while coughing:	(1)	(2)	(3)	(4)	(5)	(6)
c. Chest tightness - difficulty taking a deep breath or pressure in the chest:	(1)	(2)	(3)	(4)	(5)	(6)
d. Wheezy, whistling, or musical sound in the chest:	(1)	(2)	(3)	(4)	(5)	(6)
e. Shortness of breath:	(1)	(2)	(3)	(4)	(5)	(6)
f. Nighttime symptoms - includes waking from sleep, nighttime use of albuterol, early morning chest tightness:	(1)	(2)	(3)	(4)	(5)	(6)

G. Asthma treatment history

33. Over the past 3 months, on average, how often did you use the following medications/therapies specifically for treatment of asthma:

a. Inhaled corticosteroids *(eg, Beclovent, Pulmicort, Flovent, etc)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

b. Inhaled steroidal combination medications for asthma *(eg, Advair, Symbicort)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

Combination medication:

_____
specify

c. Non-steroidal combination medications for asthma *(eg, Combivent)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

Combination medication:

_____
specify

d. Oral anti-leukotriene *(eg, Singulair, Accolate, Zyflo)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

e. Inhaled anticholinergic bronchodilators *(eg, Atrovent, Spiriva)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

f. Inhaled short-acting beta-agonist bronchodilators *(eg, Albuterol, Proventil, Ventolin, Maxair, Xopenex, etc)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

g. Inhaled long-acting beta-agonist bronchodilators *(eg, Serevent, Foradil)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

h. Cromolyn sodium/nedocromil *(eg, Intal, Nasalcrom/Alocril, Tilade):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

i. Oral beta-agonist *(eg, Proventil repetabs):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

j. Methylxanthines *(eg, theophylline):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

k. Oral corticosteroid *(eg, prednisone pills or liquid):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

l. Omalizumab *(Xolair):*

2 times per month (1)
1 time per month (2)
Less than 1 time per month (3)
Never (5)

m. Steroid injections:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

n. Acupuncture:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

o. Allergy shots:

1 or more times per week (1)
1-3 times per month (2)
Less than 1 time per month (3)
Never (5)

p. Chiropractic treatments:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

q. Herbal or natural treatments, vitamins, etc:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

r. Other asthma treatment:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

Asthma treatment:

_____
specify

H. Cigarette smoking history

34. Smoking status *(check only one):*

Former (1)
Never (fewer than 20 packs in lifetime) (2)

38. ┘

35. How many years in total did you smoke *(years; use decimal value for less than 1 year):*

____ ____ • ____
years

36. On average, how many packs of cigarettes per day did you smoke:

____ • ____
# of packs

37. Total number of pack-years *(pack-years = years smoked times number of packs per day; multiply item 35 x item 36):*

____ ____
pack years

I. Current smoking exposure

38. Are you exposed to second hand smoke in your home or work place:

Yes (1) No (2)

39. Do you frequently go places other than your home or work place where you are exposed to second hand smoke:

Yes (1) No (2)

J. General medical conditions

40. Do you have now or have you had during the last year any of the medical conditions from the following list

	Yes	No
a. COPD:	(1)	(2)
b. Gastroesophageal reflux:	(1)	(2)
c. Eczema:	(1)	(2)
d. Hay fever or allergic rhinitis:	(1)	(2)
e. Food allergies:	(1)	(2)
f. Other allergies:	(1)	(2)

_____
specify

g. Cancer *(other than skin cancer):*	(1)	(2)

_____
specify

h. Endocrine disease:	(1)	(2)
i. Thyroid disease:	(1)	(2)
j. Coronary artery disease:	(1)	(2)
k. Congestive heart failure:	(1)	(2)
l. Stroke:	(1)	(2)
m. Severe hypertension:	(1)	(2)
n. Diabetes mellitus:	(1)	(2)

If Yes, specify Type I (juvenile) or Type II (adult onset):

_____
specify

o. Renal failure:	(1)	(2)
p. Liver disorders:	(1)	(2)
q. Immunodeficiency states:	(1)	(2)
r. Major neuropsychiatric disorder:	(1)	(2)
s. Glaucoma or any other condition leading to an increase in intraocular pressure:	(1)	(2)
t. Sleep disorder:	(1)	(2)

_____
specify

41. Are you on hormone replacement therapy or had an ovariectomy *(if male skip this item):*

Yes (1) No (2)

42. Do you have any conditions related to allergies *(check all that apply)*

a. Nasal polyps: (1)

b. Runny nose: (1)

c. Nasal congestion: (1)

d. Sinus infections: (1)

e. Other *(specify):* (1)

_____
condition

f. None: (1)

43. Have you had sinus surgery:

Yes (1) No (2)

44. Do you have any of the following conditions *(check all that apply)*

a. Vocal cord dysfunction: (1)

b. Anxiety: (1)

c. Depression: (1)

d. Hyperventilation syndrome: (1)

e. Panic attacks: (1)

f. None: (1)

K. Health and development questions

45. Do you have a history of asthma in your blood relatives (parents, brothers/sisters, or children):

Yes (1)
No (2)
Don't know (3)

46. Have you ever been diagnosed with sleep apnea:

Yes (1) No (2)

47. Do you use Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP):

Yes (1) No (2)

48. Have you ever been told you snore:

Yes (1) No (2)

49. Has anyone ever noticed that you stop breathing during your sleep:

Yes (1) No (2)

50. Do you often take naps during the day:

Yes (1) No (2)

51. What was your birthweight *(check only one):*

More than or equal to 5 lbs 8 ozs (1)
Less than 5 lbs 8 ozs (2)
Unknown (3)

52. What was (is) your approximate weight at the age of 18 years *(skip this question if less than 18 years):*

____ ____ ____
pounds

53. What was your age of first menstrual period *(answer a, b, or c)*

a. Age: ____ ____ years

b. Don't know (1)

c. Not applicable (1)

54. Waist circumference *(measured; enter only a or b):*

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ ____ centimeters

55. Hip circumference *(measured; enter only a or b):*

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ ____ centimeters

56. Neck circumference *(measured; enter only a or b)*

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

L. Background information

57. What is your relationship to the participant *(check only one):*

Self (1) **60.**
Mother (2)
Father (3)
Grandmother (4)
Grandfather (5)
Other relative *(specify)* (6)

_____
relationship

Not related *(specify)* (7)

_____
relationship

58. Are you the participant's primary caregiver:

Yes (1) No (2)

59. Does the child (participant) live with you more than half the time:

Yes (1) No (2)

60. What is your current marital status *(check only one):*

Married (1)
Single, living with significant other (2)
Single, not living with significant other (3)
Separated (4)
Divorced (5)
Widowed (6)

61. What is your occupation:

_____
specify

62. Household

For these questions, household refers to where the participant currently lives most of the time.

a. How many adults live in your/the child's home:

____ ____
number

b. How many children live in your/the child's home:

____ ____
number

c. Which of the following categories best describes the total income for the last year for the household where you/the child lives *(please include income from all sources such as wages, public assistance or investments; check only one):*

Less than $14,999 (1)
$15,000 - 21,999 (2)
$22,000 - 43,999 (3)
$44,000 - 60,000 (4)
More than $60,000 (5)
Don't know (6)
Refused to answer (7)

63. Educational attainment

For adult participants complete only item 63a. For child participants complete items 63b and 63c.

a. ***Ask adult participant***: ''What is the highest level of education **you** have COMPLETED''; check only one and skip to item 64:

Eighth grade or less (1)
More than 8th grade, but not a high school graduate (2)
High school graduate or equivalent (3)
Some college (4)
Graduate of two-year college or technical school (5)
Graduate of four year college (6)
Post-graduate studies (7)
Refused to answer (8)

b. ***Ask child's parent/caregiver***: ''What is the highest level of education the **child's primary caregiver** COMPLETED'' *(check only one)*

- Eighth grade or less (1)
- More than 8th grade, but not a high school graduate (2)
- High school graduate or equivalent (3)
- Some college (4)
- Graduate of two-year college or technical school (5)
- Graduate of four year college (6)
- Post-graduate studies (7)
- Don't know (8)
- Refused to answer (9)

c. ***Ask child's parent/caregiver***: ''What is the highest level of education the **head of the household** of the child's home COMPLETED'' *(check only one)*

- Respondent is both primary caregiver and head of household (1)
- Eighth grade or less (2)
- More than 8th grade, but not a high school graduate (3)
- High school graduate or equivalent (4)
- Some college (5)
- Graduate of two-year college or technical school (6)
- Graduate of four year college (7)
- Post-graduate studies (8)
- Don't know (9)
- Refused to answer (10)

64. What is your/the child's source of health insurance *(check only one):*

- Private Insurance (eg, Blue Cross/Blue Shield or other insurance purchased by you or your employer) (1)
- Public Insurance (eg, Medicaid,S-CHIP, paid for by government) (2)
- Self-Pay (No health insurance) (3)
- Don't know (4)
- Other (5)

65. How do you pay for your/the child's prescription drugs *(check only one):*

- Out of pocket (pay entire amount with own money) (1)
- Co-pay (insurance pays some and family pays the rest) (2)
- Pay nothing (insurance pays for all cost of prescriptions) (3)
- Don't know (4)
- Other (5)

M. Administrative information

66. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

67. Clinic coordinator PIN: ____ ____ ____

68. Clinic coordinator signature *(do not key):*

_____

Clinic Visit Form

Purpose: To record information about diary cards, asthma symptoms, medications, and other visit procedures.
When: V2, V4-V7.
Respondent: Participant, or parent/guardian, or both.
Instructions: Complete form at clinic visit (at V4, "last study visit" refers to V2, not the phone visit V3). Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant, and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of clinic visit:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

0 3 - D E C - 1 2
day mon year

B. Diary cards

7. Number of Diary Cards not returned since the last study visit:

____ ____

8. Reason for missing Diary Cards *(check all that apply)*

a. None missing: (1)
b. Participant forgot to return: (1)
c. Did not complete: (1)
d. Lost or destroyed: (1)
e. In the mail: (1)
f. Other *(specify):* (1)

_____
reason

Review proper completion of Diary Card with participant.

If any Diary Cards are missing, complete a Missed Data (MD) form.

C. Unscheduled contacts since last study visit

9. Phone contacts

a. Did you have any unscheduled phone contacts with this clinic since the last study visit *(ignore calls to change appointment time)*:

Yes (1) No (2)
10.

b. If Yes, specify how many: ____ ____

10. Clinic visits

a. Did you have any extra visits at this clinic since the last study visit:

Yes (1) No (2)
11.

b. If Yes, specify how many: ____ ____

D. Study device history

11. Is this V2 or V7:

Yes (1) No (2)
16.

12. On average, how many nights per week did you **NOT** use your study device:

0 nights missed - used device every night (1)
14.
Less than 1 night per week (2)
1-2 nights per week (3)
3-4 nights per week (4)
5 or more nights per week (5)

13. Why did you not use your study device *(check all that apply)*

- **a.** Forgot: (1)
- **b.** Too busy: (1)
- **c.** Did not have study device on hand: (1)
- **d.** Lost CPAP device or mask: (1)
- **e.** Difficulty using CPAP device: (1)
- **f.** Mask is not comfortable: (1)
- **g.** Device or mask too noisy: (1)
- **h.** Interrupts my sleep: (1)
- **i.** Disturbs others at home: (1)
- **j.** Cold symptoms: (1)
- **k.** Side effects: (1)

_____
specify

- **l.** Other *(specify)*: (1)

_____
reason

- **m.** Permanently stopped using study device *(complete TT form)*: (1)

14. On the nights that you used your CPAP device, did you use it for at least 4 hours per night on average:

Yes (1) No (2)

16.

15. Specify reason for using CPAP less than 4 hours per night *(check all that apply)*

- **a.** Too busy: (1)
- **b.** Difficulty using CPAP device: (1)
- **c.** Mask is not comfortable: (1)
- **d.** Device or mask is too noisy: (1)
- **e.** Interrupts my sleep: (1)
- **f.** Disturbs others at home: (1)
- **g.** Cold symptoms: (1)
- **h.** Side effects: (1)

_____
specify

- **i.** Other *(specify)*: (1)

_____
reason

- **j.** Permanently stopped using study device *(complete TT form)*: (1)

Review adherence with participant, and resolve any issues with mask fit or device.

E. Asthma medications

16. Record use of quick relief (rescue bronchodilator) drugs since last study visit *(if V1 and V2 are on the same day, record rescue medications used in the last 3 weeks; check all that apply)*

	Drug name (Trade names)	**Yes**
a.	NA, no quick relief asthma drugs taken:	(1)
b.	Albuterol Nebulizer (0.083%):	(1)
c.	Albuterol Nebulizer (0.5%):	(1)
d.	Albuterol Metered Dose Inhaler:	(1)
e.	Levalbuterol (Xopenex):	(1)
f.	Pirbuterol (Maxair):	(1)
g.	Ipratropium bromide (Atrovent Nebulizer):	(1)
h.	Ipratropium bromide (Atrovent HFA):	(1)
i.	Ipratropium bromide and albuterol (Combivent DuoNeb, Combivent HFA):	(1)
j.	Other: _____ specify	(1)
k.	Other: _____ specify	(1)
l.	Other: _____ specify	(1)

17. Are you currently taking medications specifically for the treatment of asthma:

Yes (1) No (2) → **26.**

If "Yes," record drug information for most recent use of medication for items 18-25.

18. Single agent long-acting bronchodilator drugs participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
a.	NA, no long-acting bronchodilator drugs taken:	(1)		
b.	Salmeterol (Serevent inhalation aerosol, Serevent Diskus inhalation powder):	(1)	___ ___ ___ mcg	___ ___ num
c.	Albuterol, sustained-release (Volmax, Proventil Repetabs, VoSpire ER)	(1)	___ ___ ___ mcg	___ ___ num
d.	Formoterol (Foradil, Perforomist):	(1)	___ ___ ___ mcg	___ ___ num
e.	Tiotropium bromide (Spiriva):	(1)	___ ___ ___ mcg	___ ___ num
f.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
g.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
h.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num

19. Single agent inhaled corticosteroid participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
a.	NA, no single agent inhaled corticosteroid drugs taken:	(1)		
b.	Beclomethasone (Beclovent, Vanceril, QVar, Vanceril Double Strength):	(1)	___ ___ ___ mcg	___ ___ num
c.	Budesonide (Pulmicort):	(1)	___ ___ ___ mcg	___ ___ num
d.	Flunisolide (AeroBid, Aerospan):	(1)	___ ___ ___ mcg	___ ___ num
e.	Fluticasone (Flovent):	(1)	___ ___ ___ mcg	___ ___ num
f.	Triamcinolone (Azmacort):	(1)	___ ___ ___ mcg	___ ___ num
g.	Mometasone furoate (Asmanex):	(1)	___ ___ ___ mcg	___ ___ num
h.	Ciclesonide (Alvesco):	(1)	___ ___ ___ mcg	___ ___ num
i.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
j.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
k.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num

20. Combination of inhaled corticosteroid and long-acting beta-agonist participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
a.	NA, no combination ICS/LABA drugs taken:	(1)		
b.	Budesonide and Formoteral (Symbicort):	(1)	___ ___ ___ / ___ • ___ mcg	___ ___ num
c.	Fluticasone and Salmeterol (Advair):	(1)	___ ___ ___ / ___ ___ mcg	___ ___ num
d.	Fluticasone and Salmeterol (Advair HFA):	(1)	___ ___ ___ / ___ ___ mcg	___ ___ num
e.	Mometasone and Formoterol (Dulera):	(1)	___ ___ ___ / ___ ___ mcg	___ ___ num
f.	Other combination: _____ specify	(1)	___ ___ ___ / ___ ___ mcg	___ ___ num

21. Oral corticosteroid participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Tablets/Elixirs per day**
a.	NA, no oral corticosteroid drugs taken:	(1)		
b.	Prednisone (Cortan, Deltasone, Orasone, Prednicen-M, Sterpred):	(1)	___ ___ ___ mg	___ ___ num
c.	Prednisolone (Pepiapred, Prelone, Delta-Cortef):	(1)	___ ___ ___ mg	___ ___ num
d.	Methylprednisolone (Medrol):	(1)	___ ___ ___ mg	___ ___ num
e.	Other: _____ specify	(1)	___ ___ ___ mg	___ ___ num
f.	Other: _____ specify	(1)	___ ___ ___ mg	___ ___ num

22. Methylxanthines participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Tablets/Elixirs per day**
a.	NA, no methylxanthines taken:	(1)		
b.	Theophylline, sustained-release (Slo-Phyllin, Uniphyl, Theo-Dur, Slo-Bid, others):	(1)	___ ___ ___ mg	___ ___ num
c.	Other: _____ specify	(1)	___ ___ ___ mg	___ ___ num

23. Oral antileukotriene drugs participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Tablets per day**
a.	NA, no oral antileukotriene drugs taken:	(1)		
b.	Montelukast (Singulair):	(1)	___ ___ ___ mg	___ ___ num
c.	Zafirlukast (Accolate):	(1)	___ ___ ___ mg	___ ___ num
d.	Zileuton (Zyflo):	(1)	___ ___ ___ mg	___ ___ num
e.	Other: _____ specify	(1)	___ ___ ___ mg	___ ___ num

24. Other asthma medications participant is currently taking *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
a.	NA, no other asthma drugs taken:	(1)		
b.	Cromolyn sodium (Intal Nebulizer):	(1)	___ ___ ___ mg	___ ___ num
c.	Cromolyn sodium (Intal Metered Dose Inhaler):	(1)	___ ___ ___ mcg	___ ___ num
d.	Nedocromil sodium (Tilade):	(1)	___ ___ ___ mg	___ ___ num
e.	Other: _____ specify	(1)	_____	_____
f.	Other: _____ specify	(1)	_____	_____
g.	Other: _____ specify	(1)	_____	_____
h.	Omalizumab (Xolair):	(1)	___ ___ ___ mg	**Injections per month** ___ ___ num

25. Since the last study visit, have there been any changes in asthma medications, including dose changes, or stopping drugs *(if V1 and V2 are on the same day, check "No")*

Yes (1) No (2)

If "Yes," name drug, action taken, and explain circumstances concerning any changes:

_____

_____

_____

If additional space is needed, list at the end of the form and key into the note section when entering the form into the data system.

26. Since the last study visit, did you take the following medication to treat sinus symptoms *(if V1 and V2 are on the same day, record medications used in the last 3 weeks)*

	Yes (1)	No (2)
a. Nasal spray decongestants: *eg, Afrin, phenylephrine*		
b. Oral decongestants: *eg, Sudafed, Contac*		
c. Antihistamines: *eg, Benadryl, Claritin, Allegra, Astelin, Zyrtec*		
d. Nasal saline:		
e. Allergy immunotherapy: *eg, allergy shots, sublingual immunotherapy*		
f. Nasal steroids		
g. Other *(specify)*:		

_____
specify

27. Since the last study visit, did you take medications other than those for asthma and sinus symptoms *(if V1 and V2 are on the same day, record medications used in the last 3 weeks)*:

Yes (1) No (2)

If "Yes," specify other medications:

_____

_____

_____

_____

_____

If additional space is needed, list at the end of the form and key into the note section when entering the form into the data system.

F. Interim medical history

For items 28-36, if V1 and V2 are on the same day, record symptoms since the last 3 weeks.

28. Since the last visit, rate the severity of the following symptoms *(ask about all listed symptoms)*

Mild: Just noticeable and considered unpleasant, but does not interfere with usual activities or sense of well-being.

Moderate: Interferes with usual activities or sense of well-being, but does not limit the participant

Severe: Prevents activities or participant seeks medical care

	None	Mild	Moderate	Severe
a. Chest pain:	(0)	(1)	(2)	(3)
b. Chest discomfort:	(0)	(1)	(2)	(3)
c. Headaches:	(0)	(1)	(2)	(3)
d. Increase work of breathing:	(0)	(1)	(2)	(3)
e. Acute upper respiratory tract infection:	(0)	(1)	(2)	(3)
f. Drying of nose, mouth and/or throat:	(0)	(1)	(2)	(3)
g. Nose bleeds:	(0)	(1)	(2)	(3)
h. Nose irritation:	(0)	(1)	(2)	(3)
i. Bloating/gas:	(0)	(1)	(2)	(3)
j. Ear or sinus discomfort:	(0)	(1)	(2)	(3)
k. Eye irritation:	(0)	(1)	(2)	(3)
l. Skin rashes:	(0)	(1)	(2)	(3)
m. Congestion, runny nose, sneezing:	(0)	(1)	(2)	(3)
n. Mask discomfort:	(0)	(1)	(2)	(3)

29. Since the last study visit, have you had other symptoms:

Yes (1) No (2)

31.

30. Specify symptoms and rate the severity of them

Mild: Just noticeable and considered unpleasant, but does not interfere with usual activities or sense of well-being.

Moderate: Interferes with usual activities or sense of well-being, but does not limit the participant

Severe: Prevents activities or participant seeks medical care

		Mild	**Moderate**	**Severe**
a.	Other: _____ *symptom*	(1)	(2)	(3)
b.	Other: _____ *symptom*	(1)	(2)	(3)
c.	Other: _____ *symptom*	(1)	(2)	(3)
d.	Other: _____ *symptom*	(1)	(2)	(3)

Note: For items 28 and 30, clinics should complete an Unusual Event (UE) form or a Serious Adverse Event (SR) form as appropriate for all symptoms rated as severe (see MOP).

31. Since the last study visit, have you had any of the following diagnoses

		Yes	No
a.	Hypertension:	(1)	(2)
b.	Pneumonia:	(1)	(2)
c.	Bronchitis:	(1)	(2)
d.	Strep throat:	(1)	(2)
e.	Acute sinusitis:	(1)	(2)
f.	Diabetes:	(1)	(2)
g.	Nasal infection:	(1)	(2)
h.	Other new diagnosis *(specify)*: _____ new diagnosis	(1)	(2)

32. Serious adverse events

a. Since the last study visit, have you experienced a serious adverse event or been hospitalized:

Yes (1) No (2)

34.

b. Specify event(s):

_____

_____

_____

_____

For hospitalization(s) or other serious adverse events that occurred after the participant enrolled in the study, complete a Serious Adverse Event (SR) form for each event.

33. Since the last study visit, number of hospitalizations: ____ ____

34. Since the last study visit, how many times have you seen or contacted a healthcare provider for asthma or asthma treatment: ____ ____

35. Since the last study visit, how many times have you seen or contacted a healthcare provider for upper airway symptoms *(cold, sinusitis, rhinitis)*: ____ ____

36. Other significant medical events or illnesses since the last visit:

_____

_____

_____

_____

For significant medical events that occurred after the participant enrolled in the study, complete an Unusual Event (UE) form for each event.

G. SD card information

37. Is this V2:

Yes (1) No (2)

40.

38. SD cards collected *(check all that apply)*

a. SD card A: (1)
b. SD card B: (1)
c. SD card C: (1)
d. No SD card collected: (1)

Complete an SD Card Transmittal Sheet (SD) and ship collected cards to the DCC (see MOP). Cards are due to be collected at V4, V5, and V6.

H. Specimen collection

Specimen Instructions:

- *Write participant name code on each barcode label*
- *For each available sample attach the specified barcode label on sample and its matching barcode in appropriate box below*
- *Data enter barcode **number** (scanned or keyed)*

39. *Item left blank intentionally*

40. Were specimens for DNA/genotyping collected *(expected at V2 only if participant consented to donate DNA and have it stored)*:

Yes (1) No (2)

42.

41. DNA specimens processed and available for shipping

a. Plasma aliquot 1: Yes (1) No (2)

i. *Plasma Aliquot 1 barcode here*

b. Plasma aliquot 2: Yes (1) No (2)

i. *Plasma Aliquot 2 barcode here*

c. Packed cells vacutainer: Yes (1) No (2)

i. *Packed cells barcode here*

42. Was serum for inflammatory biomarkers collected *(expected at V2, V6, V7)*: Yes (1) No (2)

44.

43. Serum processed and available for shipping

a. Serum aliquot 1: Yes (1) No (2)

i. *Serum Aliquot 1 barcode here*

b. Serum aliquot 2: Yes (1) No (2)

i. *Serum Aliquot 2 barcode here*

44. Eosinophil count *(expected at V2, V6, V7)*

a. Eosinophil blood specimen collected: Yes (1) No (2)

45.

i. *Eosinophil specimen barcode here*

b. Record results of eosinophil analysis:

_____ _____ _____ _____
cells/µL

I. Administrative information

45. Date form reviewed:

_____ _____ - _____ _____ _____ - _____ _____
day mon year

46. Clinic coordinator PIN: ____ ____ ____

47. Clinic coordinator signature *(do not key)*:

_____

CPAP Diary Card

Fill out information inside the box each Morning and Evening. If information is missing, leave that item blank.

A. Asthma symptoms

		Mon	Tue	Wed	Thur	Fri	Sat	Sun
MORNING	**1.** Date *(month/day)*:	__/__	__/__	__/__	__/__	__/__	__/__	__/__
	2. Morning peak flow *(highest of 3, before bronchodilator)*:							
	For item 3 check (✓) if occurred							
	3. Awakened by asthma last night:	( )	( )	( )	( )	( )	( )	( )
	NOTE: Complete CPAP device use log (item 17) on the second page of the diary card.							
EVENING	**4.** Drug use for quick relief of asthma symptoms *(do not count uses to prevent symptoms, for example before exercise; if none record as "0")*							
	a. # puffs per day by metered dose inhaler:							
	b. # uses per day by nebulizer:							
	For items (5 -7) check (✓) if occurred today							
	5. Did you use your regular asthma medicine:	( )	( )	( )	( )	( )	( )	( )
	6. Used oral or IV prednisone/steroids for asthma:	( )	( )	( )	( )	( )	( )	( )
	7. Urgent unscheduled healthcare contact for asthma (ED/hospital/clinic or doctor visit):	( )	( )	( )	( )	( )	( )	( )
	8. Asthma score:							

0 = No asthma episodes
1 = 1-3 asthma episodes, each lasting 2 hours or less -- all mild
2 = 4 or more mild asthma episodes, or 1 or more asthma episodes that interfered with activity, play, school, or sleep for less than 2 hours
3 = 1 or more asthma episodes which last longer than 2 hours, or result in shortening normal activity, seeing a doctor, or going to a hospital

B. Administrative information

To be completed by clinic

9. Date diary started: ___ ___ - ___ ___ ___ - ___ ___ (day - mon - year)

10. Clinical center ID: ____ ____ ____ ____

11. Participant ID: ____ ____ ____ ____ ____

12. Name code: ____ ____ ____ ____ ____

13. Form version date: 1 2 - S E P - 1 2 (day - mon - year)

14. Date diary returned: ___ ___ - ___ ___ ___ - ___ ___ (day - mon - year)

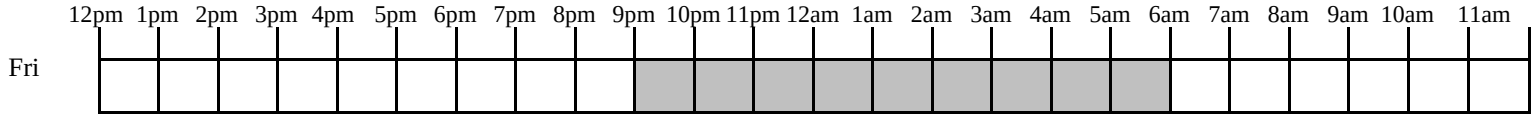
15. Clinic coordinator PIN: ____ ____ ____

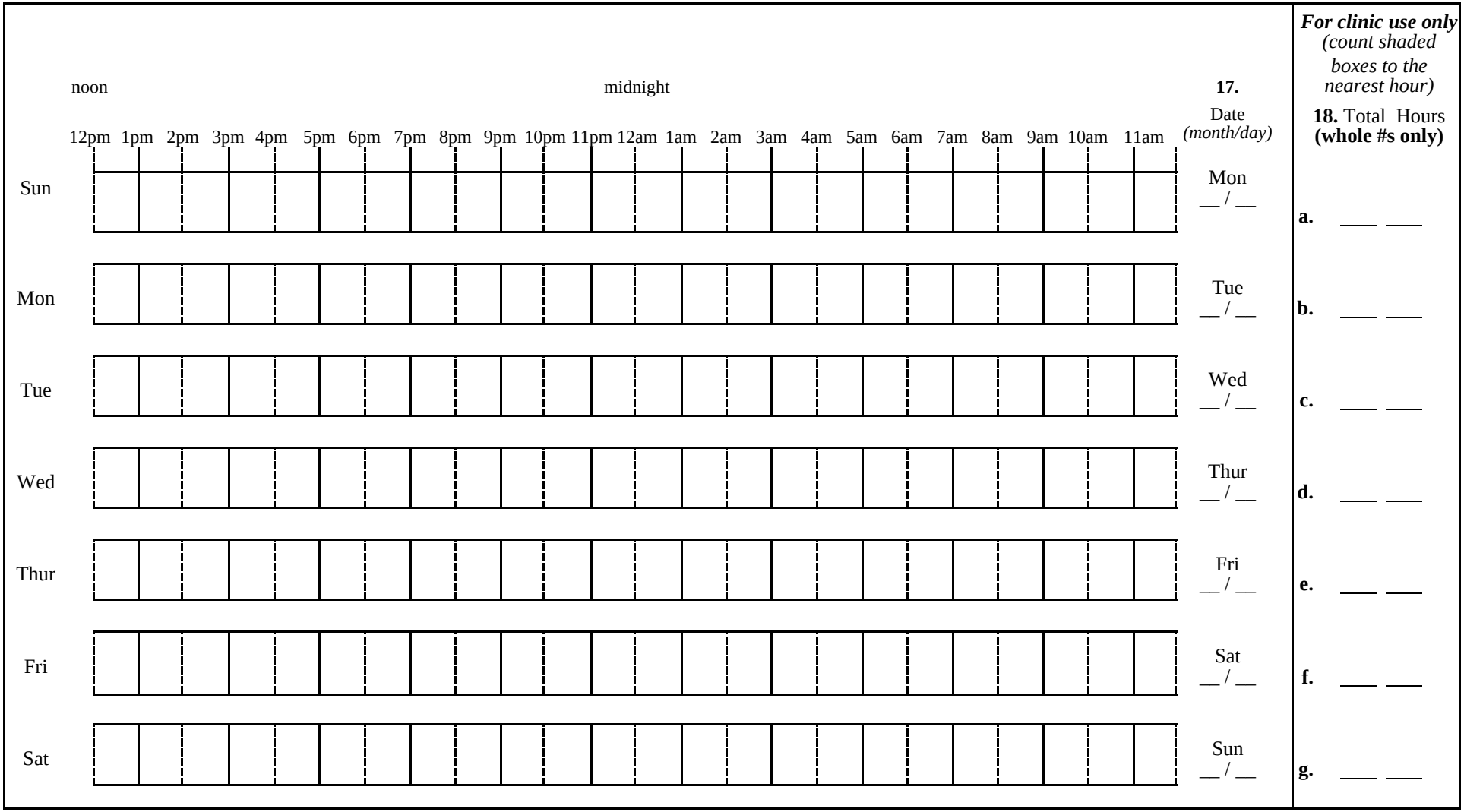
16. Clinic coordinator signature *(do not key)*: _____

Sequential diary card # for this participant *(optional)*: _____

C. CPAP device use log

Fill in the boxes each morning for the hours you used your CPAP device.
Example: On Friday, Joe turned on his CPAP at 9pm and went to bed. He turned off his machine at 6am on Saturday when he got up.





Device Dispensing and Return

Purpose: To record the issuing and collecting of study kit and masks to and from participant.
When: Dispensing at V2, returning at V6, and whenever study masks are issued, or returned/due to be returned.
Instructions: One study kit will be assigned per participant. Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant, and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date form completed:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: ____ ____
(record "N" if not associated with a clinic visit)

6. Form version date:

2 8 - J U N - 1 2
day mon year

B. Study treatment information

7. Kit ID *(from box)*:

P - ____ ____ ____ ____

8. Action taken *(check all that apply and complete required section(s))*

a. Dispense study device ***(complete sections C and D)***: (1)
b. Dispense mask ***(complete section D)***: (1)
c. Return study device, or due to be returned ***(complete sections E and F)***: (1)
d. Return mask, or due to be returned ***(complete section F)***: (1)

Reminder
- Device is due:
  - At V6
  - If a new kit is issued to participant
- Mask is due:
  - At V6
  - If participant asks for a different mask
  - If a new kit is issued to participant
  - Whenever device is due
- Device and mask are due at V7 if participant doesn't return them at V6

C. Dispense study device

9. Date device dispensed:

____ ____-____ ____ ____-____ ____
day mon year

10. Study device issued *(key Device ID [P-__ __ __ __] from label)*:

affix device label here

Make sure the issuance of the Study Kit is recorded on the Study Kit Accountability Log (DA).

Check that the Device ID on affixed label matches the Kit ID in item 7.

Other items dispensed with device: *(do not data enter)*

( ) Power supply unit and power cord
( ) Air tubing
( ) Device travel bag
( ) CPAP instruction packet
( ) Chin strap
( ) SD card
( ) Soap
( ) CPAP flash drive

D. Dispense study mask

11. Date mask dispensed:

_____ _____-_____ _____ _____-_____ _____
day mon year

12. Mask ID: P - _____ _____ _____ _____

Check that the Mask ID matches the Kit ID in item 7.

13. Mask type dispensed *(check only one)*:

Mirage FX (1)
Mirage FX - Wide (2)
Swift FX - Small pillows (3)
Swift FX - Medium pillows (4)
Swift FX - Large pillows (5)

E. Return study device

14. Reason for returning device *(check all that apply)*

a. End of treatment: (1)
b. Device malfunction: (1)
c. Other *(specify)*: (1)

_____
specify

d. Device due, but not returned: (1)

17.

For a, b, and c, record on Study Kit Accountability Log (DA).

15. Date device returned:

_____ _____-_____ _____ _____-_____ _____
day mon year

16. Device ID: P - _____ _____ _____ _____

Check that the Device ID on affixed label matches the Kit ID in item 7.

17. Other study materials returned (*check all that apply)*

a. Power supply and power cord: (1)
b. Air tubing: (1)
c. Humidifier and tub: (1)
d. No other materials returned: (1)

18. If study device not returned, give reason *(check all that apply)*

a. N/A, device returned: (1)
b. Forgot, still at home: (1)
c. Discarded: (1)
d. Lost/destroyed: (1)
e. Unable to reach participant: (1)
f. Other *(specify)*: (1)

_____
specify

If participant still has the device, make arrangements to have it returned to the clinic as soon as possible.

F. Return study mask

19. Reason for returning mask *(check all that apply)*

a. End of treatment: (1)
b. Poor fit: (1)
c. Uncomfortable: (1)
d. Other *(specify)*: (1)

_____
specify

e. Mask due, but not returned: (1)

22.

20. Mask type returned *(check all that apply)*

a. Mirage FX: (1)
b. Mirage FX - Wide: (1)
c. Swift FX - Small pillows: (1)
d. Swift FX - Medium pillows: (1)
e. Swift FX - Large pillows: (1)

21. Date mask returned:

_____ _____-_____ _____ _____-_____ _____
day mon year

22. If study mask not returned, give reason *(check all that apply)*

a.	N/A, mask returned:	(1)
b.	Forgot, still at home:	(1)
c.	Discarded:	(1)
d.	Lost/destroyed:	(1)
e.	Unable to reach participant:	(1)
f.	Other *(specify)*:	(1)

_____
specify

If participant still has the mask, make arrangements to have it returned to the clinic as soon as possible.

G. Administrative information

23. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

24. Clinic coordinator PIN: _____ _____ _____

25. Clinic coordinator signature:

_____

Return checklist

- At the end of treatment (V6) make sure all masks for participant are at clinic. Make sure all parts of CPAP device are returned:
  - ( ) CPAP device
  - ( ) Humidifier unit and tub
  - ( ) Power supply unit and power cord
  - ( ) Air tubing
  - ( ) SD card - ship to DCC at V6
- Complete Device Transmittal Sheet (CT) and ship to Distribution Center at V7.
- If device not returned by V7 complete a UE form for not returning study device.

Methacholine Challenge Testing

Purpose: Record results of methacholine challenge testing.

When: Visits V1, V5, V6, and V7.

Instructions: Complete sections A-G before proceeding with section H. Methacholine challenge test should be administered at the same time of the day, preferably in the morning. Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of methacholine challenge:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID *(indicate visit nearest to date of test):* ____ ____

6. Form version date:

1 0 – S E P – 1 3
day mon year

B. Absolute contraindications

7. Is participant taking any beta-adrenergic blocking agent: (Yes 1) (No 2)

8. Has participant had a stroke or heart attack in last three months: (Yes 1) (No 2)

9. Does participant have a known aortic aneurysm: (Yes 1) (No 2)

10. Does the participant have uncontrolled hypertension (ie, SBP > 200, DBP > 100): (Yes 1) (No 2)

Males or females not of child bearing potential proceed to item 12.

11. Did the participant have a positive pregnancy test: (Yes 1) (No 2)

A pregnancy test is required <u>before</u> each methacholine challenge test unless the participant is not of child-bearing potential. If pregnancy testing is not performed, do not continue methacholine challenge testing.

12. Are any of items 7-11 answered ''Yes'': (Yes 1) (No 2)

If *''Yes''*, STOP, do not perform methacholine challenge testing; proceed to section K.

C. Relative contraindications

13. Does the participant have any of the following conditions *(check all that apply)*

a. Epilepsy: (1)

b. Any cardiovascular disease accompanied by bradycardia (slow heart beat): (1)

c. Vagotonia: (1)

d. Peptic ulcer disease: (1)

e. Thyroid disease: (1)

f. Urinary tract obstruction: (1)

g. Current use of cholinesterase-inhibitor medication: (1)

h. Other serious illness in last four weeks *(specify):* (1)

_____
name of illness

i. None of the above: (1)

14. Is participant wheezing or showing other signs of asthma: (Yes 1) (No 2)

15. Are any items 13 a-h checked or is item 14 answered ''Yes'':

(Yes 1) (No 2)

18. ____

16. Has a study physician reviewed the relative contraindications:

(Yes 1) (No 2)

If *"No"*, do not proceed until the item can be answered *"Yes"*, ie, the study physician has reviewed the relative contraindications.

17. Based on review of relative contraindications, did study physician approve the performance of the MeCh test:

(Yes 1) (No 2)

If *"No"*, STOP, do not perform methacholine challenge testing; proceed to section K.

D. Medication holds

18. Has participant taken any of the following medications within the indicated time period *(check all that apply)*

a. Short-acting bronchodilator within past 6 hours *(eg, albuterol, Ventolin, Proair, Proventil, Xopenex, isoproterenol, metaproterenol):* (1)

b. Medium-acting bronchodilator within past 24 hours *(eg, ipratropium, Combivent, oral albuterol, Choledyl):* (1)

c. Long-acting bronchodilator within past 24 hours *(eg, salmeterol, formoterol, Advair, Serevent, Symbicort, Dulera):* (1)

d. Ultra-long-acting bronchodilator within past 48 hours *(eg, tiotropium):* (1)

e. Oral theophylline within past 48 hours *(eg, Theodur, Uniphyl):* (1)

f. Cromolyn within past 8 hours: (1)

g. Nedocromil within past 24 hours: (1)

h. Leukotriene modifier within past 24 hours *(eg, Singulair, Accolate, montelukast, zafirlukast):* (1)

i. Antihistamines within past 48 hours *(eg, Zyrtec, cetirizine, fexofenadine, Xyzal, hydroxyzine):* (1)

If any of the above is checked, STOP, do not perform methacholine challenge testing; proceed to section K.

j. None of the above: (1)

E. Confounders

19. Has participant consumed caffeine (eg, tea, coffee, cola drink, Mountain Dew, energy drink, Anacin, chocolate) within past 6 hours:

(Yes 1) (No 2)

20. Has participant engaged in vigorous exercise within the past 6 hours:

(Yes 1) (No 2)

21. Has participant smoked a cigarette, cigar, or pipe within the past 6 hours:

(Yes 1) (No 2)

22. Has participant had a cold or upper respiratory infection within the past 4 weeks:

(Yes 1) (No 2)

23. Has participant had a known exposure to an allergen causing asthma within the past week:

(Yes 1) (No 2)

F. Other checks

24. Were vials of methacholine prepared and handled according to CPAP Manual of Procedures guidelines:

(Yes 1) (No 2)

25. Equipment

	Yes	No
a. KoKo spirometer:	(1)	(2)
b. KoKo dosimeter:	(1)	(2)
c. Nebulizer cups, pre-calibrated for CPAP:	(1)	(2)

26. Is a supervising physician immediately available in case of emergency:

(Yes 1) (No 2)

27. Are oxygen, stethoscope, pulse oximeter, and sphygmomanometer available in case of emergency:

(Yes 1) (No 2)

28. Is albuterol (both via MDI and via nebulizer) immediately available:

(Yes 1) (No 2)

29. Is atropine or equivalent anticholinergic medication (eg, Ipratropium) immediately available:

(Yes 1) (No 2)

30. Are all of items 24-29 answered ''Yes'':

(Yes 1) (No 2)

If *''No''*, do not proceed until all items can be answered ''Yes''.

G. Pre-diluent lung function

If participant is unable to perform acceptable and reproducible spirometry test during pre-diluent session, the methacholine challenge test should not be conducted.

31. Height *(measured; enter only a or b)*

a. Inches: ____ ____ • ____ ____ inches

b. Centimeters: ____ ____ ____ • ____ ____ cm

32. Weight *(measured; enter only a or b)*

a. Pounds: ____ ____ ____ lbs

b. Kilograms: ____ ____ ____ kg

33. Pre-diluent FEV_1: ____ • ____ ____ ____ liters

Obtain at least 3 and no more than 8 efforts to achieve acceptability and reproducibility criteria as set by ATS guidelines.

34. Was the spirometry maneuver acceptable and reproducible:

(Yes 1) (No 2)

V1: If *''No''*, STOP, proceed to section K.

V5, V6, V7: If *''No''*, select the highest FEV_1 from an acceptable maneuver (or the highest if none are acceptable) and proceed with the next step.

35. Is pre-diluent FEV_1 (item 33) less than 1 liter:

(Yes 1) (No 2)

If *''Yes''*, STOP, proceed to section K.

36. Pre-diluent FVC: ____ • ____ ____ ____ liters

37. Predicted FEV_1 (from Manual of Procedures or as calculated online at www.cctrials.org/alaacrc):

____ • ____ ____ ____ liters

38. Pre-diluent FEV_1 % predicted *(100* item 33 / item 37):* ____ ____ ____

39. Is pre-diluent FEV_1 predicted (item 38) *[enter only a or b]*

	Yes	No
a. For V1: Less than 75%:	(1)	(2)
b. For V5, V6, V7: Less than 70%:	(1)	(2)

If *''Yes''*, STOP, do not perform methacholine challenge testing; proceed to section K.

H. Diluent administration

Administer saline diluent (no methacholine) according to protocol. Perform spirometry about 30 seconds after methacholine dose. Repeat spirometry about every minute. Record the highest FEV_1 as the result for that time period. Obtain at least 3 and no more than 8 efforts to achieve acceptability and reproducibility criteria as set by ATS guidelines. See MOP for details.

40. Time diluent administered:

____ ____ : ____ ____ (1) am (2) pm
hour minute

41. Was the spirometry maneuver acceptable and reproducible:

(Yes 1) (No 2)

V1: If *''No''*, STOP, proceed to section K.

V5, V6, V7: If *''No''*, select the highest FEV_1 from an acceptable maneuver (or the highest if none are acceptable) and proceed with the next step.

42. Post-diluent FEV_1: ____ • ____ ____ ____ liters

43. Post-diluent FVC: ____ • ____ ____ ____ liters

44. Is Post-diluent FEV_1 (item 42) less than or equal to 80% of the pre-diluent FEV_1 *(0.8 * item 33)*:

Yes (1) No (2)

If *"Yes"*, STOP, proceed to section J.

45. Target FEV_1 *(0.8 * item 42 [post-diluent FEV_1])*: ___ • ___ ___

liters

This is the target FEV_1 for subsequent doses of MeCh.

I. Methacholine administration

Items 46-56: Administer methacholine vials in order shown. For each step: Perform spirometry about 30 seconds after methacholine dose. Repeat spirometry about every minute (minimum 2 attempts; maximum 5 attempts), until 2 acceptable spirometry tests obtained. Report the highest FEV_1. If none of the 5 spirometry tests meets acceptability criteria, then report the highest FEV_1. STOP if FEV_1 less than or equal to Target FEV_1. Consult MOP for details on methacholine administration and spirometry.

	a. Vial	b. Dose *(Concentration mg/mL)*	c. FEV_1 *(Liters)*	d. FVC *(Liters)*	e. Is column c less than or equal to target FEV_1?
46.	K	0.03125	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
47.	J	0.0625	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
48.	I	0.125	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
49.	H	0.25	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
50.	G	0.5	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
51.	F	1.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
52.	E	2.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
53.	D	4.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
54.	C	8.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*
55.	B	16.0	___ . ___ ___	___ . ___ ___	Yes ( ) No* ( ) → *Go to section J*
*** 56.**	A	32.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section J*

** If item 55e is a "No" at Visit 1, do not perform 32.0 mg/mL level, leave item 56 blank and proceed to item 60.*

Items 57-59 left blank intentionally.

60. Is vial A FEV_1 (item 56c, or item 55c if V1) greater than or equal to 90% pre-diluent FEV_1 *(0.9 * item 33):*

( ) Yes (1) ( ) No (2)

68. ____

J. Recovery

Administer 2 puffs albuterol via MDI and wait 10 minutes, per protocol.

61. Time of bronchodilator administration:

____ ____ : ____ ____ ( ) am (1) ( ) pm (2)
hour minute

62. Post-BD FEV_1: ____ ____ • ____ ____ liters

63. Post-BD FVC: ____ ____ • ____ ____ liters

64. Is Post-BD FEV_1 (item 62) greater than or equal to 90% pre-diluent FEV_1 *(0.9 * item 33):*

( ) Yes (1) ( ) No (2)

68. ____

Administer 2 additional puffs albuterol via MDI and wait 10 minutes, per protocol.

65. 2nd Post-BD FEV_1: ____ ____ • ____ ____ liters

66. 2nd Post-BD FVC: ____ ____ • ____ ____ liters

67. Is 2nd Post-BD FEV_1 (item 65) greater than or equal to 90% of the pre-diluent FEV_1 *(0.9 * item 33):*

( ) Yes (1) ( ) No (2)

If ''No,'' Consult physician before releasing the participant.

68. Did participant experience any complications of the methacholine challenge:

( ) Yes (1) ( ) No (2)

70. ____

69. Specify complications:

_____

_____

_____

70. Participant's FEV_1 was less than or equal to Target FEV_1 following the administration of any concentration of methacholine *(ie, are any responses in column e, items 46-56, checked ''Yes''):*

( ) Yes (1) ( ) No (2)

72. ____

Calculate PC_{20} for FEV_1 as directed in protocol or using calculator online at www.cctrials.org/alaacrc:

71. PC_{20} FEV_1:

____ ____ ____ • ____ ____ ____ ____
mg/mL MeCh

Note: At V1 the PC_{20} must be less than or equal to 8 mg/mL to be eligible.

72. Person administering test

a. Name:

_____

b. PIN: ____ ____ ____

K. Administrative information

73. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

74. Clinic coordinator PIN: ____ ____ ____

75. Clinic coordinator signature *(do not key):*

_____

Missed Data

Purpose: Record information about missed study data.

When: After a visit window has closed for a randomized participant and visit/contact forms were missed. Complete a separate Missed Data (MD) form for each visit that is missed or that has missing data.

Instructions: Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date completed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

2 1 – A U G – 1 2
day mon year

B. Missed visit information

7. Was visit or phone contact missed completely:

(Yes 1) (No 2)

8. Forms missed
(check all that apply)

a. BA (Baseline Asthma and Medical History): (1)
b. CV (Clinic Visit Form): (1)
c. DD (Device Dispensing and Return Form): (1)
d. NO (Nitric Oxide Form): (1)
e. PC (Phone Contact): (1)
f. PE (Physical Exam): (1)
g. MC (Methacholine Challenge Testing): (1)
h. TT (Treatment Termination): (1)
i. UM (Unmasking): (1)
j. RT (HRCT Scan Acquisition Form): (1)
k. Other *(specify):* (1)

_____
form

l. N/A, none missed: (1)

9. Questionnaires missed
(check all that apply)

a. TA (Asthma Control Test): (1)
b. AS (Asthma Symptom Utility Index): (1)
c. MQ (Marks Quality of Life Questionnaire): (1)
d. MP (MAP Questionnaire): (1)
e. BQ (Berlin Sleep Questionnaire): (1)
f. ES (Epworth Sleep Questionnaire): (1)
g. SQ (Pittsburgh Sleep Quality Index): (1)
h. NQ (Sino-Nasal Questionnaire - 6 week): (1)
i. EV (Study Evaluation): (1)
j. Other *(specify):* (1)

_____
questionnaire

k. N/A, none missed: (1)

Note: For specimens that were collected but not shipped, are lost, or are destroyed, complete a UE form.

10. Are diary cards missing:

Yes (1) No (2)

14.

If Yes, list the start and end dates for intervals with missing diary cards. For items 11-13, each date should be on or before date of visit or close of window.

11. First interval missed

a. Start date:

____ ____–____ ____ ____–____ ____
day mon year

b. End date:

____ ____–____ ____ ____–____ ____
day mon year

12. Second interval missed

a. Start date:

____ ____–____ ____ ____–____ ____
day mon year

b. End date:

____ ____–____ ____ ____–____ ____
day mon year

13. Third interval missed

a. Start date:

____ ____–____ ____ ____–____ ____
day mon year

b. End date:

____ ____–____ ____ ____–____ ____
day mon year

14. Reason for missed visit or data *(check all that apply)*

a. Participant was ill: (1)

b. Participant was temporarily away from area: (1)

c. Participant has permanently moved from area: (1)

d. Participant refused: (1)

e. Unable to contact participant: (1)

f. Participant forgot: (1)

g. Could not schedule participant within window: (1)

h. Problem at facility *(specify):* (1)

_____
problem

i. Other *(specify):* (1)

_____

_____

15. Additional notes/explanations:

_____

_____

_____

_____

_____

C. Administrative information

16. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

17. Clinic coordinator PIN: ____ ____ ____

18. Clinic coordinator signature:

_____

Nitric Oxide Form

Purpose: To record the fractional concentration of exhaled nitric oxide (eNO) in exhaled breath.

When: V2, V6, V7.

Instructions: Study participant should not eat or drink anything for 1 hour before the test. eNO to be measured prior to or one hour after spirometry. Record eNO results on this form. **If result of eNO is less than 5 ppb, enter "000"**. Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date eNO performed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

6. Form version date:

1 2 – J U N – 1 2
day mon year

B. Procedure

7. Confounders *(check only one for each subitem)*

a. Did participant have a spirometry test in the hour before eNO testing:
- Yes (1)
- No (2)
- Don't know (3)

b. Did participant eat or drink anything in the hour before eNO testing:
- Yes (1)
- No (2)
- Don't know (3)

c. Did participant do any strenuous exercise in the hour before eNO testing:
- Yes (1)
- No (2)
- Don't know (3)

d. Did participant use a bronchodilator in the 2 hours before eNO testing:
- Yes (1)
- No (2)
- Don't know (3)

e. Does participant have an upper and/or lower respiratory tract infection:
- Yes (1)
- No (2)
- Don't know (3)

8. Oral/inhaled corticosteroid use

a. Did participant use oral/inhaled corticosteroids today:

(Yes 1) (No 2)

9.

b. Time most recently used:

____ ____ : ____ ____ (am 1) (pm 2)
hour minute

9. Result of daily quality control test for NIOX MINO:

(Pass 1) (Fail 2)

10. Date participant eNO measured *(read off the NIOX MINO device):*

____ ____ – ____ ____ ____ – ____ ____
day mon year

11. Time participant eNO measured *(read off the NIOX MINO device):*

____ ____ : ____ ____ (am 1) (pm 2)
hour minute

12. Participant eNO test results for the NIOX MINO

a. Test one: ____ ____ ____ ppb

b. Test two: ____ ____ ____ ppb

13. Unable to get test result due to *(check all that apply)*

a. Not applicable, test successful: (1)

b. Equipment problem: (1)

c. Participant problem: (1)

d. Other *(specify):* (1)

_____

_____

C. Administrative information

14. Date form reviewed:

____ ____ ____ ____ ____ ____
day mon year

15. Clinic coordinator PIN: ____ ____ ____

16. Clinic coordinator signature:

_____

Phone Contact

Purpose: To assess CPAP adherence, side effects, trouble-shooting. Encourage participant to talk about how they are using the device (eg, where they put the device, are they using a grounded wall outlet, are they emptying tub before each use).
When: V3.
Instructions: Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant, and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of phone contact:

____ ____-____ ____ ____-____ ____
day mon year

5. Visit ID: V 3

6. Form version date:

2 7-J U N-1 2
day mon year

Identify yourself as clinic staff and state the purpose of the call (eg, "Hi! This is _____ from the CPAP Asthma Study. I'm calling to see how you're doing. Would now be a good time to answer a few questions about using your CPAP device?")

B. Study treatment

7. Did you use your CPAP device all night, every night since V2:

Yes (1) No (2)

10.

8. How many hours **or** nights have you missed wearing the CPAP device *(enter only a or b)*:

a. Hours: ____ ____ • ____ ____
hours

OR

b. Nights: ____ ____
nights

9. Why did you miss using the CPAP device *(check all that apply)*

a. Forgot: (1)
b. Too busy: (1)
c. Did not have study device on hand: (1)
d. Lost CPAP device or mask: (1)
e. Difficulty using CPAP device: (1)
f. Mask is not comfortable: (1)
g. Device or mask too noisy: (1)
h. Interrupts my sleep: (1)
i. Disturbs others at home: (1)
j. Cold symptoms: (1)
k. Side effects *(specify)* (1)

_____
specify side effect

l. Other *(specify)*: (1)

_____
specify reason

10. Are you comfortable with study device use:

Yes (1) No (2)

11. Are you comfortable with applying the mask:

Yes (1) No (2)

12. Do you understand temperature adjustment:

Yes (1) No (2)

13. Do you clean the mask:

Yes (1) No (2)

14. Do you use fresh, distilled or boiled tap water for each use:

Yes (1) No (2)

15. Since your last visit, have you had any symptoms (eg, nose bleeds, stuffy nose, cold symptoms, ear fullness, mask irritation) that you think might be related to the use of CPAP device:

Yes (1) No (2)

If "Yes," specify:

_____

_____

If the participant reports difficulty with CPAP device, coordinator should attempt trouble-shooting over the phone. If participant reports mask difficulty (eg, poor fit, irritation) coordinator should conduct an extra study visit to refit mask.

C. Study procedures

16. Did you complete the diary card:

Yes (1) No (2)

17. Why did you not complete diary card *(check all that apply)*

a. Forgot: (1)
b. Hard to understand: (1)
c. Lost or destroyed: (1)
d. Other *(specify)*: (1)

_____
specify reason

18. Do you have any questions:

Yes (1) No (2)

D. Coordinator actions *(confirm)*

19. Reminded participant to *(check all that apply)*

a. Use Asthma Action Plan in an emergency: (1)
b. Review instruction packet: (1)
c. Consult private physician for asthma care: (1)
d. Complete diary cards: (1)

20. V4 appointment confirmed and/or rescheduled:

Yes (1) No (2)

V4 appointment information *(not data entered)*

Date:

_____ _____-_____ _____ _____-_____ _____
day mon year

Time: _____ _____:_____ _____ ( ) am ( ) pm

If unable to keep appointment, try to reschedule on phone.

Rescheduled V4 appointment

Date:

_____ _____-_____ _____ _____-_____ _____
day mon year

Time: _____ _____:_____ _____ ( ) am ( ) pm

E. Administrative information

21. Date form reviewed:

_____ _____-_____ _____ _____-_____ _____
day mon year

22. Clinic coordinator PIN: _____ _____ _____

23. Clinic coordinator signature:

_____

Physical Exam

Purpose: To record information about a participant's health.
When: Randomization (V2).
Instructions: Completed by certified study physician or designee. Items marked with an "*" are mandatory. Note abnormalities and briefly describe; use extra sheets if necessary. Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of exam:

____ ____ - ____ ____ ____ - ____ ____
day mon year

5. Visit ID: V 2

6. Form version date:

1 2 - J U N - 1 2
day mon year

B. Physical exam

***7.** Blood Pressure

a. Systolic: ____ ____ ____ mmHg

b. Diastolic: ____ ____ ____ mmHg

***8.** Heart Rate: ____ ____ ____ beats/min

***9.** Temperature:
°C (1) °F (2) ____ ____ ____ . ____

***10.** Respiration Rate: ____ ____ breaths/min

* **11.**	General appearance: _____	Normal (1)	Abnormal (2)	
* **12.**	Chest: _____	Normal (1)	Abnormal (2)	
* **13.**	Heart: _____	Normal (1)	Abnormal (2)	
* **14.**	HEENT/Neck: _____	Normal (1)	Abnormal (2)	
15.	Abdomen: _____	Normal (1)	Abnormal (2)	Not Examined (3)
16.	Extremities: _____	Normal (1)	Abnormal (2)	Not Examined (3)
17.	Skin: _____	Normal (1)	Abnormal (2)	Not Examined (3)
18.	Neurological: _____	Normal (1)	Abnormal (2)	Not Examined (3)
19.	Other *(specify)*: _____	Normal (1)	Abnormal (2)	Not Examined (3)

C. Physician signature *(V2)*

20. Is examiner a CPAP certified study physician:

Yes (1) → **22.** No (2)

If No, then form must be countersigned by overseeing CPAP certified Study Physician.

21. Examiner

a. Examiner signature:

_____

b. Examiner name *(print)*:

_____

c. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

22. CPAP certified study physician

a. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

b. CPAP certified study physician PIN:

____ ____ ____

c. CPAP certified study physician signature:

_____

D. Administrative information

23. Date form reviewed:

____ ____-____ ____ ____-____ ____
day mon year

24. Clinic coordinator PIN: ____ ____ ____

25. Clinic coordinator signature:

_____

Randomization Form

Purpose: To document eligibility for randomization and record treatment assignment.

When: V2 after all other forms and activities are completed.

Instructions: If participant meets all eligibility criteria, key into CPAP data system at www.cctrials.org/alaacrc. Screening form (SC) must be keyed prior to obtaining treatment assignment. **It is recommended that the responsible study physician sign this form prior to randomization. However, if that is not logistically possible, the physician should sign this form within a prudent period of time after randomization.** If any item checked is marked with [STOP], participant is ineligible for randomization; complete section G but do not key form into data system.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Visit date:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: V 2

6. Form version date:

0 5 – S E P – 1 2
day mon year

B. Inclusion criteria for randomization

7. Pre-bronchodilator FEV_1

a. Pre-bronchodilator FEV_1 greater than or equal to 75% predicted at V1:

Yes (1) No (2) STOP

b. Percent predicted pre-bronchodilator FEV_1 at V1:

____ ____ ____
%

8. Airways reactivity

a. Methacholine bronchial challenge with PC_{20} less than or equal to 8 mg/mL for FEV_1 at V1:

Yes (1) No (2) STOP

b. PC_{20} value at V1:

____ ____ ____ • ____ ____ ____ ____
mg/mL MeCh

9. Stable asthma defined by no change in asthma treatment, ED visit, hospitalization, or urgent care visit for asthma since V1:

Yes (1) No (2) STOP

10. If receiving immunotherapy, stable therapy since V1:

Yes (1)
No (2) STOP
Not receiving immunotherapy (3)

11. Accessible by telephone:

Yes (1) No (2) STOP

C. Exclusion criteria for randomization

12. Acute respiratory illness since V1:

Yes (1) → STOP No (2)

13. Systemic corticosteroid therapy since V1:

Yes (1) → STOP No (2)

14. Known intolerance to methacholine:

Yes (1) → STOP No (2)

15. Contraindications for methacholine challenge test

	Yes	No
a. Current use of beta blocker:	(1) → STOP	(2)
b. Heart attack or stroke in past 3 months:	(1) → STOP	(2)
c. Uncontrolled hypertension:	(1) → STOP	(2)
d. Known aortic aneurysm:	(1) → STOP	(2)

16. For women of childbearing potential: currently pregnant, lactating, or unwilling to practice effective contraception for the duration of study:

Yes (1) → STOP

No (2)

Not applicable (3)

Note: A pregnancy test should have been administered to women of childbearing potential prior to Methacholine Challenge Test.

D. Procedures

17. Verify that the following baseline procedures were completed or checked

	Yes	No
a. Physical Exam (PE):	(1)	(2)
b. Exhaled nitric oxide (eNO):	(1)	(2)
c. Blood specimen collected:	(1)	(2)
d. Diary cards reviewed:	(1)	(2)
e. Questionnaires completed:	(1)	(2)

All of the above should be done before proceeding.

E. Final check

18. Verify informed consent signed:

Yes (1) No (2) → STOP

19. Was permission granted in main or separate consent/assent to donate DNA and have it stored:

Yes (1) No (2)

20. Participant meets all eligibility criteria for randomization:

Yes (1) No (2) → STOP

F. HRCT substudy

21. Has participant agreed to participate in HRCT substudy:

Yes (1)

No/not applicable *(clinic not participating in substudy)* (2)

23.

22. HRCT consent form signed:

Yes (1) No (2)

STOP

If item 21 is ''Yes,'' then do not continue until item 22 can be answered ''Yes.''

G. Administrative information

23. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

24. Clinic coordinator PIN: ____ ____ ____

25. Clinic coordinator signature *(do not key):*

_____

Items below are not required for non-randomized patients.

26. Study physician PIN: ____ ____ ____

27. Study physician signature *(do not key):*

_____

28. Date study physician signed:

____ ____–____ ____ ____–____ ____
day mon year

Note: · **Print copy of treatment assignment from data system and attach to this form.**
· **Affix tear-off label from assigned device to DD form.**

H. Randomization data *(generated by DCC data system)*

29. Kit ID *(assigned by data system):*

P –____ ____ ____ ____

Screening Form

Purpose: To document eligibility for enrollment.

When: V1.

Instructions: If participant meets screening criteria, key into CPAP data system at www.cctrials.org/alaacrc. It is recommended that the responsible study physician sign this form prior to Methacholine Challenge test. However, if that is not logistically possible, the physician should sign this form within a prudent period of time after screening. If any item checked is marked with [STOP], participant is ineligible for enrollment; complete section G. Do not key form for participants who fail screening.

A. Clinical center, participant and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID *(from next sequentially numbered label on Clinic Label Sheet):*

3. Name code: ____ ____ ____ ____ ____

4. Date of screening:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit ID: V 1

6. Form version date:

2 9 – A U G – 1 2
day mon year

B. Inclusion criteria

7. Age at screening: ____ ____ years

8. 15-60 years of age:

Yes (1) No (2) STOP

9. Physician diagnosed asthma:

Yes (1) No (2) STOP

10. On prescribed medication for asthma for at least the past 12 months:

Yes (1) No (2) STOP

11. Stable asthma defined by no change in treatment, ED visit, hospitalization, or urgent care visit for asthma for the past 8 weeks:

Yes (1) No (2) STOP

12. If receiving immunotherapy, stable therapy for the past 8 weeks:

Yes (1)
No (2) STOP
Not receiving immunotherapy (3)

13. Non-smoker for more than 6 months:

Yes (1) No (2) STOP

14. Less than or equal to 10 pack-year history of smoking *(10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):*

Yes (1) No (2) STOP

15. Hours in bed per night

a. Hours spent in bed per night on average: ____ ____

b. Number of hours is greater than or equal to 6:

Yes (1) No (2) STOP

16. Willingness to sleep in the same place for 5 days a week on average for the next 4 months:

( ) Yes (1) ( ) No (2) STOP

17. Ability and willingness to provide informed consent:

( ) Yes (1) ( ) No (2) STOP

18. Accessible by telephone:

( ) Yes (1) ( ) No (2) STOP

C. Exclusion criteria

19. Height *(measured; enter only a or b)*

a. Inches: ____ ____ • ____ inches

b. Centimeters: ____ ____ ____ • ____ cm

20. Weight *(measured; enter only a or b)*

a. Pounds: ____ ____ ____ lbs

b. Kilograms: ____ ____ ____ kg

21. Weight less than or equal to 66 pounds (30 kg):

( ) Yes (1) STOP ( ) No (2)

22. Body Mass Index (BMI)

a. BMI: ____ ____ kg/m^2

b. BMI greater than or equal to 35:

( ) Yes (1) STOP ( ) No (2)

BMI=[(weight (kg))/(height (m))^2]

As calculated online at www.cctrials.org/alaacrc. See MOP for conversions.

23. Acute respiratory illness in the past month:

( ) Yes (1) STOP ( ) No (2)

24. Systemic corticosteroid therapy during the past 3 months:

( ) Yes (1) STOP ( ) No (2)

25. Self-reported history of sleep apnea:

( ) Yes (1) STOP ( ) No (2)

26. Multivariable Apnea Prediction (MAP) Index probability greater than or equal to 20%:

( ) Yes (1) STOP ( ) No (2)

27. Known sleep disorder currently being treated by a sleep specialist:

( ) Yes (1) STOP ( ) No (2)

28. Previous use of CPAP for any reason:

( ) Yes (1) STOP ( ) No (2)

29. Current enrollment of household member in this CPAP study:

Yes (1) STOP No (2)

30. Chronic disease that in the opinion of the investigator would interfere with participation in trial or put participant at risk by participation *(eg, non-skin cancer, chronic disease of the lung (other than asthma), chronic heart diseases, liver, kidney or nervous system diseases, endocrine diseases, or immunodeficiency):*

Yes (1) STOP No (2)

31. Pre-existing condition that in the opinion of the study physician may be a contra-indication for positive airway pressure *(eg, severe bullous lung disease, pneumo-thorax, pathologically low blood pressure, dehydration, cerebrospinal fluid leak, recent cranial surgery, trauma, bypassed upper (supraglottic) airway):*

Yes (1) STOP No (2)

32. Known intolerance to methacholine:

Yes (1) STOP No (2)

33. Contraindications for methacholine challenge test

Yes No

a. Current use of beta blockers: (1) STOP (2)

b. Heart attack or stroke in past 3 months: (1) STOP (2)

c. Uncontrolled hypertension: (1) STOP (2)

d. Known aortic aneurysm: (1) STOP (2)

34. Use of investigative drugs or participation in intervention trial in the past 30 days:

Yes (1) STOP No (2)

35. Homeless:

Yes (1) STOP No (2)

36. Intention to move out of area within the next 4 months:

Yes (1) STOP No (2)

D. Screening review

37. Verify informed consent signed:

Yes (1) No (2) STOP

38. Participant meets screening criteria:

Yes (1) No (2) STOP

39. For women of childbearing potential currently pregnant (per participant history), lactating, or unwilling to practice effective contraception for the duration of study:

Yes (1) STOP

No (2)

Not applicable (3)

A pregnancy test will be administered to women of childbearing potential prior to Methacholine Challenge Test.

40. V1 methacholine challenge (preceded by pregnancy test as applicable) completed or scheduled before V2:

Yes (1) No (2)

Methacholine challenge (preceded by pregnancy test if applicable) must be completed before V2.

E. Peak expiratory flow rate

41. Peak flow measured by Mini-Wright peak flow meter

a. First reading: ____ ____ ____ L/min

b. Second reading: ____ ____ ____ L/min

c. Third reading: ____ ____ ____ L/min

F. HRCT substudy

42. Has participant agreed to participate in HRCT substudy:

Yes (1)

No/not applicable *(clinic not participating in substudy)* (2)

45.

43. Screening criteria

	Yes	No
a. 18 years or older:	(1)	(2)
b. Able to hold breath for at least 15 seconds:	(1)	(2)
c. Able to lie flat for at least 30 minutes:	(1)	(2)
d. Claustrophic in CT scanner:	(1)	(2)

45.

44. HRCT substudy informed consent signed:

Yes (1) No (2)

Obtain HRCT consent before randomization.

G. Administrative information

45. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

46. Clinic coordinator PIN: ____ ____ ____

47. Clinic coordinator signature *(do not key):*

_____

Items below are not required for screen fails.

48. Study physician PIN: ____ ____ ____

49. Study physician signature *(do not key):*

_____

50. Date physician signed:

____ ____–____ ____ ____–____ ____
day mon year

51. Asthma action plan values *(use values calculated by data system)*

a. Personal best peak flow *(best of 3 from item 41):* ____ ____ ____

b. Red zone: below ____ ____ ____

c. Yellow zone:

____ ____ ____ to ____ ____ ____

d. Green zone: above ____ ____ ____

Copy values to Asthma Action Plan card.

Summary V1

Forms/procedures required:

- Baseline Asthma and Medical History (BA)
- Questionnaires:
  - Multivariable Apnea Prediction Questionnaire (MP)
  - Berlin Sleep Questionnaire (BQ)
  - Epworth Sleepiness Scale (ES)
  - Pittsburgh Sleep Quality Index (SQ)
- Pregnancy test for women of childbearing potential*
- Methacholine Challenge Testing (MC)*

**Pregnancy test for women of childbearing potential and methacholine challenge may be done on a different day than rest of V1 data collection, but must be completed before V2.*

Treatment Termination

Purpose: Record permanent termination of study device use.

When: V6 or during trial.

Instructions: Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant, and visit identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of report:

____ ____–____ ____ ____–____ ____
day mon year

5. Visit ID: ____ ____
Indicate "N" as visit ID if not associated with a scheduled visit.

6. Form version date:

2 9 - A U G - 1 2
day mon year

B. Termination

7. Date of last study device use:

____ ____–____ ____ ____–____ ____
day mon year

8. Type of termination *(check only one):*

Study device permanently stopped before V6 (1)
At V6 (2)

9. Main reasons for device termination *(check all that apply)*

a. Participant completed V6: (1)

b. Adverse event *(specify event):* (1)

_____
specify

c. Side effects *(specify):* (1)

_____
specify

d. Asthma symptoms: (1)

e. Participant request: (1)

f. Unable to reach participant: (1)

g. Pregnancy: (1)

h. Other *(specify):* (1)

_____
specify

NOTE: If participant did not return device, complete a UE form.

10. Were study device and mask collected from participant at this time:

Yes (1) No (2)

If "yes", complete the Device Dispensing and Return (DD) form.

Note: If participant required unmasking, complete the Unmasking (UM) form.

C. Administrative information

11. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

12. Clinic coordinator PIN: ____ ____ ____

13. Clinic coordinator signature:

_____

Unmasking

Purpose: Record unmasking of study treatment.

When: V7 or when study treatment is unmasked.

Instructions: Key into CPAP data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

1. Clinical center: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of report:

____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID: ____ ____

Indicate "N" as visit ID if not associated with a scheduled visit.

6. Form version date:

2 9 – A U G – 1 2
day mon year

B. Unmasking

7. ID of study kit issued:

P – ____ ____ ____ ____

8. Date unmasked:

____ ____ – ____ ____ ____ – ____ ____
day mon year

9. Type of unmasking *(check only one):*

Unscheduled unmasking *(before V6)* (1)

Unscheduled unmasking *(between V6 and V7)* (2)

Scheduled unmasking at end of trial *(at V7)* (3)

11.

Reminder: Treatment Termination (TT) form to be completed if treatment has been terminated.

10. Reason for unscheduled unmasking *(specify):*

_____

_____

_____

11. Treatment assignment revealed from *(check only one):*

Standard unmasking envelope (1)

Study kit ID on treatment unmasking envelope:

_____

Web emergency unmasking site (2)

DCC (3)

Other *(specify)* (4)

_____
identify method

12. Were any CPAP staff intentionally unmasked:

Yes (1) No (2)

14.

13. CPAP staff member(s) unmasked *(specify):*

_____

_____

C. Administrative information

14. Date form reviewed:

____ ____ – ____ ____ ____ – ____ ____
day mon year

15. Clinic coordinator PIN: ____ ____ ____

16. Clinic coordinator signature:

_____