Baseline Asthma and Medical History

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

When: Visit 1 (V1).

Instructions: Key into STAN 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. Visit date:

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

5. Visit ID: V 1

6. Form version date:

3 0 – J U N – 1 1
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)

_____
specify

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. Asthma diagnosis and onset

16. Who made your original diagnosis of asthma *(check only one):*

Primary care doctor *(family doctor, pediatrician)* (1)
Lung doctor (2)
Allergy doctor (3)
Other *(specify)* (4)

_____
specify

17. Who makes the main decisions about your asthma care *(eg, who is currently prescribing your asthma medications; check only one):*

Primary care doctor *(family doctor, pediatrician)* (1)
Lung doctor (2)
Allergy doctor (3)
Other *(specify)* (4)

_____
specify

18. Did your asthma develop after an upper respiratory tract infection/bronchitis:

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

E. Emergency care

19. 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)

20. 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)

21. 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)

22. 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)

F. Asthma triggers

Do any of the following make your asthma worse:

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

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

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

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

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

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

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

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

27. Food additives:

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

28. Weather changes:

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

29. Exercise:

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

30. Cleaning supplies:

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

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

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

_____
specify

e. None: (1)

32. 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 36.

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

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

34. Association of your asthma with pregnancy:

Yes (1)
No (2)
Never pregnant (3)

35. Are you on hormone replacement therapy or had an ovariectomy:

Yes (1) No (2)

36. 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)

_____
specify

f. None: (1)

37. Have you had sinus surgery:

Yes (1) No (2)

38. 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)

39. What is your occupation:

_____
specify occupation

40. Effect of change of occupation on your asthma *(check only one):*

Change made asthma better (1)
Change made asthma worse (2)
Not sure (3)
Did not change occupation (4)
Did not change asthma (5)

41. Effect of change of residence on your asthma *(check only one):*

Change made asthma better (1)
Change made asthma worse (2)
Not sure (3)
Did not change residence (4)
Did not change asthma (5)

G. Family history

Do any of your biological family members have the following conditions *(check as applicable)*:

		a. Father	b. Mother	c. Any brothers or sisters	d. Any of your children	e. None
42.	Asthma:	(1)	(1)	(1)	(1)	(1)
43.	Hay fever or allergies:	(1)	(1)	(1)	(1)	(1)
44.	Eczema:	(1)	(1)	(1)	(1)	(1)

H. Symptoms

45. 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)

I. Asthma treatment history

46. Over the past 6 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. 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. 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)

d. 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)

e. 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)

f. 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)

g. 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)

h. 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)

i. Methylxanthines *(theophylline)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

j. 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)

k. Omalizumab *(Xolair)*:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
Never (5)

l. 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)

m. 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

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:
Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Less than 1 time per month (4)
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

J. Cigarette Smoking History

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

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

51.

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

____ ____ • ____
years

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

____ • ____
# of packs

50. Total number of pack-years *(multiply item 48 and item 49):*

____ ____
pack years

K. Current smoking exposure

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

Yes (1) No (2)

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

Yes (1) No (2)

L. Sinusitis and rhinitis history

53. Have you had hay fever or allergic rhinitis in the last year:

Yes (1) No (2)

56.

54. Which seasons do you have symptoms of hay fever/allergic rhinitis *(check all that apply)*

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

55. How old were you when these symptoms of allergic rhinitis or hay fever started:

____ ____
years

56. Number of episodes of sinusitis in last year:

0 episodes (1)
1-3 episodes (2)
More than 3 episodes (3)

57. Number of courses of antibiotics for sinusitis in last year:

0 courses (1)
1-3 courses (2)
More than 3 courses (3)

58. Have you ever had sinus surgery:

Yes (1) No (2)

59. Have you ever had nasal polyps:

Yes (1) No (2)

60. Over the last 6 months, how often, on average, did you have the following symptoms

a. Runny nose:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

b. Post nasal drip:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

c. Need to blow nose:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

d. Cough:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

e. Sneezing:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

f. Facial pain/pressure:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

g. Thin clear nasal discharge:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

h. Thick nasal discharge:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

i. Discolored nasal discharge:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

j. Nasal obstruction:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

k. Nasal itching:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

l. Loss of or altered sense of smell:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

m. Loss of or altered sense of taste:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

M. Sinusitis and rhinitis medications

61. Over the past 3 months, on average, how often did you use the following medications specifically for your nose and/or sinus symptoms

a. Nasal steroids *(Rhinocort, Nasonex, Flonase, Nasocort):*
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

b. Nasal spray decongestants *(Afrin, phenylephrine):*
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

c. Oral decongestants:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

d. Antihistamines *(Benadryl, Claritin, Allegra, Astelin, Zyrtec):*
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

e. Nasal saline:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

f. Allergy shots:
- Daily (1)
- 2-6 times per week (2)
- 1-4 times per month (3)
- Never (4)

g. Other *(specify):*

Yes (1) No (2)

_____
specify

N. General Medical Conditions

62. 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 (Chronic Obstructive Pulmonary Disease):	(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 *(specify):*	(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. Other condition(s) that would interfere with participation in the study:	(1)	(2)

_____
specify

O. Health and development questions

63. Have you ever been diagnosed with sleep apnea:

Yes (1) No (2)

64. Do you use Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BIPAP):

Yes (1) No (2)

65. Have you ever been told you snore:

Yes (1) No (2)

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

Yes (1) No (2)

67. Do you often take naps during the day:

Yes (1) No (2)

68. Have you ever been diagnosed with Gastroesophageal Reflux disease:

Yes (1) No (2)

69. How often do you get symptoms of indigestion or heartburn:

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Never (4)

70. How often do you take an over the counter antacid *(eg, Tums, Maalox, Mylanta, etc):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Never (4)

71. How often do you take H_2 antagonists *(eg, Zantac, Pepcid, Ranitidine, Famotidine, Cimetidine):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Never (4)

72. How often do you take proton pump inhibitors *(eg, Prilosec, Omeperazole, Protonix, Aciphex, Nexium):*

Daily (1)
2-6 times per week (2)
1-4 times per month (3)
Never (4)

73. Do you have diabetes:

Yes (1) No (2) → **76.**

74. How old were you when you were diagnosed with diabetes: ____ ____ years

75. How is your diabetes controlled *(check only one):*

Diet alone (1)
Tablets alone (2)
Insulin alone (3)
Insulin and tablets (4)
None apply (5)

76. 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)

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

____ ____ ____ pounds

78. What was your age of first menstrual period

a. Age: ____ ____ years

b. Don't know (1)

c. Not applicable (1)

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

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

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

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

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

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

P. Administrative information

82. Date form reviewed:

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

83. Clinic coordinator PIN: ____ ____ ____

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

_____

STAN Reference #: _____

Clinic Visit Form

Purpose: To record information about diary cards, asthma and sinus symptoms, medications, specimen collection, and other visit procedures.

When: Visits V2, V3, V4, and V5.

Respondent: Participant, parent/guardian, or both.

Instructions: Complete form at clinic visit. Key into STAN data system at www.cctrials.org/alaacrc within 10 working days. In all items ''you'' refers to participant.

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: ____ ____

6. Form version date:

2 7 – A P R – 1 1
day mon year

B. Diary Cards

7. Since the last study visit, how many Diary Cards has the participant submitted: ____ ____

8. Number of Diary Cards not returned since last study visit: ____ ____

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

a. N/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)

_____
identify reason

10. Review of proper completion of Diary Card with participant *(check all that apply)*

a. N/A, diary card completion not reviewed: (1)
b. Dates: (1)
c. Peak flow: (1)
d. Drug use for quick relief: (1)
e. Study nasal spray: (1)
f. Other diary card items: (1)

11. Explain problems, if any, when reviewing proper completion of diary card *(specify):*

_____

_____

C. Unscheduled contacts since last study visit

12. Phone contacts

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

Yes (1) No (2)
13.

b. If Yes, specify how many: ____ ____

13. Clinic visits

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

Yes (1) No (2)
14.

b. If Yes, specify how many: ____ ____

D. Interim Medical History

14. Is this Visit 2:

Yes (1) No (2)

17. ___

15. Since the last study visit, how many days have you NOT used your study nasal spray: ____ ____ days

16. Why did you miss taking your study nasal spray *(check all that apply)*

a. N/A, took study nasal spray everyday: (1)

b. Permanently stopped study nasal spray: (1)

c. Temporarily stopped study nasal spray *(specify):* (1)

_____
identify reason

d. Forgot: (1)

e. Ran out of study nasal spray: (1)

f. Did not have study nasal spray on hand: (1)

g. Lost study nasal spray: (1)

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

_____
list side effects

i. Too busy: (1)

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

_____
identify reason

17. Since the last study visit, have you taken medications specifically for the treatment of asthma:

Yes (1) No (2)

26. ___

18. Rescue bronchodilator drugs participant taken since last visit *(check all that apply)*

	Drug name (Trade names)	**Yes**	**Estimate # of uses**
a.	NA, no bronchodilator drugs taken:	(1)	
b.	Albuterol nebulizer (0.083%):	(1)	___ ___ ___ num
c.	Albuterol nebulizer (0.5%):	(1)	___ ___ ___ num
d.	Albuterol metered dose inhaler:	(1)	___ ___ ___ num
e.	Levalbuterol (Xopenex):	(1)	___ ___ ___ num
f.	Pirbuterol (Maxair):	(1)	___ ___ ___ num
g.	Ipratropium bromide (Atrovent Nebulizer):	(1)	___ ___ ___ num
h.	Ipratropium bromide (Atrovent HFA):	(1)	___ ___ ___ num
i.	Ipratropium bromide and albuterol (Combivent DuoNeb):	(1)	___ ___ ___ num
j.	Other: _____ specify	(1)	___ ___ ___ num
k.	Other: _____ specify	(1)	___ ___ ___ num
l.	Other: _____ specify	(1)	___ ___ ___ num

19. 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 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

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

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
h.	NA, no inhaled corticosteroid drugs taken:	(1)		
i.	Beclomethasone (Beclovent, Vanceril, QVar, Vanceril Double Strength):	(1)	___ ___ ___ mcg	___ ___ num
j.	Budesonide (Pulmicort):	(1)	___ ___ ___ mcg	___ ___ num
k.	Flunisolide (AeroBid, Aerospan):	(1)	___ ___ ___ mcg	___ ___ num
l.	Fluticasone (Flovent):	(1)	___ ___ ___ mcg	___ ___ num
m.	Triamcinolone (Azmacort):	(1)	___ ___ ___ mcg	___ ___ num
n.	Mometasone furoate (Asmanex):	(1)	___ ___ ___ mcg	___ ___ num
o.	Ciclesonide (Alvesco):	(1)	___ ___ ___ mcg	___ ___ num
p.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
q.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num
r.	Other: _____ specify	(1)	___ ___ ___ mcg	___ ___ num

21. 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 inhaled corticosteroid 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.	Other combination: _____ specify	(1)	___ ___ ___ / ___ ___ mcg	___ ___ num

22. 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

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

	Drug name (Trade names)	**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

24. 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

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

	Drug name (Trade names)	**Yes**	**Dose**	**Puffs/Ampules per day**
a.	NA, no non-steroidal 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)	_____	_____
			Dose	**Injections per month**
h.	Omalizumab (Xolair):	(1)	___ ___ ___ mg	___ ___ num

26. Since the last study visit, have there been any changes in asthma medications, including dose changes, adding drugs, or stopping drugs:

Yes (1) No (2)

If ''Yes,'' name drug and 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.

27. Since the last study visit, did you take nasal steroids other than the study nasal spray *(eg, Rhinocort, Flonase, Nasocort):*

Yes (1) No (2)

28. Since the last study visit, did you take the following medication to treat sinus symptoms

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

29. Since the last study visit, did you take other prescription medications *(besides study nasal spray and those listed for asthma or nasal symptoms):*

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.

30. Since the last study 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*

a. Headache:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

b. Sore throat:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

c. Nasal bleeding:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

d. Nasal irritation/pain:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

e. Rash:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

f. Itching:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

g. Dizziness:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

h. Upper respiratory tract infection:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

i. Trouble breathing:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

j. Swelling:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

k. Coughing:
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

l. Severe menstrual symptoms (dysmenorrhea) *(if applicable):*
- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)

31. List other symptoms and their severity experienced since the last study visit *(specify):*

_____

_____

_____

_____

32. Since the last study visit, did you have any of the following *(check all that apply)*

a. Upper respiratory tract infection: (1)

b. Thrush: (1)

c. Strep throat: (1)

d. Bronchitis: (1)

e. Pneumonia: (1)

f. Ear infection: (1)

g. Acute sinusitis *(sinus infection):* (1)

h. Other viral infection: (1)

i. N/A, none since last study visit: (1)

33. Serious adverse events

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

Yes (1) No (2)

35.

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 Report (SR) for each event.

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

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

____ ____

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

____ ____

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

_____

_____

_____

_____

E. Study procedures

38. Were the following procedures and their forms completed

	Yes	No
a. Asthma Control Test (TA or TP) *(all clinic visits):*	(1)	(2)
b. Asthma Symptom Utility Index (AS) *(all clinic visits):*	(1)	(2)
c. Marks Asthma Quality of Life (MQ or PQ) *(all clinic visits):*	(1)	(2)
d. Health Quality of Life (MO or CH) *(all clinic visits):*	(1)	(2)
e. Sinus and Nasal Quality of Life (SN or SV) *(all clinic visits):*	(1)	(2)
f. Sinus Symptom Score (SS) *(all clinic visits):*	(1)	(2)
g. Sino-nasal Questionnaire (SI) *(visits 1 and 2):*	(1)	(2)
h. Exhaled Nitric Oxide (NO) *(visits 2 and 5):*	(1)	(2)
i. Methacholine Testing (MC) *(visits 1 and 5):*	(1)	(2)
j. Pulmonary Function Testing (PF) *(all clinic visits):*	(1)	(2)
k. Asthma in Females Questionnaire (FQ) *(visit 2):*	(1)	(2)
l. Smoking Questionnaire (SQ) *(visit 2):*	(1)	(2)
m. Drug dispensed/collected (DD) *(visits 2, 3-5 if applicable):*	(1)	(2)
n. Physical exam (PE) *(visits 1 and 5):*	(1)	(2)
o. Allergy Skin Testing (ST) *(visit 2):*	(1)	(2)
p. Exit Interview (EI) *(visit 5):*	(1)	(2)
q. Treatment Termination (TT) *(visit 5 or as needed):*	(1)	(2)
r. Unmasking (UM) *(visit 5 or as needed):*	(1)	(2)

39. If required procedures and their forms not conducted, explain:

_____

_____

F. Nasal mucosa exam

40. Presence of nasal symptoms/complications *(check all that apply)*

- **a.** Normal and healthy: (1)
- **b.** Epistaxis *(nasal bleeding):* (1)
- **c.** Nasal perforation: (1)
- **d.** Other *(specify):* (1)

_____
specify

G. Specimen collection

41. Serum collected for ECP and eotaxins evaluation *(visits 2 and 5):*

Yes (1) No (2)

43. ⌊_⌋

42. Serum aliquots collected *(check all that apply)*

- **a.** Aliquot 1: (1)
- **b.** Aliquot 2: (1)

43. Nasal lavage specimen collected *(visits 2 and 5):*

Yes (1) No (2)

45. ⌊_⌋

44. Nasal lavage (1.0 mL) aliquots were collected *(check all that apply)*

- **a.** Aliquot 1: (1)
- **b.** Aliquot 2: (1)
- **c.** Aliquot 3: (1)
- **d.** Aliquot 4: (1)
- **e.** Aliquot 5: (1)

45. Whole blood collected for pharmacogenetics *(expected at Visit 2; only if participant consented to donate DNA and have it stored):*

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

46. Specify any unusual conditions associated with specimen collection:

_____

_____

_____

H. Administrative information

47. Date form reviewed:

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

48. Clinic coordinator PIN: ____ ____ ____

49. Clinic coordinator signature:

_____

STAN Diary Card

Participant: Fill out information each morning (AM) and evening (PM). If information is missing, leave that blank.

			Mon __/__	Tue __/__	Wed __/__	Thur __/__	Fri __/__	Sat __/__	Sun __/__
AM	**1.**	Date *(month/day)*:							
AM	**2.**	Morning peak flow *(highest of 3, before bronchodilator)*:							
		For items 3 and 4 check (✓) if occurred							
AM	**3.**	Used study nasal spray:	( )	( )	( )	( )	( )	( )	( )
AM	**4.**	Awakened by asthma last night:	( )	( )	( )	( )	( )	( )	( )
PM	**5.**	Rescue 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:							
PM	**6.**	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 lasting longer than 2 hours, or resulting in shortening normal activity, or seeing a doctor, or going to a hospital							
PM	**7.**	Sinus symptom score *(sinus symptoms include runny nose, nasal congestion, itching, or sneezing)*:							
		0 = None (symptoms not noticeable) 1 = Mild (symptoms noticeable but not bothersome) 2 = Moderate (symptoms noticeable and bothersome some of the time) 3 = Severe (symptoms bothersome most of the time and/or very bothersome some of the time)							
		For items 8-12 check (✓) if occurred							
PM	**8.**	Used oral prednisone/steroids for asthma:	( )	( )	( )	( )	( )	( )	( )
PM	**9.**	New or increased dose of asthma medicine other than drugs listed in 3, 5a, 5b, or 8:	( )	( )	( )	( )	( )	( )	( )
PM	**10.**	Urgent unscheduled healthcare contact for asthma (ER/hospital/clinic or doctor visit):	( )	( )	( )	( )	( )	( )	( )
PM	**11.**	Used additional medication for nasal or sinus symptoms *(eg, cold or allergy medicine)*:	( )	( )	( )	( )	( )	( )	( )
PM	**12.**	Urgent unscheduled healthcare contact for nasal or sinus symptoms *(ER/hospital/clinic or doctor visit)*:	( )	( )	( )	( )	( )	( )	( )

The following items are to be completed by clinic staff:

13. Start date of diary: ___ ___ - ___ ___ ___ - ___ ___
day mon year

14. Clinical Center ID: _____ _____ _____ _____

15. Participant ID: _____ _____ _____ _____ _____

16. Name code: _____ _____ _____ _____ _____

17. Clinic coordinator PIN: _____ _____ _____

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

_____

Mail or fax completed card to:

Each week, mail the completed diary card in the envelope provided or bring unmailed card(s) to the next visit.

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

Drug Dispensing and Counting

Purpose: To record the issuing and collecting of nasal spray bottles to and from participant.
When: Whenever bottles of nasal spray are issued or collected and retained by the clinic.
By whom: Clinic staff and other STAN authorized personnel.
Instructions: Dispensing: At visit 2 (randomization) one study kit will be assigned per participant. At visit 2, 3 and 4 (and interim times if needed) dispense bottle(s) from the participant's Kit box. Key into STAN data system at www.cctrials.org/alaacrc within 10 working days. Complete section D for bottles returned by the participant and retained by the clinic.

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 *(V2-V4, N)*: ____ ____
(record "N" if not associated with a clinic visit)

6. Form version date:

1 5 - S E P - 1 0
day mon year

B. Study treatment information

7. Identify kit *(complete a or b)*

a. Attach kit label *(if kit is being used for the first time)*:

affix kit label here

b. Kit ID: **N** -____ ____ ____ ____

c. If replacement kit is issued, attach kit label:

affix kit label here

8. Action taken *(check all that apply)*

a. Dispense bottle of study nasal spray *(complete items 9-12)*: (1)
b. Bottles returned *(complete items 13-17)*: (1)

C. Dispense study tablet bottles

9. Date dispensed:

____ ____-____ ____ ____-____
day mon year

10. Number of bottles dispensed: ____

11. Delivered to the participant *(check only one):*

In person (1)
By mail (2)
Other *(specify)* (3)

_____
specify

12. Study spray bottle(s) issued *(record kit number followed by the letter written on bottom of bottle by coordinator; eg, Bottle "D" for Kit N-7654 would be N-7654-D)*

a. First bottle: **N** -____ ____ ____ ____ - ____

b. Second bottle: **N** -____ ____ ____ ____ - ____

c. Third bottle: **N** -____ ____ ____ ____ - ____

d. Fourth bottle: **N** -____ ____ ____ ____ - ____

e. Fifth bottle: **N** -____ ____ ____ ____ - ____

f. Sixth bottle: **N** -____ ____ ____ ____ - ____

g. Seventh bottle: **N** -____ ____ ____ ____ - ____

D. Bottles returned

13. Total bottles returned: _____

If no bottles are returned, record "0" and skip to item 17.

14. Sequence of bottle(s) returned

a. First bottle: **N** -____ ____ ____ ____-____

b. Second bottle *(if applicable)*:

N -____ ____ ____ ____-____

c. Third bottle *(if applicable)*:

N -____ ____ ____ ____-____

d. Fourth bottle *(if applicable)*:

N -____ ____ ____ ____-____

e. Fifth bottle *(if applicable)*:

N -____ ____ ____ ____-____

f. Sixth bottle *(if applicable)*:

N -____ ____ ____ ____-____

g. Seventh bottle *(if applicable)*:

N -____ ____ ____ ____-____

15. Was compliance reviewed with participant:

Yes	No
(1)	(2)

16. Were all outstanding bottles returned:

Yes	No
(1)	(2)

→ **18.**

17. If some or all bottles were not returned, give reason *(check all that apply)*

a. Consumed and discarded: (1)
b. Lost/destroyed: (1)
c. Forgot, still at home: (1)
d. Open, still using: (1)
e. Other *(specify)*: (1)

_____
specify

E. Administrative information

18. Date form reviewed:

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

19. Clinic coordinator PIN: _____ _____ _____

20. Clinic coordinator signature:

_____

Exit Interview

STAN Reference #: _____

Purpose: To evaluate a participant's experience in STAN.

When: Visit 5 (V5).

Respondent: Participant, parent/guardian, or both.

Instructions: Conduct interview at the end of Visit 5 or earlier visit if participant terminates earlier. Key into STAN data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center and participant information

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Visit date:

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

5. Visit ID: ____ ____

6. Form version date:

2 6 – O C T – 1 0
day mon year

B. Exit questions for participants

7. Exit questions for participant

a. How would you rate your experience as a study participant in the study *(check only one):*

Excellent (1)
Good (2)
Fair (3)
Poor (4)

b. What did you think about the study:

_____

_____

_____

_____

c. How could we have improved the study:

_____

_____

_____

_____

8. Exit questions for participant

a. Do you have any idea which study medication was assigned *(check only one):*

Active drug (nasal spray)	(1)
Inactive drug (placebo)	(2)
Don't know	(3)

b. Do you want to continue with this treatment:

Yes	No
(1)	(2)

c. Comments:

_____

_____

_____

C. Exit questions for participant's parent/guardian

9. Was participant's parent/guardian at clinic for this visit:

Yes	No
(1)	(2)

12.

10. Exit questions for parent/guardian

a. How would you rate the study overall *(check only one):*

Excellent	(1)
Good	(2)
Fair	(3)
Poor	(4)

b. What did you think about your child's participation in the study:

_____

_____

_____

_____

c. How could we have improved the study:

_____

_____

_____

_____

11. Exit questions for parent/guardian

a. Do you have any idea which study medication was assigned *(check only one):*

Active drug (nasal spray)	(1)
Inactive drug (placebo)	(2)
Don't know	(3)

b. Do you want your child to continue with this treatment:

Yes	No
(1)	(2)

c. Comments:

_____

_____

_____

D. Exit procedures

12. Exit materials distributed

	Yes	No
a. Exit letter:	(1)	(2)
b. Final spirometry test results:	(1)	(2)
c. Treatment unmasking envelope:	(1)	(2)

E. Administrative information

13. Date form reviewed:

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

14. Clinic coordinator PIN: ____ ____ ____

15. Clinic coordinator signature:

_____

16. Who was interviewed *(check all that apply)*

a. Participant: (1)

b. Parent/guardian: (1)

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

_____
relationship to participant

Methacholine Challenge Testing

Purpose: Record results of methacholine challenge testing.

When: Visits V1 and V5.

Instructions: Complete sections A-G before proceeding with section H. Key into STAN data system at www.cctri-als.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:

2 2 – F E B – 1 2
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 before 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 J.

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 MeCl test:

(Yes 1) (No 2)

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

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):* (1)

d. Ultra-long-acting bronchodilator within past 72 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):* (1)

j. Non-steroidal nasal spray within past 24 hours *(eg, Afrin, oxymetazoline):* (1)

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

k. 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 STAN Manual of Operations 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 STAN:	(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. Baseline lung function (pre-bronchodilator)

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. Baseline FEV_1: ____ • ____ ____ ____ liters

34. Is baseline FEV_1 (item 33) less than 1 liter:

(Yes 1) (No 2)

Warning: If ''Yes,'' review predicted values (items 36 and 37) and/or consult physician before proceeding. An FEV_1 less than 1 liter may be within the normal range for younger children depending on their size and age.

35. Baseline FVC: ____ • ____ ____ ____ liters

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

____ ____ • ____ ____ liters

37. Baseline FEV_1 % predicted *(100* item 33 / item 36):* ____ ____ ____

38. Is baseline FEV_1 predicted (item 37) less than 70%:

(Yes 1) (No 2)

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

H. Methacholine challenge

Administer saline diluent (no methacholine) according to protocol. Record spirometry at 30 and 90 seconds following the 5th breath, taking the highest FEV_1 as the result for that time period. Obtain at least 3 and no more than 5 efforts to achieve acceptability and reproducibility criteria as set by ATS guidelines.

39. Time diluent administered:

____ ____ : ____ ____ hour minute

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

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

42. Is Post-diluent FEV_1 (item 40) less than or equal to 80% of the baseline FEV_1 *(0.8 * item 33):*

(Yes 1) (No 2)

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

43. Target FEV_1 *(0.8 * item 40):*

____ ____ • ____ ____ liters

This is the target FEV_1 for subsequent doses of MeCl.

Items 44-54: Administer methacholine vials in order shown and then perform spirometry, according to protocol. 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 item 43?**
44.	J	0.03125	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
45.	I	0.0625	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
46.	H	0.125	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
47.	G	0.25	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
48.	F	0.5	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
49.	E	1.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
50.	D	2.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
51.	C	4.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
52.	B	8.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*
53.	A	16.0	___ . ___ ___	___ . ___ ___	Yes ( ) No ( ) → *Go to section I*

54. Is vial A FEV_1 (item 53c) less than 90% of baseline FEV_1 *(0.9 * item 33)*:

Yes ( ) No ( )

68.

Items 55-59 left blank intentionally.

I. Recovery

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

60. Time of bronchodilator administration:

____ ____ : ____ ____
hour minute

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

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

63. Is Post-BD FEV_1 (item 61) greater or equal to 90% of the baseline FEV_1 *(0.9 * item 33):*

( ) Yes (1) ( ) No (2)
68.

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

64. 2nd Post-BD FEV_1: ____ • ____ ____
liters

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

66. Is 2nd Post-BD FEV_1 (item 64) greater or equal to 90% of the baseline FEV_1 *(0.9 * item 33):*

( ) Yes (1) ( ) No (2)
68.

Consult physician and proceed as directed.

67. Was physician consulted:

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

If *"No"*, STOP, consult physician.

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

( ) Yes (1) ( ) No (2)
70.

69. Specify complications:

_____

_____

_____

70. Did participant's FEV_1 fall below the target FEV_1 following the administration of any concentration of methacholine *(ie, are any responses in column e, items 44-54, 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 MeCl

J. Administrative information

72. Person administering test

a. Name:

_____
specify

b. PIN: ____ ____ ____

73. Date form reviewed:

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

74. Clinic coordinator PIN: ____ ____ ____

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

_____

Missed Data

Purpose: Record information about what study data are missing.

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

Instructions: Key into STAN 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 6 – O C T – 1 0
day mon year

7. Was visit or phone contact missed completely:

(Yes 1) (No 2)

B. Missed visit information

8. Forms missed
(check all that apply)

a. BA (Baseline Asthma and Medical History) *(visit 1):* (1)

b. CV (Clinic Visit Form) *(all clinic visits):* (1)

c. DD (Drug Dispensing and Counting Form): (1)

d. EI (Exit Interview): (1)

e. MC (Methacholine Challenge Testing) *(visits 1 and 5):* (1)

f. NO (Nitric Oxide Form) *(visits 2 and 5):* (1)

g. PC (Phone Contact) *(visits P1, 2 and 3):* (1)

h. PE (Physical Exam): (1)

i. PF (Pulmonary Function Testing) *(all clinic visits):* (1)

j. TT (Treatment Termination): (1)

k. UM (Unmasking): (1)

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

_____
form

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

9. Questionnaires missed
(check all that apply)

a. AS (Asthma Symptom Utility Index): (1)

b. TA (Asthma Control Test - 12 years and older) *[all clinic visits]:* (1)

c. TP (Asthma Control Test 4-11 years) *[all clinic visits]:* (1)

d. CH (Child Health Questionnaire) *(all clinic visits):* (1)

e. FQ (Asthma in Females Questionnaire) *(visit 2):* (1)

f. MO (Medical Outcomes Study) *(all clinic visits):* (1)

g. MQ (Marks Quality of Life Questionnaire) *(all clinic visits):* (1)

h. PQ (Children's Health Survey for Asthma (CHSA)) *(all clinic visits):* (1)

i. SI (Sino-nasal Questionnaire (SNQ)) *(visits 1 and 2):* (1)

j. SN (Sino-nasal Outcome Test (SNOT-20)) *(all clinic visits):* (1)

k. SQ (Smoking Questionnaire) *(visit 2):* (1)

l. SS (Sinus Symptom Score) *(all clinic visits):* (1)

m. ST (Allergy Skin Testing) *(visits 2 and 5):* (1)

n. SV (Sinus and Nasal Quality of Life (SN-5)) *(all clinic visits):* (1)

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

_____
questionnaire

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

10. Are diary cards missing:

Yes (1) No (2)

14. ____

If Yes, list the start and end dates for intervals with missing diary cards. Each date should be on or before date of visit or close of window for missed visit (items 10-12).

11. First interval

a. Start date:

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

b. End date:

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

12. Second interval

a. Start date:

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

b. End date:

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

13. Third interval

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 refused: (1)

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

e. Unable to contact participant: (1)

f. Participant forgot: (1)

g. 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:

_____

STAN Reference #: _____

Nitric Oxide Form

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

When: Visit 2 and 5; before spirometry or Methacholine Challenge testing.

Instructions: Study participant should not eat or drink anything for 1 hour before the test. Record eNO results on this form. **If result of eNO < 5 ppb, enter "0" ppb**. Key into STAN data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center and participant information

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Visit date:

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

5. Visit ID: ____ ____

6. Form version date:

0 7 – O C T – 1 0
day mon year

B. Procedure

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

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

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

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

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

8. Current acute upper and/or lower respiratory tract viral infection:
- Yes (1)
- No (2)
- Don't know (3)

9. Oral/inhaled corticosteroid use

a. Did participant use oral/inhaled corticosteroids today:

(Yes 1) (No 2)

10. ____

b. Time most recently used:

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

10. Participating in eNO Comparison Substudy:

(Yes 1) (No 2)

12. ____

11. Order of testing for eNO Comparison Substudy *(assigned by data system at each clinic visit):*
- NIOX MINO A first (1)
- NIOX MINO B first (2)

NIOX MINO device A

If not participating in substudy, answer items 12-16 below.

12. Result of daily quality control test for NIOX MINO A:

Pass (1) Fail (2)

13. Date participant eNO tested *(read off the NIOX MINO A device):*

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

14. Time participant eNO tested *(read off the NIOX MINO A device):*

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

15. Participant eNO test results for the NIOX MINO A

a. Test one: ____ ____ ____ ppb

b. Test two: ____ ____ ____ ppb

16. Ambient NO result for the NIOX MINO A *(record as "0" if result is < 5 ppb):*

____ ____ ____ ppb

Skip to item 22 if <u>not</u> participating in eNO Comparison Substudy.

NIOX MINO device B

17. Result of daily quality control test for NIOX MINO B:

Pass (1) Fail (2)

22.

18. Date participant eNO tested *(read off the NIOX MINO B device):*

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

19. Time participant eNO tested *(read off the NIOX MINO B device):*

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

20. Participant eNO test results for the NIOX MINO B

a. Test one: ____ ____ ____ ppb

b. Test two: ____ ____ ____ ppb

21. Ambient NO results for the NIOX MINO B *(record as "0" if result is < 5 ppb):*

____ ____ ____ ppb

22. Record any problems with tests or consistency of results:

_____

_____

_____

_____

_____

_____

D. Administrative information

23. Date form reviewed:

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

24. Clinic coordinator PIN: ____ ____ ____

25. Clinic coordinator signature:

_____

Phone Contact

Purpose: To assess compliance, side effects, asthma control, and sinus control.
When: Phone contacts (P1-P3).
Respondent: Participant, parent/guardian, or both.
Instructions: In all items, "you" refers to participant. Key into STAN 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. Call date:

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

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

5. Phone visit ID: P ____

6. Form version date:

1 7 - F E B - 1 2
day mon year

B. Study Treatment

7. How are you doing with the study nasal spray:

_____

_____

8. Since the last clinic visit, how many days have you NOT used your study nasal spray:

____ ____
days

9. Why did you miss taking your nasal spray *(check all that apply)*

a. N/A, took study nasal spray every day: (1)
b. Permanently stopped study nasal spray: (1)
c. Temporarily stopped study nasal spray *(specify)*: (1)

_____
identify reason

d. Forgot: (1)
e. Ran out of study nasal spray: (1)
f. Did not have study nasal spray on hand: (1)
g. Lost study nasal spray: (1)
h. Side effects *(specify)*: (1)

_____
list side effects

i. Too busy: (1)
j. Other *(specify)*: (1)

_____
identify reason

10. Symptoms

a. Since your last clinic visit or phone contact, were there any symptoms (eg, headache, sore throat, nasal bleeding, nasal irritation/pain, rash, itching, dizziness, trouble breathing, swelling) that may be related to the study nasal spray:

Yes (1) No (2) → 11.

b. If "Yes," specify:

_____

_____

C. Asthma and health

11. Were any rescue medications (ie, short acting bronchodilator) used for asthma since the last clinic visit or phone contact *(do not count uses to prevent symptoms, eg, medication before exercise)*:

Yes (1) No (2) → **13.**

12. How many times since your last clinic visit or phone contact was asthma rescue medication used other than to prevent symptoms:

_____ _____ _____
times

13. Were there significant events since your last clinic visit or phone contact *(check all that apply)*

a. Hospitalization or urgent care visit for asthma: (1)
b. Used oral corticosteroids: (1)
c. Upper respiratory infection *(eg, cold or sinus infection)*: (1)
d. Other *(specify)*: (1)

_____
name event

e. N/A, no significant events occurred: (1)

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

14. Did you use nasal medications (saline, anti-histamines, allergy medications, decongestant, anti-leukotrienes) for sinus symptoms since last clinic visit or phone contact:

Yes (1) No (2)

D. Study procedures

15. Have you been filling out your diary cards:

Yes (1) No (2)

16. Have you missed any days *(check all that apply)*

a. N/A, none missing: (1)
b. Forgot: (1)
c. Hard to understand: (1)
d. Lost or destroyed: (1)
e. Other *(specify)*: (1)

_____
identify reason

17. Do you have any questions: Yes (1) No (2)

18. Next clinic visit appointment

a. Date:

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

b. Time: _____ _____:_____ _____ (1) am (2) pm

c. Participant able to keep appointment:

Yes (1) No (2) → **20.**

If No, try to reschedule on phone.

19. Rescheduled clinic visit appointment

a. Date:

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

b. Time: _____ _____:_____ _____ (1) am (2) pm

20. Participant reminded to *(check all that apply)*

a. Use Asthma Action Plan in an emergency: (1)
b. Consult private physician for asthma care: (1)
c. Complete diary cards: (1)
d. N/A, no reminders given: (1)

E. Administrative information

21. Date form reviewed:

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

22. Clinic coordinator PIN: _____ _____ _____

23. Clinic coordinator signature:

_____

Physical Exam

Purpose: To assess information about a participant's health.
When: Screening (V1) and Visit 5 (V5).
Instructions: Completed by certified study physician or designee. Items in Section B marked with an "*" are mandatory. Note abnormalities and briefly describe; use extra sheets if necessary. Key into STAN 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:

1 5 - S E P - 1 0
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.**	Nasal polyps: _____	Normal (1)	Abnormal (2)	
16.	Abdomen: _____	Normal (1)	Abnormal (2)	Not Examined (3)
17.	Extremities: _____	Normal (1)	Abnormal (2)	Not Examined (3)
18.	Skin: _____	Normal (1)	Abnormal (2)	Not Examined (3)

19. Neurological: _____ Normal (1) Abnormal (2) Not Examined (3)

_____

20. Other *(specify)*: _____ Normal (1) Abnormal (2) Not Examined (3)

_____

C. Physician signature

21. Examiner

a. Examiner signature:

_____

b. Examiner name *(print)*:

_____

22. Is examiner a STAN certified study physician:

Yes (1) → **24.** No (2)

If No, then form must be countersigned by overseeing STAN certified Study Physician. Complete items 21-26.

23. STAN certified study physician

a. Study physician PIN: _____ _____ _____

b. Study physician signature:

_____

D. Administrative information

24. Date form reviewed:

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

25. Clinic Coordinator PIN: _____ _____ _____

26. Clinic Coordinator signature:

_____

Pulmonary Function Testing

STAN Reference #: _____

Purpose: To record results of pulmonary function tests.

When: Visits V1, V2, V3, V4, and V5.

Instructions: Key into STAN 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: ____ ____
(Indicate "N" as visit ID if testing is not associated with a particular visit)

6. Form version date:

0 8 – D E C – 1 0
day mon year

B. General PFT data

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

a. In inches: ____ ____ • ____
inches

b. In centimeters: ____ ____ ____ • ____
cm

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

a. In pounds: ____ ____ ____
lbs

b. In kilograms: ____ ____ ____
kg

9. Choose one dominant race category as identified by participant *(used to calculate predicted values):*

White (1)
Black (2)
Latino (3)
Other (4)

10. Did participant take any of the following medications before visit

	Yes	No
a. Short-acting bronchodilator within last 4 hours:	(1)	(2)
b. Long-acting bronchodilator within last 12 hours:	(1)	(2)

11. Mini-Wright peak flow measurement *(highest of 3 at clinic):*

____ ____ ____
Liters/min

C. Pre-bronchodilator data

12. Pre-bronchodilator FVC: ____ • ____ ____
Liters

13. Pre-bronchodilator FEV_1: ____ • ____ ____
Liters

14. Predicted FEV_1 *(from Manual of Operations or as calculated online at www.cctrials.org/alaacrc):*

____ • ____ ____
Liters

15. Percent predicted pre-bronchodilator FEV_1:

____ ____ ____
%

Calculation: (100 x pre-bronchodilator FEV_1/predicted FEV_1; ie, 100 x item 13/item 14)

D. Post-bronchodilator data

16. Was post-bronchodilator testing done:

(Yes 1) (No 2)

21.

All participants will have post-BD testing at V1, V2, V3, V4 and V5.

17. Post-bronchodilator FVC: ____ • ____ ____ ____
Liters

18. Post-bronchodilator FEV_1: ____ • ____ ____ ____
Liters

E. Reversibility data

19. Percent predicted post-bronchodilator FEV_1:

____ ____ ____
%

Calculation: (100 x post-BD FEV_1/predicted FEV_1); ie, (100 x item 18/item 14)

20. Percent reversibility: ____ ____ ____
%

Calculation: [(post-BD FEV_1 - pre-BD FEV_1)/pre-BD FEV_1) x 100; ie, [(item 18 - item 13)/item 13] x 100]

F. Administrative information

21. Person administering test

a. Name:

_____
specify

b. PIN: ____ ____ ____

22. Date form reviewed:

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

23. Clinic coordinator PIN: ____ ____ ____

24. Clinic coordinator signature:

_____

Randomization Form

STAN Reference #: _____

Purpose: To document eligibility and treatment assignment.

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

Instructions: Key into STAN data system at www.cctrials.org/alaacrc to obtain treatment assignment. 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 item checked is marked with [STOP], participant is ineligible for randomization; complete section H and do not data enter.

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 6 - D E C - 1 0
day mon year

B. General inclusion criteria

7. Age 6 or older:

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

a. Date of birth *(asked on BA form as well; needed to determine dosage at RZ):*

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

b. Age on date of randomization *(do not round):*

____ ____
years

8. Physician diagnosed asthma:

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

9. A mean score of 1 or greater on the Sino-Nasal Questionnaire (SI) at V1 and V2:

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

a. Score at V1: ____ • ____ ____

b. Score at V2: ____ • ____ ____

10. Score on Asthma Control Test (TP or TA; answer as appropriate)

Participants 6-11 years (TP form)

a. A score of 19 or less on the Child - Asthma Control Test (TP) at V1 and V2:

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

b. Score at V1: ____ ____

c. Score at V2: ____ ____

Participants 12 or older (TA form)

d. A score of 19 or less on the Asthma Control Test (TA) at V1 and V2:

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

e. Score at V1: ____ ____

f. Score at V2: ____ ____

C. Lung function criteria

11. Percent predicted pre-bronchodilator FEV_1 greater than or equal to 50% at V1 and V2:

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

12. Bronchodilator reversibility *(documented within last 2 years)*

a. Participant demonstrate 12% or greater reversibility:

( ) Yes (1) ( ) No (2) → **13.**

b. Pre-bronchodilator FEV_1:

____ ____ ____ ____
liters

c. Post-bronchodilator FEV_1:

____ ____ ____ ____
liters

d. Date reversibility demonstrated:

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

13. Methacholine PC_{20} FEV_1 *(documented within last 2 years)*

a. PC_{20} less than 16 mg/mL:

( ) Yes (1) ( ) No (2) → **14.**

b. PC_{20} value:

____ ____ ____ ____ ____ ____ ____
mg/mL MeCl

c. Date PC_{20} FEV_1 demonstrated:

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

(Keep documentation of lung function test results in participant's file at clinic).

One of the above items 12-13 must be checked "Yes". If both items 12-13 are checked "No", then **STOP***; participant is ineligible for the study. Complete section H.*

D. Exclusion criteria

14. Medication use

	Yes (1)	No (2)
a. Systemic corticosteroid use within past 4 weeks:	( )	( )
b. Nasal corticosteroid use within past 4 weeks:	( )	( )
c. Anti-leukotriene use within past 2 weeks:	( )	( )
d. Use of investigational treatments within past 6 weeks:	( )	( )

If Yes → STOP

15. Sinus surgery within last 6 months:

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

16. History of fever greater than 38.3° C (100.9° F) within last 10 days:

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

17. Active smoking within 6 months:

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

18. Greater than 10 pack-years smoking history (10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):

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

19. History or physician diagnosis of cystic fibrosis, insulin dependent diabetes mellitus or immunodeficiency disorders, or other co-morbidity that predisposes to complicated rhinosinusitis:

Yes (1) → STOP No (2)

20. Cataracts or history of glaucoma, or other conditions resulting in increased intraocular pressure:

Yes (1) → STOP No (2)

21. Women of childbearing potential: currently pregnant, lactating, or unwilling to practice effective contraception for duration of study:

Yes (1) → STOP

No (2)

Not applicable (3)

Note: A pregnancy test should be administered to women of child-bearing potential at Visit 1 and Visit 2.

22. Current upper airway symptoms lasting less than 8 weeks *(eg, seasonal allergies):*

Yes (1) → STOP No (2)

23. Acute respiratory illness *(eg, cold)* within past 8 weeks:

Yes (1) → STOP No (2)

24. Allergy or intolerance to nasal mometasone:

Yes (1) → STOP No (2)

25. Chronic diseases (other than asthma) that in the opinion of the investigator would prevent participation in the trial or put participant at risk by participation, eg, chronic diseases of the lung (other than asthma), heart, liver, kidney or nervous system:

Yes (1) → STOP No (2)

26. Inaccessible by telephone:

Yes (1) → STOP No (2)

27. Intention to move out of the area in the next 6 months:

Yes (1) → STOP No (2)

E. Procedures

28. Signed consent and/or assent as per local IRB requirements:

Yes (1) No (2) → STOP

29. Permission granted in main or separate consent/assent to donate DNA and have it stored:

Yes (1) No (2)

30. Were the following baseline procedures completed or checked

	Yes	No
a. Baseline history (BA form) *(at V1):*	(1)	(2)
b. Physical exam *(at V1):*	(1)	(2)
c. Pregnancy test *(at V1 and V2):*	(1)	(2)
d. Diary cards reviewed *(at V2):*	(1)	(2)
e. Questionnaires completed (TA/TP, AS, SN/SV, SQ, SS, FQ, SI, MQ/PQ, and CH/MO):	(1)	(2)
f. Spirometry *(at V1 and V2):*	(1)	(2)
g. Methacholine challenge test *(at V1):*	(1)	(2)
h. Exhaled nitric oxide (eNO) test *(at V2):*	(1)	(2)
i. Nasal lavage *(at V2):*	(1)	(2)
j. Allergy skin test *(at V2):*	(1)	(2)
k. Blood specimen collected *(at V2):*	(1)	(2)

31. Was the following V1 form keyed into the data system *(SC form must be entered before participant can be randomized)*

a. Screening form (SC):

Yes	(1)
No	(2)

F. Peak flow from diary cards

32. Peak flow from diary cards for last 14 days of run-in period (participant must complete diary cards on at least 10 of last 14 days to be eligible)

a. Day 1: ____ ____ ____

b. Day 2: ____ ____ ____

c. Day 3: ____ ____ ____

d. Day 4: ____ ____ ____

e. Day 5: ____ ____ ____

f. Day 6: ____ ____ ____

g. Day 7: ____ ____ ____

h. Day 8: ____ ____ ____

i. Day 9: ____ ____ ____

j. Day 10: ____ ____ ____

k. Day 11: ____ ____ ____

l. Day 12: ____ ____ ____

m. Day 13: ____ ____ ____

n. Day 14: ____ ____ ____

G. Final check

33. Participant meets all eligibility criteria for randomization:

( ) Yes (1)

( ) No (2)

STOP

H. Administrative information

34. Study physician

a. Study physician PIN: ____ ____ ____

b. Study physician signature:

_____

c. Date signed:

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

35. Date form reviewed:

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

36. Clinic coordinator

a. Clinic coordinator PIN: ____ ____ ____

b. Clinic coordinator signature:

_____

Note: · Print copy of treatment assignment and drug dosage from data system and attach to this form.
· Affix bottom of RZ kit label on DD form item 7a.

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

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

a. Personal best peak flow: ____ ____ ____

b. Red zone: below ____ ____ ____

c. Yellow zone:

____ ____ ____ to ____ ____ ____

d. Green zone: above ____ ____ ____

Copy values to Asthma Action Plan card.

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

N ____ ____ ____ ____

39. Dose assignment *(sprays per nostril once daily in the morning):* ____

STAN

Reference #: _____

Screening Form

Purpose: To check preliminary eligibility criteria.

When: Visit 1 (V1) after initial forms and procedures are completed, prior to methacholine challenge test and physical exam.

Respondent: Participant, parent/guardian, or both.

Instructions: If participant is eligible, key into STAN data system at www.cctrials.org/alaacrc. Must be keyed immediately after visit has been completed. If item checked is marked with a STOP, participant is ineligible for the study. Proceed to section G. Do not key form for participants who fail screening.

A. Clinical center, participant and visit information

1. Clinical center ID: ____ ____ ____ ____

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

3. Name code: ____ ____ ____ ____ ____

4. Visit date:

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

5. Visit ID: ____ ____

6. Form version date:

2 2 - F E B - 1 2
day mon year

B. Preliminary screening

7. Age 6 or older:

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

8. Physician diagnosed asthma:

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

C. Poor asthma control criteria

9. Score on Asthma Control Test (TA or TP) *(answer as appropriate)*

a. *Participants 6-11 years*: A score of 19 or less on Child - Asthma Control Test (TP):

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

b. Score: ____ ____

c. *Participants 12 or older*: A score of 19 or less on Asthma Control Test (TA):

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

d. Score: ____ ____

D. Chronic rhinitis and sinusitis

10. Mean score of 1 or greater on the Sino-nasal Questionnaire (SI):

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

a. Score: ____ • ____ ____ ____

E. Lung function criteria *(documented within the last two years)*

11. Did participant demonstrate 12% or greater reversibility within the last two years:

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

12.

a. Date reversibility demonstrated:

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

12. Methacholine PC_{20} less than 16 mg/mL *(within last two years):*

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

13.

a. Date methacholine demonstrated:

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

13. Are items 11 or 12 marked ''Yes:''

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

WARNING: If ''No,'' participant must demonstrate one of these criteria by V2 to be eligible.

F. Exclusion criteria

14. Active smoking within last 6 months:

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

STOP

15. Greater than 10 pack-years smoking history *(10 pack-years = 1 pack a day for 10 years; 2 packs a day for 5 years, etc):*

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

STOP

16. Percent predicted pre-bronchodilator FEV_1 less than or equal to 50%:

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

STOP

17. History or physician diagnosis of cystic fibrosis, insulin dependent diabetes mellitus or immunodeficiency disorders, or other co-morbidity that predisposes to complicated rhinosinusitis:

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

STOP

18. Cataracts or history of glaucoma or other conditions resulting in increased intraocular pressure:

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

STOP

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

Yes ( ) (1)

STOP

No ( ) (2)

Not applicable ( ) (3)

Note: A pregnancy test should be administered to women of child-bearing potential at Visit 1.

20. Allergy or intolerance to nasal mometasone:

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

STOP

21. Major chronic illness or other condition that may interfere with participation in the study

	Yes	No
a. Non-skin cancer:	(1)	(2)
b. Bronchiectasis:	(1)	(2)
c. Myelomeningocele:	(1)	(2)
d. Sickle cell anemia:	(1)	(2)
e. Endocrine disease:	(1)	(2)
f. Congenital heart disease:	(1)	(2)
g. Congestive heart failure:	(1)	(2)
h. Stroke:	(1)	(2)
i. Severe hypertension:	(1)	(2)
j. Renal failure:	(1)	(2)
k. Liver disorder:	(1)	(2)
l. Significant neuro-developmental delay:	(1)	(2)
m. Behavioral disorders (excluding mild attention deficit hyperactivity disorder):	(1)	(2)
n. Other *(specify):*	(1)	(2)

_____
name condition

If any of above items are checked ''Yes,'' alert study physician for evaluation during physical exam. Patient may be ineligible.

22. Acute respiratory illness (eg, cold) within past 8 weeks:

Yes (1) No (2)

23. History of sinus surgery in last 6 months:

Yes (1) No (2)

24. Medication use

	Yes	No
a. Systemic corticosteroid use within past 4 weeks:	(1)	(2)
b. Nasal corticosteroid use within past 4 weeks:	(1)	(2)
c. Anti-leukotriene medication use within past 2 weeks:	(1)	(2)
d. Use of any investigational treatments in previous 6 weeks:	(1)	(2)

Warning: Items 22-24 must be checked ''No'' for patient to be eligible; if any of those items are checked ''Yes,'' the participant must demonstrate these criteria by V2 to be eligible.

25. Appears able and willing to complete baseline procedures *(peak flow measurement, 10 of 14 diary cards, etc):*

Yes (1) No (2) STOP

26. Accessible by telephone:

Yes (1) No (2) STOP

27. Intention to stay in the area for at least the next 6 months:

Yes (1) No (2) STOP

G. Administrative information

28. Date form reviewed:

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

29. Clinic coordinator PIN: ____ ____ ____

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

_____

31. Web access code *[assigned by data system; record on participant's Schedule of Visits (SOV)]:*

____ ____ ____ ____ ____

Allergy Skin Testing

Purpose: To assess sensitivity to allergens.
When: Visit 2 (V2).
Instructions: Completed by STAN certified allergy skin tester. Preferably done prior to methacholine challenge. Key into STAN 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. Visit date:

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

5. Visit ID: **V 2**

6. Form version date:

0 3 - N O V - 1 0
day mon year

B. Exclusions

7. Current use of a beta-blocker:

Yes (1) No (2)

Stop

8. Ever had a significant adverse reaction to a skin testing procedure *(eg, anaphylaxis, urticaria, angioedema, asthma, hypotension)*:

Yes (1) No (2)

Stop

9. Dermatographia:

Yes (1) No (2)

Stop

If any of items 7-9 are answered "Yes", do not conduct a skin test on this participant. Skip to section G.

C. Possible exclusions

10. FEV_1 below 70% predicted on the day of test:

Yes (1) No (2)

11. Symptoms of an acute asthma exacerbation on day of test:

Yes (1) No (2)

12. Either 10 or 11 answered "Yes":

Yes (1) No (2)

14.

13. Has supervising physician given permission to proceed with allergy skin test *(permission from supervising physician must be obtained in order to proceed with skin test if 10 or 11 are "Yes")*:

Yes (1) No (2)

Stop

If item 13 is answered "No," do not conduct a skin test unless permission is obtained and item 13 can be answered "Yes." Skip to section G.

D. Confounders

Please refer to the MOP for list of medications to be held prior to allergy skin testing.

14. Antihistamine use

a. Use of first-generation (short-acting) antihistamine in the past 3 days (72 hours):

Yes (1) No (2)

b. Use of a second-generation (longer-acting) antihistamine in the past 7 days:

Yes (1) No (2)

c. Use of a topical nasal antihistamine such as Astelin (azelastine) in the past 5 days:

Yes (1) No (2)

15. Antidepressant use

a. Use of doxepin (topical or oral) in the past 7 days:

Yes (1) No (2)

b. Use of a tricyclic antidepressant in the past 3 days:

Yes (1) No (2)

16. Use of an H2 antagonist in the past 3 days (72 hours):

Yes (1) No (2)

17. Use of restricted herbal supplements *(see MOP)* in the past 3 days:

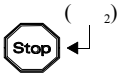
Yes (1) No (2)

E. Safety measures

18. Are the following readily available

a. Physician knowledgeable in anaphylaxis treatment:

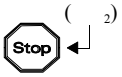
Yes (1) No (2)



If "No", do not proceed until item can be checked yes.

b. Injectable epinephrine (1:1000):

Yes (1) No (2)



If "No", do not proceed until item can be checked yes.

F. Allergy skin testing

19. Time testing started *(allergens applied)*:

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

Tests should be read 20 minutes after the application of all allergens.

20. Time tests were read *("time read" is time when wheals were outlined with felt tip pen)*:

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

After 20 minutes have passed, outline each wheal, apply a piece of transparent tape over each wheal, and transfer tape to the corresponding space below. Measure largest diameter (A) and largest diameter perpendicular to A (B) to the nearest millimeter. Calculate mean diameter (C), C=(A+B)/2 and follow ACRC rounding rules (see MOP section 4.4.3).

Battery A

21. Positive control: **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm	**25. Negative control:** **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm
22. Standardized house dust mite mix: **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm	**26. Cockroach mix:** **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm
23. Mouse epithelia: **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm	**27. Rat epithelia:** **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm
24. Penicillium mix: **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm	**28. Alternaria alternata:** **a.** Largest diameter (A): ___ ___ mm **b.** Perpendicular diameter (B): ___ ___ mm **c.** Mean diameter (C): ___ ___.___ mm

Battery B

29. Center-specific allergen (1st):

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm
d. Name of allergen tested: _____

30. Center-specific allergen (2nd):

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm
d. Name of allergen tested: _____

31. Center-specific allergen (3rd):

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm
d. Name of allergen tested: _____

32. Center-specific allergen (4th):

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm
d. Name of allergen tested: _____

33. Cladosporium herbarium:

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm

34. Dog epithelia:

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm

35. Standardized cat hair:

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm

36. Aspergillis mix:

a. Largest diameter (A): ___ ___ mm
b. Perpendicular diameter (B): ___ ___ mm
c. Mean diameter (C): ___ ___.___ mm

G. Administrative Information

37. Date form reviewed:

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

38. Skin tester PIN: ____ ____ ____

39. Skin tester signature:

_____

40. Center Coordinator PIN: ____ ____ ____

41. Center Coordinator signature:

_____

STAN Reference #: _____

Treatment Termination

Purpose: Record permanent termination of study nasal spray.

When: Treatment termination during or at end of trial.

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

A. Clinical center, participant and report identification

1. Clinical center ID: ____ ____ ____ ____

2. Participant ID: ____ ____ ____ ____ ____

3. Name code: ____ ____ ____ ____ ____

4. Date of report:

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

5. Visit ID: ____ ____

6. Form version date:

2 6 – O C T – 1 0
day mon year

B. Termination

7. Date of last study nasal spray use:

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

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

Study nasal spray permanently stopped before end of trial (1)
End of trial (2)

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

a. Participant completed study: (1)

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

_____
specify

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

_____
specify

d. Required open label nasal steroid spray: (1)

e. Poor asthma control: (1)

f. Participant request: (1)

g. Lost to followup: (1)

h. Pregnancy: (1)

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

_____
specify

10. Were some or all study nasal spray bottles collected from participant at this time:

Yes (1) No (2)

If "yes", complete the Drug Dispensing (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:

_____

STAN Reference #: _____

Unmasking

Purpose: Record unmasking of study treatment.

When: When study treatment is unmasked.

Instructions: Key into STAN 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: ____ ____

6. Form version date:

0 6 – O C T – 1 0
day mon year

B. Unmasking

7. Kit ID: N –____ ____ ____ ____

8. Date unmasked:

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

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

Unscheduled unmasking *(before Visit 5)* (1)

Scheduled unmasking at end of trial *(at Visit 5)* (2)

11.

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

_____

_____

_____

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

Standard unmasking envelope (1)

Tracking number on treatment unmasking envelope:

_____

Web emergency unmasking site (2)

DCC (3)

Other *(specify)* (4)

_____
identify method

12. Were any STAN staff unmasked:

Yes (1) No (2)

14.

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

_____

_____

14. Was treatment terminated:

Yes (1) No (2)

If "Yes," fill out Treatment Termination (TT) form. If "No," explain reason(s) participant remains on treatment.

_____

_____

_____

C. Administrative information

15. Date form reviewed:

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

16. Clinic coordinator PIN: ____ ____ ____

17. Clinic coordinator signature:

_____