Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail biolincc@imsweb.com. Include the Web site and filename in your message.

Baseline Asthma and Medical History

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

When: Visit 1 (V1).

Instructions: Key into SOYA 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:

2 2 – N O V – 1 0
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 *(ie, 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 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 aggravate your asthma:

23. Respiratory infections

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

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

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

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

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

26. Drugs *(ie 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)

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)

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. Asthma treatment history

45. 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

I. Symptoms

46. 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)

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. General Medical Conditions

53. 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. Eczema:	(1)	(2)
c. Sinusitis:	(1)	(2)
d. Hay fever or allergic rhinitis:	(1)	(2)
e. Food allergies:	(1)	(2)
f. Other allergies *(specify):*	(1)	(2)

_____
specify allergy

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

_____
specify cancer

_____
specify cancer

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. Other condition(s) that would interfere with participation in the study *(specify):*	(1)	(2)

_____
specify

M. Health and development questions

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

Yes (1) No (2)

55. Have you ever been diagnosed with sleep apnea:

Yes (1) No (2)

56. Do you use CPAP or BIPAP:

Yes (1) No (2)

57. Have you ever been told you snore:

Yes (1) No (2)

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

Yes (1) No (2)

59. Do you often take naps during the day:

Yes (1) No (2)

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

Yes (1) No (2)

61. 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)

62. 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)

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

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

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

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

65. Do you have diabetes:

Yes (1) No (2) → **68.**

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

67. How is your diabetes controlled:

- Diet alone (1)
- Tablets (2)
- Insulin (3)

68. 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)

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

____ ____ ____ pounds

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

a. Age: ____ ____ years

b. Don't know (1)

c. Not applicable (1)

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

a. Inches: ____ ____ inches

b. Centimeters: *(measured; enter only a or b):* ____ ____ centimeters

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

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

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

a. Inches: ____ ____ inches

b. Centimeters: ____ ____ centimeters

N. Administrative information

74. Date form reviewed:

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

75. Clinic coordinator PIN: ____ ____ ____

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

_____

SOYA Reference #: _____

Clinic Visit Form

Purpose: To record information about diary cards, asthma symptoms, tablets, and other visit procedures.

When: Visits 2, 4-9.

Instructions: Complete form at clinic visit. Key into SOYA 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: ____ ____

6. Form version date:

2 2 – N O V – 1 0
day mon year

B. Diary Cards

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

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)

_____
specify

9. 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. Items 4-5: (1)
f. Items 8-10: (1)

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

_____

_____

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

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):*

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 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 visit, how many days have you NOT taken your study tablets: ____ ____ days

16. Why did you miss taking study tablets *(check all that apply)*

a. NA, took tablets every day: (1)

b. Permanently stopped study tablets: (1)

c. Temporarily stopped study tablets *(specify reason):* (1)

_____
identify reason

d. Forgot: (1)

e. Ran out of study tablets: (1)

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

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

_____
list side effects

h. Too busy: (1)

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

_____
identify reason

17. Are you currently taking any medications specifically for the treatment of asthma in addition to study tablets *(if applicable):*

(Yes 1) (No 2)

26.

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

	Drug name (Trade names)	**Yes**
a.	NA, no bronchodilator 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):	(1)
j.	Other: _____ (specify)	(1)
k.	Other: _____ (specify)	(1)
l.	Other: _____ (specify)	(1)

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**
a.	NA, no 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

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 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:

_____

_____

_____

_____

27. Since the last study visit, did you take medications, other than those for asthma:

(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.

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. Skin rash:	(1)	(2)	(3)	(4)
b. Itching:	(1)	(2)	(3)	(4)
c. Difficulty breathing:	(1)	(2)	(3)	(4)
d. Difficulty swallowing:	(1)	(2)	(3)	(4)
e. Low blood pressure:	(1)	(2)	(3)	(4)
f. Passing out:	(1)	(2)	(3)	(4)
g. Breast swelling or tenderness:	(1)	(2)	(3)	(4)

29. Has the participant had a menstrual cycle in the past 12 months:

Yes (1) No (2) → **36.**

30. Since the last study visit, have your menstrual cycles been regular: Yes (1) No (2)

31. Since the last study visit, has your menstrual flow become heavier: Yes (1) No (2)

32. Since the last study visit, has your menstrual flow become lighter: Yes (1) No (2)

33. Since the last study visit, have you experienced spotting or bleeding between menstrual periods: Yes (1) No (2)

34. Since the last study visit, have you experienced more discomfort or cramping than usual with your menstrual cycle: Yes (1) No (2)

35. Since the last study visit, have you experienced less discomfort or cramping than usual with your menstrual cycle: Yes (1) No (2)

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

a. Upper respiratory infection (cold): (1)
b. Sore throat: (1)
c. Strep throat: (1)
d. Bronchitis: (1)
e. Pneumonia: (1)
f. Ear infection: (1)
g. Acute sinusitis (sinus infection): (1)
h. N/A, none since last visit: (1)

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

_____
_____
_____
_____

38. Serious adverse events

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

Yes (1) No (2)

39.

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.

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

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

_____
_____
_____
_____

E. Study procedures

41. Were the following procedures and their forms completed

	Yes	No
a. Asthma Control Test (TA) *(all clinic visits):*	(1)	(2)
b. Asthma Symptoms (AS) *(all clinic visits):*	(1)	(2)
c. Asthma Quality of Life (MQ or PQ) *(all clinic visits):*	(1)	(2)
d. Health Quality of Life (CH or MO) *(visits 1 and 9):*	(1)	(2)
e. Food Frequency Questionnaire (BF or BK) *(visits 2 and 9):*	(1)	(2)
f. Soy Questionnaire (BS) *(visits 1, 2 and 9):*	(1)	(2)
g. Exhaled Nitric Oxide (NO) *(visit 2, 4-9):*	(1)	(2)
h. Pulmonary Function Testing (PF) *(all clinic visits)*	(1)	(2)
i. Tablet Dispensing and Counting (DD) *(V2-V9 if applicable):*	(1)	(2)
j. Exit Interview (EI) *(visit 9):*	(1)	(2)
k. Treatment Termination (TT) *(visit 9 or as needed):*	(1)	(2)
l. Unmasking (UM) *(visit 9 or as needed):*	(1)	(2)
m. Physical Exam (PE) *(visits 1 and 9):*	(1)	(2)
n. Asthma in Females (FQ) *(visit 2):*	(1)	(2)
o. Home Smoking Activity and Exposure to Tobacco Smoke Questionnaire (SQ) *(visit 2):*	(1)	(2)

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

_____

_____

F. Specimen collection

43. Is this visit 2, 4, or 9:

Yes (1) No (2) → **55.**

44. Exhaled Breath Condensate (EBC) specimens collected:

Yes (1) No (2) → **47.**

45. EBC aliquots

	Yes	No
a. Aliquot 1:	(1)	(2)
b. Aliquot 2:	(1)	(2)
c. Aliquot 3:	(1)	(2)

46. Pre-assessment conditions met

a. No food or beverage for one hour prior to EBC collection *(check only one):*

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

b. EBC collected before spirometry *(check only one):*

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

47. Serum for CRP and IL-6 collected:

Yes (1) No (2) → **50.**

48. Serum for CRP and IL-6

	Yes	No
a. Aliquot 1:	(1)	(2)
b. Aliquot 2:	(1)	(2)
c. Aliquot 3:	(1)	(2)
d. Aliquot 4:	(1)	(2)

49. CRP and IL-6 collection information

	Yes	No
a. Collected before other blood specimens:	(1)	(2)
b. Time sample collected:		
____ ____ : ____ ____ (hour : minute)	(1) am	(2) pm

50. Packed blood cells collected for genotyping *(expected at Visit 2; only if participant consented to donate DNA and have it stored):*

Yes (1) No (2)

51. Plasma for genistein levels

	Yes	No
a. Aliquot 1:	(1)	(2)
b. Aliquot 2:	(1)	(2)

52. Eosinophil count

a. Eosinophil blood specimen collected:

Yes (1) No (2) → **53.**

b. Record results of eosinophil analysis:

____ ____ ____ ____ cells/µL

53. Urine for LTE4

	Yes	No
a. Aliquot 1:	(1)	(2)
b. Aliquot 2:	(1)	(2)
c. Aliquot 3:	(1)	(2)
d. Aliquot 4:	(1)	(2)

54. Specify any unusual conditions associated with any specimen collected:

_____

_____

_____

G. Administrative information

55. Date form reviewed:

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

56. Clinic coordinator PIN: ____ ____ ____

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

_____

SOYA Diary Card

Fill out information inside the box each morning (AM) and evening (PM). If information is missing, leave that item 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 -5 check (✓) if occurred								
AM **3**.	Awakened by asthma last night:	( )	( )	( )	( )	( )	( )	( )
AM **4**.	Took morning study tablet:	( )	( )	( )	( )	( )	( )	( )
PM **5**.	Took evening study tablet:	( )	( )	( )	( )	( )	( )	( )
PM **6**.	Drug use for quick relief of asthma symptoms *(do not count uses to prevent symptoms, for example before exercise)*							
	a. **# puffs** per day by metered dose inhaler:							
	b. **# uses** per day by nebulizer:							
PM **7**.	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

For items 8-10 check (✓) if occurred		Mon	Tue	Wed	Thu	Fri	Sat	Sun
PM **8**.	Used oral prednisone/steroids for asthma:	( )	( )	( )	( )	( )	( )	( )
PM **9**.	New or increased dose of asthma medicine other than drugs listed in 4, 5, 6a, 6b or 8:	( )	( )	( )	( )	( )	( )	( )
PM **10**.	Urgent unscheduled healthcare contact for asthma (ER/hospital/clinic or doctor visit):	( )	( )	( )	( )	( )	( )	( )

To be completed by clinic:

11. Starting date of this diary:

___ ___ - ___ ___ ___ - ___ ___
day mon year

12. Clinical center ID: ____ ____ ____ ____

13. Participant ID: ____ ____ ____ ____ ____

14. Name code: ____ ____ ____ ____ ____

15. Date diary returned: ___ ___ - ___ ___ ___ - ___ ___
day mon year

16. Clinic coordinator PIN: ____ ____ ____

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

_____

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

Tablet Dispensing and Counting

Purpose: To record the issuing and collecting of study tablets to and from participant.
When: Whenever bottles of study tablets are issued or collected and retained by the clinic.
By whom: Clinic staff and other SOYA authorized personnel.
Instructions: Dispensing: At visit 2 (randomization) one study kit will be assigned per participant. At visit 2 and visits 4-8 (and interim times if needed) dispense one bottle from the participant's Kit box. For each bottle dispensed, affix the tear-off bottle label in item 12. Note: This form allows for the recording of two dispensed tablet bottles in unusual circumstances. Key into SOYA 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-V9, N)*: ____ ____
(record "N" if not associated with a clinic visit)

6. Form version date:

1 0 - M A Y - 1 0
day mon year

B. Study treatment information

7. Kit ID: **Y** -____ ____ ____ ____

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

a. Dispense bottle of study tablets *(complete items 9-12)*: (1)
b. Bottles returned/tablets counted *(complete items 13-20)*: (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 tablet bottle(s) issued *(key information from label)*:

a. First bottle label:

affix bottle label here

b. Second bottle label *(if necessary)*:

affix bottle label here

Make sure the issuance of the study kit is recorded on the Study Kit Accountability Log (DA) and the Patient Bottle Accountability Log (PD). Check that the first letter and numbers of the Bottle ID on affixed label matches the Kit ID in item 7.

D. Bottles returned/tablets counted

13. Total bottles returned: _____

If no bottles are returned, record "0" and skip to item 20.

14. Sequence of bottle(s) returned

a. First bottle:

Y -_____ _____ _____ _____-_____

b. Second bottle *(if applicable)*:

Y -_____ _____ _____ _____-_____

15. Date of count:

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

16. Total tablets counted: _____ _____ _____

17. Does tablet count suggest a compliance problem:

Yes (1) No (2)

→ **19.**

18. Was compliance reviewed with participant:

Yes (1) No (2)

19. Were all outstanding bottles returned:

Yes (1) No (2)

→ **21.**

20. If some or all bottles were <u>not</u> 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

21. Date form reviewed:

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

22. Clinic coordinator PIN: _____ _____ _____

23. Clinic coordinator signature:

_____

Exit Interview

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

When: Visit 9 (V9).

Respondent: Participant, parent/guardian, or both.

Instructions: Conduct interview at the end of Visit 9 or earlier visit if participant terminates early. Key into SOYA 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:

1 0 – M A Y – 1 0
day mon year

B. Exit questions for participants

7. Exit questions for participant

a. What did you think about the study:

_____

_____

_____

_____

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

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

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 supplement (Soy) (1)
Inactive supplement (placebo) (2)
Don't know (3)

b. Do you want to continue with this treatment:

Yes (1) No (2)

c. Comments:

_____

_____

_____

C. Exit questions for participant's parent/guardian

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

Yes (1) No (2)

12.

10. Exit questions for parent/guardian

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

_____

_____

_____

_____

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

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

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 supplement (Soy) (1)
Inactive supplement (placebo) (2)
Don't know (3)

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

Yes (1) No (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 - 10 Step

Purpose: Record results of Methacholine Challenge testing.

When: Visit 1 (V1) as applicable.

Instructions: Complete sections A-G before proceeding with section H. Key into SOYA 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: ____ ____

6. Form version date:

1 6 – J U N – 1 0
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 and 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 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

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, 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 guidelines in SOYA Manual of Procedures:

Yes (1) No (2)

25. Equipment

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

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 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 Procedures 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 44-59: 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 (1) No (2) → *Go to Section I*
45.	I	0.0625	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
46.	H	0.125	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
47.	G	0.25	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
48.	F	0.5	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
49.	E	1.0	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
50.	D	2.0	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
51.	C	4.0	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
52.	B	8.0	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*
53.	A	16.0	___ . ___ ___	___ . ___ ___	Yes (1) No (2) → *Go to Section I*

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

Yes (1) No (2) → **68.**

Items 55-59 left blank intentionally.

I. Recovery

Administer 2 puffs albuterol via MDI with spacer and wait 10 minutes per 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 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 44-53, 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. Date form reviewed:

____ ____ – ____ ____ – ____ ____
day mon year

73. Clinic coordinator PIN: ____ ____ ____

74. Clinic coordinator signature:

_____

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 (diaries since the last visit are associated with the upcoming visit). Complete a separate Missed Data (MD) form for each visit that is missed or that has missing data.

Instructions: Key into SOYA 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:

0 9 – A P R – 1 0
day mon year

7. Was visit or phone contact missed completely:

(Yes 1) (No 2)

B. Missed visit information

8. Forms/questionnaires missed *(check all that apply)*

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

b. BA (Baseline Asthma and Medical History): (1)

c. BF (Block 2005 Food Frequency Questionnaire): (1)

d. BK (Block 2004 Kids Food Frequency Questionnaire): (1)

e. BS (Block Soy Foods Screener): (1)

f. CH (Child Health Questionnaire): (1)

g. CV (Clinic Visit Form): (1)

h. DC (Diary Card): (1)

i. DD (Tablet Dispensing and Counting): (1)

j. EI (Exit Interview): (1)

k. FQ (Asthma in Females Questionnaire): (1)

l. MC (Methacholine Challenge Testing): (1)

m. MO (Medical Outcomes Study): (1)

n. MQ (Marks Asthma Quality of Life Questionnaire): (1)

o. NO (Nitric Oxide Form): (1)

p. PC (Phone Contact): (1)

q. PE (Physical Exam): (1)

r. PF (Pulmonary Function Testing): (1)

s. PI (Participant Information): (1)

t. PQ (Children's Health Survey for Asthma - Child Version): (1)

u. SQ (Home Smoking Activity and Exposure to Tobacco Smoke): (1)

v. TA (Asthma Control Test, 12+): (1)

w. TT (Treatment Termination): (1)

x. UM (Unmasking): (1)

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

_____
form/questionnaire

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

9. Are diary cards missing:

(Yes 1) (No 2)

13. ____

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:

10. First interval

a. Start date:

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

b. End date:

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

11. Second interval

a. Start date:

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

b. End date:

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

12. Third interval

a. Start date:

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

b. End date:

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

13. 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)

_____

_____

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

14. Additional notes/explanations:

_____

_____

_____

_____

_____

C. Administrative information

15. Date form reviewed:

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

16. Clinic coordinator PIN: ____ ____ ____

17. Clinic coordinator signature:

_____

SOYA Reference #: _____

Nitric Oxide Form

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

When: Visit 2, 4-9; before spirometry, Methacholine Challenge testing, or EBC collection.

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 SOYA 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 2 – N O V – 1 0
day mon year

B. Procedure

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

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

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

c. Did participant have an EBC collection before eNO testing:
- Yes (1)
- No (2)
- Don't know (3)

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

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

f. 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):*
- NIOX MINO A first (1)
- NIOX MINO B first (2)

NIOX MINO device A

If not participating in substudy, answer for NIOX MINO A below.

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

Pass (1) Fail (2)

Skip to item 17 if participating in eNO Comparison Substudy.

OR

Skip to item 22 if not participating.

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) am (2) pm
hour minute

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) am (2) pm
hour minute

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, and asthma control.
When: Visit 3 (V3).
Respondent: Participant, parent/guardian, or both.
Instructions: In all items, "you" refers to participant. Key into SOYA 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 SOYA Asthma Study. I'm calling to see how you're doing. Would now be a good time to answer a few questions?")

5. Visit ID: **V 3**

6. Form version date:

2 7 - M A Y - 1 0
day mon year

B. Study Treatment

7. How are you doing with the study tablets:

_____

_____

8. Missed study tablets

a. Since Visit 2, have there been any missed doses of study tablet:

Yes (1) No (2) → **10.**

b. How many doses: ____ ____ doses

9. Why was study tablet missed *(check all that apply)*

a. Forgot: (1)
b. Out of study tablets: (1)
c. Side effects *(specify)*: (1)

_____
name side effects

d. Lost bottle: (1)
e. Too busy: (1)
f. Other *(specify)*: (1)

_____
identify reason

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

10. Symptoms

a. Since Visit 2, were there any symptoms (skin rash, itching, difficulty breathing, difficulty swallowing, low blood pressure or passing out) that may be related to the study tablets:

Yes (1) No (2)

b. If "Yes," specify:

_____

_____

C. Asthma and health

11. Were any rescue medications (ie, short acting bronchodilator) used since beginning study tablets *(do not count uses to prevent symptoms, eg, medication before exercise)*:

Yes (1) No (2) → **13.**

12. How many times since beginning study tablets were rescue medication used other than to prevent symptoms (2 puff of MDI=1 use):

_____ _____ _____
times

13. How many times were you awakened by asthma symptoms since beginning study tablets:

_____ _____ _____
times

14. Were there significant events since beginning study tablets *(check all that apply)*

a. Hospitalization or urgent care visit for asthma: (1)
b. Used oral corticosteroids: (1)
c. Other *(specify)*: (1)

_____
name event

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

D. Study procedures

15. Have you been filling out diary cards, do you have any confusion *(check all that apply)*

a. Answered questions about filling out diary cards: (1)
b. Checked number of diary cards returned to clinical center: (1)
c. Reviewed quality of diary cards returned to clinical center: (1)
d. Encouraged participant to complete and bring diary cards to next visit: (1)
e. Discussed problems, impediments to completing the diary cards and returning them to the clinical center *(specify)*: (1)

_____

_____

_____

_____

f. N/A, diary cards not reviewed: (1)

16. Visit 4 appointment

a. Date:

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

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

c. Participant can make appointment: Yes (1) No (2)

18. ◀

If No, try to reschedule on phone.

17. Rescheduled Visit 4 appointment

a. Date:

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

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

18. 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. N/A, no reminders given: (1)

E. Administrative information

19. Date form reviewed:

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

20. Clinic coordinator PIN: _____ _____ _____

21. Clinic coordinator signature:

_____

22. Who was interviewed *(check all that apply)*:

a. Participant (1)
b. Parent/guardian (1)
c. Other *(specify)* (1)

_____
relationship to participant

Physical Exam

Purpose: To assess information about a participant's health.
When: Screening (V1) and Visit 9 (V9).
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 SOYA 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 0 - M A Y - 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)	Not Examined (3)
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)

20. Is examiner a SOYA certified study physician:

Yes (1) → **22.** No (2)

If No, then form must be countersigned by overseeing SOYA certified Study Physician. Complete items 21-25.

21. Examiner

a. Examiner signature:

_____

b. Examiner name *(print)*:

_____

22. SOYA certified study physician

a. Study physician PIN: _____ _____ _____

b. Study physician signature:

_____

C. Administrative information

23. Date form reviewed:

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

24. Clinic Coordinator PIN: _____ _____ _____

25. Clinic Coordinator signature:

_____

Pulmonary Function Testing

Purpose: To record results of pulmonary function tests.

When: Visits 1, 2, 4-9.

Instructions: Test must be performed with a KoKo spirometer. Key into SOYA 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:

1 0 – M A Y – 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

Note: Items 14, 15, 18 and 19 can be calculated using the online calculator.

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

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

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

____ • ____ ____
Liters

15. Percent predicted pre-bronchodilator FEV_1:

____ ____ ____
%

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

D. Post-bronchodilator data

16. Post-bronchodilator FVC: ____ ____ ____ ____
Liters

17. Post-bronchodilator FEV_1: ____ ____ ____ ____
Liters

E. Reversibility data

18. Percent predicted post-bronchodilator FEV_1:

____ ____ ____
%

Calculation: (100 x post-BD FEV_1/predicted FEV_1); ie, (100 x item 17/item 14)

19. Percent reversibility: ____ ____ ____
%

Calculation: [(post-BD FEV_1 - pre-BD FEV_1)/pre-BD FEV_1] x 100; ie, [(item 17 - item 13)/item 13] x 100]

F. Administrative information

20. Date form reviewed:

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

21. Clinic coordinator PIN: ____ ____ ____

22. Clinic coordinator signature:

_____

Randomization Form

Purpose: To document eligibility and record treatment assignment.

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

Instructions: Key into SOYA data system at www.cctrials.org/alaacrc to obtain treatment assignment. Screening form (SC) and Pulmonary Function Testing form (PF) (if applicable) 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 G.

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:

1 0 – M A Y – 1 0
day mon year

B. Inclusion criteria

7. Age 12 or older:

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

8. Physician diagnosed asthma:

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

9. Currently on a prescribed dose of daily controller asthma medication(s) *(eg, inhaled corticosteroids and/or leukotriene modifier):*

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

10. Non-smoker for the past 6 months or longer:

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

11. Less than 10 pack-year 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

12. Percent predicted pre-bronchodilator FEV_1 greater than or equal to 50%:

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

13. Bronchodilator reversibility

a. Participant demonstrated 12% or greater reversibility within the last 2 years:

( ) Yes (1) ( ) No (2) **14.**

b. Date reversibility demonstrated:

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

14. Methacholine PC_{20}

a. Participant demonstrated PC_{20} less than 16 mg/mL within the last 2 years:

Yes (1) No (2) → 15.

b. 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 13-14 must be checked "Yes". If both items 13-14 are checked "No", then **STOP***; participant is ineligible for the study. Complete section G.*

15. Participant scored 19 or less on Asthma Control Test (TA) at V1 or V2:

Yes (1) No (2)

16. Participant used a beta-agonist for asthma symptoms two or more times per week on average over the past 4 weeks:

Yes (1) No (2)

17. Nocturnal awakenings with asthma symptoms more than once per week on average over the past 4 weeks:

Yes (1) No (2)

18. Two or more episodes of asthma symptoms in the past 12 months with each episode requiring at least one of the following: ER visit, unscheduled physician visit, prednisone course, or hospitalization:

Yes (1) No (2)

One of the above items 15-18 must be checked "Yes." If all items 15-18 are checked "No," then **STOP***; participant is ineligible for the study. Complete section G.*

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

Yes (1) No (2) → STOP

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

Yes (1) No (2)

C. Exclusion criteria

21. Medication use

Yes No

a. Oral corticosteroid use within past 6 weeks: (1) → STOP (2)

b. Current or previous use of tamoxifen: (1) → STOP (2)

c. Use of any investigational treatments in previous 30 days: (1) → STOP (2)

22. Intake of soy, soy supplements or soy enriched foods four or more times within past 30 days:

Yes (1) → STOP No (2)

23. Previous adverse effects from genistein, other phytoestrogens or soy products:

Yes (1) → STOP No (2)

24. History or physician diagnosis of chronic bronchitis, emphysema, or COPD:

Yes (1) → STOP No (2)

25. Active thyroid disease:

Yes (1) → STOP No (2)

26. History of endometrial, breast or ovarian cancer:

Yes (1) → STOP No (2)

27. Condition which in the judgment of the study physician may interfere with participation in the study (eg, non-skin cancer, endocrine disease including insulin-dependent diabetes mellitus, coronary artery disease, congestive heart failure, stroke, severe hypertension, renal failure, liver disorder, malabsorption disorders, immunodeficiency state, major neuropsychiatric disorder)

Yes (1) → STOP No (2)

28. 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 and Visit 2.

29. Asthma exacerbation within past 6 weeks:

Yes (1) → STOP No (2)

30. Upper respiratory infection within past 2 weeks:

Yes (1) → STOP No (2)

31. Body weight less than 77 pounds (35 kg):

Yes (1) → STOP No (2)

32. Change in diet over the past month or expected change in diet *(eg, will initiate weight loss diet)* during the study:

Yes (1) → STOP No (2)

33. Able to swallow study tablets:

Yes (1) No (2) → STOP

34. Accessible by telephone:

Yes (1) No (2) → STOP

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

Yes (1) No (2) → STOP

D. Procedures

36. Were the following baseline procedures completed or checked

	Yes	No
a. Baseline history (BA form):	(1)	(2)
b. Physical exam:	(1)	(2)
c. Urine specimen collected:	(1)	(2)
d. Pregnancy test *(at V1 and V2):*	(1)	(2)
e. Diary cards reviewed:	(1)	(2)
f. Questionnaires completed:	(1)	(2)
g. Spirometry *(at V1 and V2):*	(1)	(2)
h. Exhaled nitric oxide (eNO) test:	(1)	(2)
i. Exhaled Breath Condensate (EBC) collected:	(1)	(2)
j. Blood specimen collected:	(1)	(2)

37. Were the following V1 forms keyed into the data system

a. Screening form (SC):

Yes (1)

No (2)

b. Pulmonary Function Testing (PF):

Yes (1)

No (2)

E. Peak flow from diary cards

38. 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: ____ ____ ____

F. Final check

39. Participant meets all eligibility criteria for randomization:

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

G. Administrative information

40. Date form reviewed:

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

41. Clinic coordinator

a. Clinic coordinator PIN: ____ ____ ____

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

_____

42. Study physician

a. Study physician PIN: ____ ____ ____

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

_____

c. Date signed:

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

Note:
- **Print copy of treatment assignment from data system and attach to this form.**
- **Affix tear-off portion of tablet bottle label on DD form item 12a.**

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

43. 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.

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

Y–____ ____ ____ ____

SOYA Reference #: _____

Screening Form

Purpose: To check preliminary eligibility criteria for the study run-in.

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

Instructions: If participant is eligible, key into SOYA data system at www.cctrials.org/alaacrc. Must be keyed real-time while the participant is at the clinic. If item checked is marked with a [STOP], participant is ineligible for the study at present time. Proceed to section C. Do not key form for participants who fail screening.

A. Clinical center, participant and visit information

1. Clinical center ID: ____ ____ ____ ____

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

3. Name code: ____ ____ ____ ____ ____

4. Visit date:

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

5. Visit ID: V 1

6. Form version date:

0 8 - D E C - 1 0
day mon year

B. Preliminary screening

7. Age 12 years or older:

Yes (1) No (2) STOP

8. Body weight greater than or equal to 77 pounds (35 kg):

Yes (1) No (2) STOP

9. Currently on a prescribed dose of daily controller asthma medication(s) *(eg, inhaled corticosteroid and/or leukotriene modifier):*

Yes (1) No (2) STOP

10. Physician diagnosed asthma:

Yes (1) No (2) STOP

11. Non-smoker for the past 6 months or longer:

Yes (1) No (2) STOP

12. Less than 10 pack-year 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

13. Percent predicted pre-bronchodilator FEV_1 greater than or equal to 50%:

Yes (1) No (2) STOP

14. Bronchodilator reversibility

a. Participant demonstrated 12% or greater reversibility within the last 2 years:

Yes (1) No (2) 15.

b. Date reversibility demonstrated:

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

15. Methacholine PC_{20}

a. Participant demonstrated PC_{20} less than 16 mg/mL within the last 2 years:

Yes (1) No (2) → **16.**

b. Date PC_{20} FEV_1 demonstrated:

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

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

WARNING: *If both items 14-15 are checked "No", then participant must demonstrate one of these criteria by V2 to be eligible.*

16. Asthma Control Test (TA) score at V1:

____ ____

17. Participant scored 19 or less on the Asthma Control Test (TA) at V1:

Yes (1) No (2)

18. Participant used a beta-agonist for asthma symptoms two or more times per week on average over the past 4 weeks:

Yes (1) No (2)

19. Nocturnal awakenings with asthma symptoms more than once per week on average over the past 4 weeks:

Yes (1) No (2)

20. Two or more episodes of asthma symptoms in the past 12 months with each episode requiring at least one of the following: ER visit, unscheduled physician visit, prednisone course, or hospitalization:

Yes (1) No (2)

One of the above items 17-20 must be checked "Yes." If all items 16-20 are checked "No," then **STOP***; participant is ineligible for the study at this time. Proceed to section C.*

21. Current or previous use of tamoxifen:

Yes (1) → STOP No (2)

22. Previous adverse effects from genistein, other phytoestrogens, or soy products:

Yes (1) → STOP No (2)

23. History or physician diagnosis of chronic bronchitis, emphysema or COPD:

Yes (1) → STOP No (2)

24. Active thyroid disease:

Yes (1) → STOP No (2)

25. History of endometrial, breast or ovarian cancer:

Yes (1) → STOP No (2)

26. Was a pregnancy test conducted at this visit for women of child bearing ability:

Yes (1)
No (2) → STOP
Not applicable (3)

27. Currently pregnant, lactating, or unwilling to practice adequate birth control for duration of study:

Yes (1) → STOP
No (2)
Not applicable (3)

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

Yes (1) No (2) → STOP

29. Accessible by telephone:

Yes (1) No (2)

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

Yes (1) No (2)

31. Signed consent statement:

Yes (1) No (2)

32. Oral corticosteroid use within past 6 weeks:

Yes (1) No (2)

33. Use of any investigational treatments in previous 30 days:

Yes (1) No (2)

34. Intake of soy, soy supplements or soy-enriched foods four or more times within the past 30 days:

Yes (1) No (2)

35. Change in diet over past month or expected change in diet *(eg, will initiate weight loss diet)* during the study:

Yes (1) No (2)

36. Asthma exacerbation within past 6 weeks:

Yes (1) No (2)

37. Unable to swallow study tablets:

Yes (1) No (2)

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

	Yes	No
a. Non-skin cancer:	(1)	(2)
b. Endocrine disease including insulin-dependent diabetes mellitus:	(1)	(2)
c. Coronary artery disease:	(1)	(2)
d. Congestive heart failure:	(1)	(2)
e. Stroke:	(1)	(2)
f. Severe hypertension:	(1)	(2)
g. Renal failure:	(1)	(2)
h. Liver disorder:	(1)	(2)
i. Immunodeficiency state:	(1)	(2)
j. Malabsorption disorder:	(1)	(2)
k. Major neuropsychiatric disorder:	(1)	(2)
l. Other *(specify):*	(1)	(2)

_____
specify

If any of above items in 38 are checked ''Yes,'' alert study physician for evaluation during physical exam. Patient may be ineligible.

39. Upper respiratory infection within past 2 weeks:

Yes (1) No (2)

Items 32-39 must be ''No'' for patient to be eligible; if any of those items are ''Yes,'' participant is ineligible at this time.

C. Administrative information

40. Date form reviewed:

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

41. Clinic coordinator PIN: ____ ____ ____

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

_____

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

____ ____ ____ ____ ____

Treatment Termination

Purpose: Record permanent termination of study tablets.

When: Treatment termination during or at end of trial.

Instructions: Key into SOYA 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:

1 0 - M A Y - 1 0
day mon year

B. Termination

7. Date of last study tablet:

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

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

Study tablet 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):* (1)

_____
name event

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

_____
name side effects

d. Poor asthma control: (1)
e. Participant request: (1)
f. Lost to followup: (1)
g. Pregnancy: (1)
h. Other *(specify):* (1)

_____
identify reason

i. N/A, treatment not terminated: (1)

10. Were some or all study tablets collected from participant at this time:

Yes (1) No (2)

Complete the Tablet Dispensing and Counting (DD) form.

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

D. 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: When study treatment is unmasked to the participant.

Instructions: Key into SOYA 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: ____ ____

6. Form version date:

1 0 – M A Y – 1 0
day mon year

B. Unmasking

7. Randomization kit ID:

Y –____ ____ ____ ____

8. Date unmasked:

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

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

Unscheduled unmasking (before Visit 9) (1)
Scheduled unmasking at end of trial *(at Visit 9)* (2)

11.

10. Reason for unscheduled unmasking

_____

_____

_____

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 SOYA staff unmasked:

Yes (1) No (2)

14.

13. SOYA 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:

_____