Baseline Asthma and Medical History

A. Clinical center, participant and visit identification			11. Age:	years	
1. Clinical center ID:			C. Asthma History		
2. Participant ID:			12. Age of onset of asthma symptoms (<i>years</i> ; <i>before first birthday record as ''01'')</i> :	if or	nse
3. Name code:				years	
4. Visit date: 	year		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:		
5. Visit ID:	<u>V</u>	1			
6. Form version date: $ \underbrace{-2}_{day} \underbrace{-N}_{mon} \underbrace{-V}_{mon} $	<u>1</u> (year)	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:		
B. Demographic information					
7. Gender (<i>check only one</i>): Male Female	((1) 2)	 15. Do you have allergies that make your asthma worse: ^{Yes} ^{Yes} 	(1	¥0 2
8. Ethnicity (check only one):			D. Asthma diagnosis and onset		
Hispanic/Latino/Spanish Not Hispanic/Latino/Spanish	((1) 2)	16. Who made your original diagnosis of asthma (<i>check only one</i>):		
9. Race (check only one):			Primary care doctor (family doctor, pediatrician)	(
White	(1)	Lung doctor	(1
Black or African American	(2)	Allergy doctor	(2
Asian	(3)	Other (<i>specify</i>)	(3
American Indian or Alaskan Native	(₄)	Outer (specify)	C	4
Hawaiian or other Pacific Islander	(₅)			
Other (<i>specify</i>)	(5) 6)	specify		

10. Date of birth:

day mon year

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 (<i>specify</i>)	(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 <i>(check only one):</i>		
	Never	(_)
	Within the last year	((2)
	Greater than one year ago	()
22.	When did you last have an ICU admission because of an asthma attack <i>(check only one):</i>		
	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 app	oly)	
a. Cat:	(1)
b. Dog:	(1)
c. Rodent:	(1)
d. Other (<i>specify</i>):	(1)
specify		
e. None:	(1)
32. A particular season (<i>check all that appl</i>)	y)	
a. Winter:	(1)
b. Spring:	(1)
c. Summer:	(1)
d. Fall:	(1)
e. None:	(1)
If male, skip to item 36.		
33. Menstruation (<i>premenstruation or during menses</i>):		
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 thera or had an ovariectomy:	ру	

36. Do you have any conditions related to allergies (<i>check all that apply</i>)	
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:	
$\begin{pmatrix} Yes \\ 1 \end{pmatrix}$	$\binom{NO}{2}$
38. Do you have any of the following conditions (<i>check all that apply</i>)	
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)

 $\begin{pmatrix} \text{Yes} & & \text{No} \\ & 1 & & \begin{pmatrix} & \text{No} \\ & 2 \end{pmatrix}$

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	Ò	2)
	1-4 times per month	Ò	3)
	Less than 1 time per month	Ò	4)
	Never	Ì	5)
b.	Steroidal combination medications for asthma (<i>eg, Advair, Symbicort</i>):		
	Daily	(1)
	2-6 times per week	Ì	-))
	1-4 times per month	Ò	3)
	Less than 1 time per month	Ò	4)
	Never	(5)

Combination medication:

specify

c.	Oral anti-leukotriene (<i>eg</i> , Singulair, Accolate, Zyflo): Daily 2-6 times per week 1-4 times per month Less than 1 time per month Never	() () () ()	
d.	Inhaled anticholinergic bronchodilators (<i>eg, Atrovent, Spiriva</i>): Daily 2-6 times per week 1-4 times per month Less than 1 time per month Never	() () () ()	

e.	6 6		
	bronchodilators (eg, Albuterol, Proventil, Ventolin, Maxair, Xopenex,		
	etc):	,	
	Daily	((((1)
	2-6 times per week 1-4 times per month	$\left\{ \right\}$	2)
	Less than 1 time per month	2	3)
	Never	È	$\binom{4}{5}$
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,		
0	Nasalcrom/Alocril, Tilade):		
	Daily	(1)
	2-6 times per week	Ì	2)
	1-4 times per month	(3)
	Less than 1 time per month	(4)
	Never	(5)
h.	Oral beta-agonist (eg, Proventil repetabs	.).	
	Daily	(.)
	2-6 times per week	è	$\frac{1}{2}$
	1-4 times per month	Ì	3)
	Less than 1 time per month	Ì	4)
	Never	Ì	5)
i.	Methylxanthines (theophylline):		
	Daily	(.)
	2-6 times per week	Ì	$\frac{1}{2}$
	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)

I. Symptoms

Never

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	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)

 $\binom{1}{2}{3}$

4)

5)

1)

2)

3)

4)

5)

1)

2)

3)

4)

5)

1)

 $\binom{2}{3}$

5)

Twice a

1)

,)

J. Cigarette Smoking History

47. Smoking status (check only one):

Former

Never (fewer than 20 packs in lifetime) 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:

٠	
# 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:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

(

(

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

$$\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

L. General Medical Conditions

53. Do you have now or have you the last year any of the media conditions from the following	cal	during	3	
	Y	es	N	ю
a. COPD (Chronic Obstruct	ive			
Pulmonary Disease):	(1)	(2)
b. Eczema:	(1)	(2)
c. Sinusitis:	(1)	(2)
d. Hay fever or allergic rhin	itis:(1)	(2)
e. Food allergies:	(1)	(2)
f. Other allergies (<i>specify</i>):	(1)	(2)

specify al	llergy			
g. Cancer (other than skin cancer):	(1)	(2)

specify can	cer			
specify can	cer			
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) 2

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

(1) (2)

n. Diabetes mellitus:

specify				
o. Renal failure:	(1)	(2) 2
p. Liver disorders:	(1)	(2)
q. Immunodeficiency states:	(1)	(2)
 Major neuropsychiatric disorder: 	(1)	(2) 2
s. Other condition(s) that wou interfere with participation in the study (<i>specify</i>):	ld (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*):

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

63.

55. Have you ever been diagnosed with sleep apnea:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

56. Do you use CPAP or BIPAP:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

57. Have you ever been told you snore:

$$\binom{\text{No}}{1}$$
 $\binom{\text{No}}{2}$

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

$$\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

59. Do you often take naps during the day:

$$\binom{\text{No}}{1}$$
 $\binom{\text{No}}{2}$

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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

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

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)

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:

Y	es	1	No
(1)	(₂)
	(58. —	

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) 2
Unknown	(з)

^{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 (<i>enter a, b, or c</i>)		
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*):

Clinic Visit Form

Purpose: To record information about diary cards, asthma symptoms, tablets, and other visit procedures. When: Visits 2, 4-9.

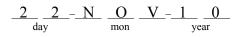
Instructions: Complete form at clinic visit. Key into SOYA data system at www.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

- **1.** Clinical center ID:
- 2. Participant ID:
- 3. Name code:
- 4. Visit date:

day mon vear

- 5. Visit ID:
- **6.** Form version date:



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)

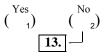
a. None missing:	(1)
b. Participant forgot to return:	(1)
c. Did not complete:	(1)
d. Lost or destroyed:	(1)
e. In the mail:	(1)
f. Other (<i>specify</i>):	(1)

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):



- **b.** If Yes, specify how many:
- **13.** Clinic visits
 - **a.** Did you have any extra visits at this clinic since the last study visit:

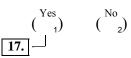


b. If Yes, specify how many:

_ ____ ___

D. Interim Medical History

14. Is this Visit 2:



15.	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 (<i>specify reason</i>):	(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 (<i>specify</i>):	(1)		
	list side effects				
	h. Too busy:	(1)		
	i. Other (<i>specify</i>):	(1)		

identify reason

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

18.	Rescu	e bronchodilator drugs participant taken since last Drug name (Trade names)	visi Ye	
	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:	(1)
	k.	Other:	(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)		
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	
f.	Other:specify	(1)	<u></u>	num
g.	Other:specify	(1)	<u>mcg</u>	num
h.	Other:specify	(1)	<u>mcg</u>	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)		
c.	Budesonide (Pulmicort):	(₁)		
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:	(₁)	mcg	num
j.	specify Other:	(₁)	mcg	num
k.	specify Other:	(₁)	mcg	num
*	specify		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)	/·	
c.	Fluticasone and Salmeterol (Advair):	(₁)	mcg	num
d.	Fluticasone and Salmeterol (Advair HFA):	()	mcg	num
u.	Thureasone and Sameteror (Advan Th A).	(₁)	/	num
e.	Other combination:			
	specify	(₁)	/ /	

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

Orar	Tablets/Elixirs per day			
a.	NA, no oral corticosteroid drugs taken:	(₁)		
b.	Prednisone (Cortan, Deltasone, Orasone, Prednicen-M, Sterpred):	(₁)		
c.	Prednisolone (Pepiapred, Prelone, Delta- Cortef):	(₁)	mg	num
d.	Methylprednisolone (Medrol):	(₁)	mg mg	num num
e.	Other:	(1)		
f.	Other:	(1)	mg	

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

	Drug name (Trade names)		11 07	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:	(1)		

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

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

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

oune	Drug name (Trade names)	Yes	Dose	Puffs/Ampules per day
a.	NA, no non-steroidal drugs taken:	(₁)		
b.	Cromolyn sodium (Intal Nebulizer):	(₁)		
c.	Cromolyn sodium (Intal Metered Dose Inhaler):	(₁)	mg	num
d.	Nedocromil sodium (Tilade):	(₁)	mcg	
e.	Other:	(₁)	mg	num
f.	specify Other: specify	(₁)		
g.	Other: specify	(₁)		·
h.	Omalizumab (Xolair):	()	Dose	Injections per month
11.	Omanzamao (Aolan).	(₁)	mg	num

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

> $\binom{\text{Yes}}{1}$ (^{No}₂)

> > (^{No}

2)

Yes (1)

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:

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:

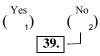
Yes No (1) (2)**36.**

- **30.** Since the last study visit, have your menstrual cycles been regular: Yes No (__1) (__2)
- **31.** Since the last study visit, has your menstrual flow become heavier: Yes No
- **32.** Since the last study visit, has your menstrual flow become lighter: Yes No
- **33.** Since the last study visit, have you experienced spotting or bleeding between menstrual periods: Yes No (__1) (__2)
- **34.** Since the last study visit, have you experienced more discomfort or cramping than usual with your menstrual cycle: Yes No
- **35.** Since the last study visit, have you experienced less discomfort or cramping than usual with your menstrual cycle: Yes No

- **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: (**c.** Strep throat: d. Bronchitis: e. Pneumonia: **f.** Ear infection: g. Acute sinusitis (sinus infection): (
 - h. N/A, none since last visit: (
- **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:



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

1)

1)

1)

1)

1)

1)

,)

41. Were the following procedures and their forms completed Vac

ionnis completed	Y	es	N	0
a. Asthma Control Test (TA) <i>(all clinic visits):</i>	(1)	(2)
b. Asthma Symptoms (AS) (all clinic visits):	(1)	(2)
c. Asthma Quality of Life (MQ or PQ) (<i>all clinic visits</i>):	2 (1)	(2)
d. Health Quality of Life (CH MO) (<i>visits 1 and 9</i>):	or (1)	(2)
e. Food Frequency Questionna (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) (<i>visit 2, 4-9</i>):	(1)	(2)
h. Pulmonary Function Testing (PF) (all clinic visits)	g (1)	(2)
i. Tablet Dispensing and Coun (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) (<i>visit 2</i>):	(1)	(2)
o. Home Smoking Activity and Exposure to Tobacco Smoke Questionnaire (SQ) (visit 2)	e	1)	(2)

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

F. Specimen collection

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

44. Exhaled Breath Condensate (EBC) specimens collected:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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:



No

Vac

48. Serum for CRP and IL-6

	1 65	INO
a. Aliquot 1:	(₁)	(₂)
b. Aliquot 2:	(₁)	(₂)
c. Aliquot 3:	(₁)	(₂)
d. Aliquot 4:	(₁)	(₂)

Participant ID:

49. CRP and IL-6 collection information

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

(_____2)

(____1)

51. Plasma for genistein levels

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

52. Eosinophil count

53.

a. Eosinophil blood specimen collected:

Yes	No
$\begin{pmatrix} & 1 \end{pmatrix}$	$\begin{pmatrix} 2 \end{pmatrix}$
5	.
5	

b. Record results of eosinophil analysis:

	cells/µL	
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.

AM 1 .	Date (month/day):	M	on /	T	ue /	W	/ed /	Tł	nur /	F	°ri /	S	at /	Su/	in /
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 l	befoi	re ex	cerci	ise)										
	a . # puffs per day by metered dose inhaler:														
	b . # uses per day by nebulizer:														
PM 7.	Asthma score: 0 = No asthma episodes														
	 a = 1-3 asthma episodes, each lasting 2 hours or less All mild a = 4 or more mild asthma episodes, or 1 or more asthma episodes a = 1 or more asthma episodes lasting longer than 2 hours, or result a hospital 	that i ting i	nterfe n sho	ered v rtenii	with ng no	activ ormal	ity, pl activ	lay, so vity, o	chool r see	, or s ing a	leep docto	for le or, or	ss tha going	n 2 h g to	ours
For items	8-10 check (🖌) if occurred	М	on	Т	ue	W	/ed	Tl	ıu	F	Fri	S	at	St	ın
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 comp	pleted by clinic:	16.	Cli	nic c	oor	linat	or PI	N:							

11. Starting date of this diary:

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

		day		
12	Clinical center ID:			your
14.	Clinical center ID.	-		
13.	Participant ID:			
14.	Name code:			
15.	Date diary returned:	day	<u></u>	year

Sequential diary card # for this participant (optional):

Tablet Dispensing and Counting

When: The second	e: To record the issuing and collecting of study tablets to a Whenever bottles of study tablets are issued or collected at m: Clinic staff and other SOYA authorized personnel. tions: Dispensing: At visit 2 (randomization) one study kit im times if needed) dispense one bottle from the participar i ni item 12. Note: This form allows for the recording of tw A data system at www.cctrials.org/alaacrc within 10 work cipant and <u>retained</u> by the clinic.	nd <u>retaine</u> t will be a nt's Kit bo wo dispen	d by the clinic. ssigned per participant. At visit 2 and visits 4-8 (and ox. For each bottle dispensed, affix the tear-off bottle sed tablet bottles in unusual circumstances. Key into
A. Clinic	cal center, participant, and visit identification	11.	Delivered to the participant (check only one):
1.	Clinical center ID:		In person (1) By mail (2)
2.	Participant ID:		By mail(2)Other (specify)(3)
3.	Name code:		
4 .	Date form completed:	12.	specify Study tablet bottle(s) issued (<i>key information from</i> <i>label</i>):
	day mon year		a. First bottle label:
5. 6. B. Study	Visit ID (V2-V9, N): (record "N" if not associated with a clinic visit) Form version date:		affix bottle label here
7.	Kit ID: Y		b. Second bottle label (<i>if necessary</i>):
8. C. Disne	 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) 		affix bottle label here
9.	Date dispensed:	I	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
	day mon year		affixed label matches the Kit ID in item 7.
10.	Number of bottles dispensed:		

D.

Bottle	s returned/tablet	s counted	
13.	Total bottles retu	ırned:	
	If no bottles are item 20.	returned, record "(" and skip to
14.	Sequence of bott	le(s) returned	
	a. First bottle	:	
	Y		
	b. Second bot	tle (<i>if applicable</i>):	
	Y		
15.	Date of count:		
	dav		year
16.	Total tablets cou	nted:	
17.	Does tablet coun	t suggest a complia Yes ()	nce problem: No $\begin{pmatrix} 2 \end{pmatrix}$
18.	Was compliance	reviewed with part Yes	icipant: No (2)
19.	Were all outstand	ding bottles returned Yes () 21.	d: No ()
20.	If some or all bo (check all that ap	ttles were <u>not</u> return pply)	ed, give reasor
	a. Consumedb. Lost/destroc. Forgot, stil		$\begin{pmatrix} & 1 \\ & 1 \\ & & 1 \end{pmatrix}$

specify

Open, still using:

Other (*specify*):

E. Administrative information

22.

21. Date form reviewed:

day	mon	year
Clinic coordinator PIN:		

23. Clinic coordinator signature:

d.

e.

1)1)1)

(

Exit Interview

SOYA

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 ead data system at www.cctrials.org/alaacrc within 10 worki	
A. Clinical center and participant information	B. Exit questions for participants
1. Clinical center ID:	7. Exit questions for participant
2. Participant ID:	a. What did you think about the study:
3. Name code:	
4. Visit date:	
	b. How would you rate your experience as a study participant in the study (<i>check only one</i>):
5. Visit ID.	Excellent (1)
6. Form version date:	Good $\begin{pmatrix} & & \\ & & \\ & & \end{pmatrix}$
	Fair (3)
$\underbrace{-1}_{day} \underbrace{0}_{mon} \underbrace{-M}_{mon} \underbrace{-M}_{year} \underbrace{-1}_{year} \underbrace{0}_{year}$	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) 2) Inactive supplement (placebo) Don't know 3)

b. Do you want to continue with this treatment:

 $\begin{pmatrix} Yes \\ 1 \end{pmatrix}$ No (2)

c. Comments:

C. Exit questions for participant's parent/guardian

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



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
	(chec	ck only	one):			

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

Participant ID:

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 (Sov)

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 $\begin{pmatrix} 2 \end{pmatrix}$

c. Comments:

D. Exit procedures

12. Exit materials distributed

	Yes		1	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: (

a. Participant:	(1)
b. Parent/guardian:	(1)
c. Other (<i>specify</i>):	(1)

relationship to participant

Reference #:

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.cctrials.org/alaacrc within 10 working days.

A. Clinical center, participant and visit identification

- 1. Clinical center ID: _____ ____
- 2. Participant ID: _____ ___ ___
- 3. Name code: _____ ___ ___ ___
- **4.** Date of methacholine challenge:



5. Visit ID:

6. Form version date:

$$\underbrace{-1}_{day} \underbrace{-J}_{mon} \underbrace{-U}_{mon} \underbrace{-N}_{year} \underbrace{-1}_{year}$$

(

B. Absolute contraindications

7. Is participant taking any beta-adrenergic blocking agent:

$$\frac{\text{Yes}}{1} \qquad (\frac{\text{No}}{2})$$

8. Has participant had a stroke or heart attack in last three months:

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

9. Does participant have a known aortic aneurysm:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

10. Does the participant have uncontrolled hypertension (ie, SBP > 200, DBP > 100):

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$$
 $\begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

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

11. Did the participant have a positive pregnancy test:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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.

(

Yes

12. Are any of items 7-11 answered "Yes:"

) (^{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 <i>(specify):</i>	(1)

name of illness

14. Is participant wheezing or showing other signs of asthma:

 $\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

16. Has a study physician reviewed the relative contraindications:

(Yes No

> No ₂)

> > ,)

1)

1)

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:

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*):
 - **b.** Medium-acting bronchodilator within past 24 hours (eg, ipratropium, Combivent, oral albuterol, Choledyl): ,)
 - 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:
 - **h.** Leukotriene modifier within past 24 hours (eg. Singulair, Accolate, montelukast, zafirlukast):

Participant ID:

i. Antihistamines within past 48 hours (eg, Zyrtec, cetirizine, fexofenadine, Xyzal): _) 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:
$$\begin{pmatrix} 1 \end{pmatrix}$$

E. Confounders

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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

> Yes No (_) ₂)

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

> Yes No 1) 2)

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

$$\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

(

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

F. Other Checks

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

$$\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

25. Equipment

	Y	es	N	0
a. KoKo spirometer:	()	()
b. KoKo dosimeter:	()	()
c. Nebulizer cups, pre-cali for ACRC:	brated ()	()

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

 $\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$

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

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

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

 $\begin{pmatrix} Yes \\ 1 \end{pmatrix}$ $\begin{pmatrix} No \\ 2 \end{pmatrix}$

29. Is atropine immediately available:

 $\begin{array}{c} \text{Yes} \\ 1 \end{array} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

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

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$ $\begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

liters

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)

33. Baseline FEV₁:

Participant ID:

34. Is baseline FEV₁ (item 33) less than 1 liter:

 $\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

Warning: If "Yes," review predicted values (items 36 and 37) and/or consult physician before proceeding. An FEV₁ less than 1 liter may be within the normal range for younger children depending on their size and age.

36. Predicted FEV₁ (from Manual of Procedures or as calculated online at www.cctrials.org/alaacrc):

liters

- **37.** Baseline FEV₁ % Predicted (100* item 33 / item 36):
- **38.** Is baseline FEV₁ predicted (item 37) less than 70%:

 $\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$

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 FEV₁ 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 :	•	ers
41. Post-diluent FVC:	•	ers
42. Is Post-diluent FEV ₁ (ite or equal to 80% of the ba $(0.8 * item 33)$:	/	an
	(Yes 1)	(^{No} ₂)
If "Yes," STOP, procee	d to Section I	<i>.</i>

43. Target FEV₁ (0.8 * *item* 40):

This is the target FEV_1 for subsequent doses of *MeCl*.

liters

Participant ID:

<i>Items 44-59: Administer methacholine vials in order shown and then perform spirometry, according to protocol.</i>
Consult MOP for details on methacholine administration and spirometry.

	a. Vial	b. Dose (Concentration mg/mL)	c. FEV ₁ (<i>Liters</i>)	d. FVC (Liters)	e. Is column c less than or equal to item 43?
44.	J	0.03125	·	·	Yes No (1) $(2)\Box Go to Section I$
45.	Ι	0.0625	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
46.	Н	0.125	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
47.	G	0.25	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
48.	F	0.5	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
49.	Е	1.0	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
50.	D	2.0	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
51.	С	4.0	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
52.	В	8.0	·	·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I
53.	А	16.0	_·	_·	Yes No $\begin{pmatrix} 1 \end{pmatrix}$ $\begin{pmatrix} 2 \end{pmatrix}$ \downarrow Go to Section I

54. Is vial A FEV₁ (item 53) less than 90% of baseline FEV₁ (0.9*item 33):

Yes No (1) (2)

Items 55-59 left blank intentionally.

I. Recovery

61. Post-BD

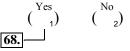
62. Post-BD

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

60. Time of bronchodilator administration:

	hour	minute
FEV ₁ :	•	
	lit	ers
FVC:	•	. <u></u>
	lit	ers

63. Is Post-BD FEV₁ (item 61) greater or equal to 90% of the baseline FEV₁ (0.9 * item 33):



liters

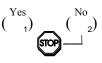
- Administer 2 additional puffs albuterol via MDI with spacer and wait 10 minutes per protocol

65. 2nd Post-BD FVC:

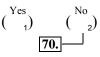
66. Is 2nd Post-BD FEV₁ (item 64) greater or equal to 90% of the baseline FEV₁ (0.9 * item 33):

Consult physician and proceed as directed.

67. Was physician consulted:



- If "No," STOP, consult physician.
- **68.** Did participant experience any complications of the methacholine challenge:

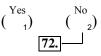


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69. Specify complications:

Participant ID:

70. Did participant's FEV₁ fall below the target FEV₁ following the administration of any concentration of methacholine (*ie, are any responses in column e, items 44-53, checked "Yes"*):



Calculate PC₂₀ for FEV₁ as directed in protocol or using calculator online at www.cctrials.org/alaacrc:

J. Administrative information

72. Date form reviewed:



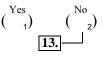
- 73. Clinic coordinator PIN:
- **74.** Clinic coordinator signature:

	Μ	lissed	Data		
Purpose: Record information about what study d	lata a	re mis	sing.		
	ipcor		ticipant and visit/contact procedures were missed (isit). Complete a separate Missed Data (MD) form		
Instructions: Key into SOYA data system at ww	w.cc	trials.c	org/alaacrc within 10 working days.		
A. Clinical center, participant and visit			g. CV (Clinic Visit Form):	(1.
identification			h. DC (Diary Card):	(1.
1. Clinical center ID:			i. DD (Tablet Dispensing and Counting):	(1.
Desting and ID:			j. EI (Exit Interview):	(1.
 2. Participant ID:			k. FQ (Asthma in Females Questionnaire):	(1.
5. Name code			I. MC (Methacholine Challenge Testing):	(1,
4. Date completed:			m. MO (Medical Outcomes Study):	(1,
			n. MQ (Marks Asthma Quality of Life Questionnaire):	(, 1.
day mon	year		o. NO (Nitric Oxide Form):	(1.
5. Visit ID:			p. PC (Phone Contact):	(1.
C Former complete datas			q. PE (Physical Exam):	(1,
6. Form version date:			r. PF (Pulmonary Function Testing):	(1.
$\underbrace{0}_{\text{day}} \underbrace{9}_{\text{mon}} \underbrace{P}_{\text{mon}} \underbrace{R}_{-1}$	(year)	s. PI (Participant Information):	(1,
7. Was visit or phone contact missed	-		t. PQ (Children's Health Survey for Asthma - Child Version):	(1.
completely: $\binom{\text{Yes}}{1}$	(^N	° ₂)	u. SQ (Home Smoking Activity and Exposure to Tobacco Smoke):	(, 1,
B. Missed visit information			v. TA (Asthma Control Test, 12+):	(1.
			w. TT (Treatment Termination):	(1.
8. Forms/questionnaires missed (check all that apply)			x. UM (Unmasking):	(1.
a. AS (Asthma Symptom Utility Index):	(1)	y. Other (<i>specify</i>):	(1,
b. BA (Baseline Asthma and Medical History):	(1)	form/questionnaire		
c. BF (Block 2005 Food Frequency Questionnaire):	(1)	z. N/A, none missed:	(1.
d. BK (Block 2004 Kids Food Frequency Questionnaire):	(1)	9. Are diary cards missing:	(^N	No (
e. BS (Block Soy Foods Screener):	(1)	(₁) [13	۲.	2.
f. CH (Child Health Questionnaire):	(1)			
				,	•.1

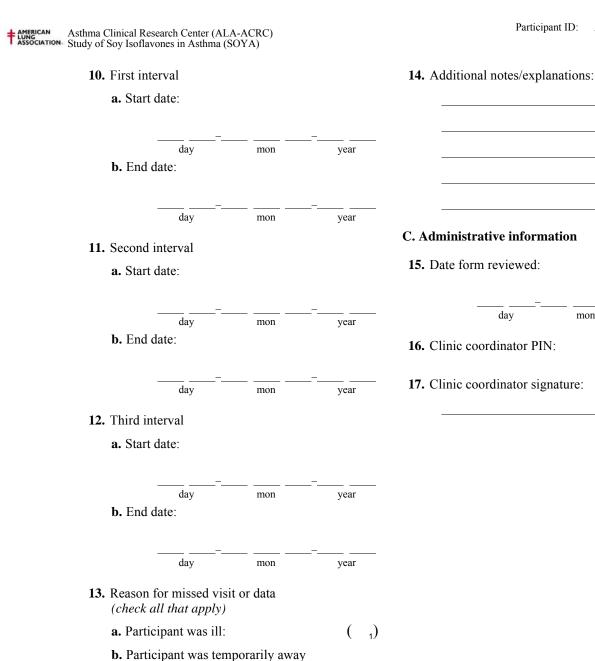
8,		
g. CV (Clinic Visit Form):	(1)
h. DC (Diary Card):	(1)
i. DD (Tablet Dispensing and Counting):	(1)
j. EI (Exit Interview):	(1)
k. FQ (Asthma in Females Questionnaire):	(1)
I. MC (Methacholine Challenge Testing):	(₁)
m. MO (Medical Outcomes Study):	(1)
n. MQ (Marks Asthma Quality of Life Questionnaire):	(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 (<i>specify</i>):	(1)

none	missed:	

- (₁)
- cards missing:



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:



17. Clinic coordinator signature:

day

year

mon

Participant ID:

d. Participant has permanently moved

e. Unable to contact participant:

from area:

from area:

c. Participant refused:

f. Participant forgot:

g. Other (specify):

1) 1)

1)

1)

1)

₁)

1)

(

Reference #:

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

year

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:

5. Visit ID:

6. Form version date:

day

mon

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 ړ) b. Did participant have a spirometry test before eNO testing: Yes ₁) No 2) Don't know c. Did participant have an EBC collection before eNO testing: Yes 1) 2) No Don't know ړ)

d. Did participant eat or drink anything for 1 hour before eNO testing:	
Yes	$\begin{pmatrix} & 1 \end{pmatrix}$
No	$\begin{pmatrix} & & \\ & & \\ & & 2 \end{pmatrix}$
Don't know	$\begin{pmatrix} 2 \\ -2 \end{pmatrix}$
e. Did participant do any strenuous exercise for 1 hour before eNO testing	g:
Yes	$\begin{pmatrix} & 1 \end{pmatrix}$
No	$\begin{pmatrix} 2 \end{pmatrix}$
Don't know	$\begin{pmatrix} & 2 \\ & 3 \end{pmatrix}$
f. Did participant use a bronchodilator for 2 hours before eNO testing:	
Yes	(₁)
No	$\begin{pmatrix} & \\ & 2 \end{pmatrix}$
Don't know	$\begin{pmatrix} & & \\ & & \\ & & \end{pmatrix}$
 8. Current acute upper and/or lower respiratory tract viral infection: Yes No Don't know 9. Oral/inhaled corticosteroid use Did participant usp cont/inhaled 	$\begin{pmatrix} & & \\ & & 1 \end{pmatrix}$ $\begin{pmatrix} & & & \\ & & & 2 \end{pmatrix}$ $\begin{pmatrix} & & & \\ & & & & \\ & & & & & \end{pmatrix}$
L	
b. Time most recently used:	
: ()	$\begin{pmatrix} 2 \end{pmatrix}$
hour minute am	pm
10. Participating in eNO Comparison Substudy:	$(^{No})$
(1)	(2)

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) (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*):

15. Participant eNO test results for the NIOX MINO A

a. Test one:

ppb

ppb

ppb

22

Fail

Fail

₂)

b. Test two:

Comparison Substudy.

17. Result of daily quality control test for

NIOX MINO device B

NIOX MINO B:

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

Skip to item 22 if not participating in eNO

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

$$\frac{1}{1} \frac{1}{1} \frac{1}$$

20. Participant eNO test results for the NIOX MINO B

a. Test one:

b. Test two:

ppb ppb

ppb

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

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

D. Administrative information

23. Date form reviewed:



- 24. Clinic coordinator PIN:
- **25.** Clinic coordinator signature:
- **18.** Date participant eNO tested (*read off the NIOX MINO B device*):

day mon year

Pass

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.

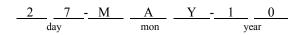
A. Clinical center, participant, and visit identification

- 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: <u>V</u> 3
- 6. Form version date:



B. Study Treatment

7. How are you doing with the study tablets:

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

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

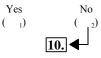
name side effec	ets	-
d. Lost bottle:	(1))
e. Too busy:	(1))
f. Other (<i>specify</i>):	(1))

	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 No (_1) (_2)
- **b**. If "Yes," specify:

- 8. Missed study tablets
 - **a**. Since Visit 2, have there been any missed doses of study tablet:



b. How many doses:

doses

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*):



AMERICAN LUNG ASSOCIATION Asthma Clinical Research Centers (ALA-ACRC) Study of Soy Isoflavones in Asthma (SOYA)

14.

- **12.** How many times since beginning study tablets were rescue medication used other than to prevent symptoms (2 puff of MDI=1 use):
- # times13. How many times were you awakened by asthma symptoms since beginning study tablets:

W 7	are there significant events since besig	nina	
	ere there significant events since begin dy tablets (<i>check all that apply</i>)	uning	
a.	Hospitalization or urgent care visit		
	for asthma:	(1
b.	Used oral corticosteroids:	(1
	Other (<i>specify</i>):	(1
C.			

d. N/A, no significant events occurred: $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$

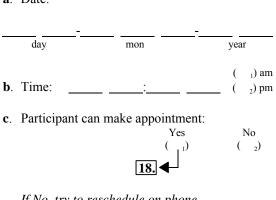
D. Study procedures

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

Answered questions about filling out		
diary cards:	(1)
Checked number of diary cards returned		
to clinical center:	(1)
Reviewed quality of diary cards returned		17
1 5 5	(.)
Encouraged participant to complete and	(D
bring diary cards to next visit:	(1)
Discussed problems, impediments to		17
1 / 1		
	()
them to the chinear center (specify).	C	1)
	diary cards: Checked number of diary cards returned to clinical center: Reviewed quality of diary cards returned to clinical center: Encouraged participant to complete and	diary cards: (Checked number of diary cards returned to clinical center: (Reviewed quality of diary cards returned to clinical center: (Encouraged participant to complete and bring diary cards to next visit: (Discussed problems, impediments to completing the diary cards and returning

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

- **16.** Visit 4 appointment
 - **a**. Date:



Participant ID:

- 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 coordinat	tor PIN:	
21.	Clinic coordinat	tor signature:	

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

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

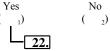
relationship to participant

1)

Physical Exam

 Purpose: To assess information about a participant's healt When: Screening (V1) and Visit 9 (V9). Instructions: Completed by certified study physician or de Note abnormalities and briefly describe; use extra shee www.cctrials.org/alaacrc within 10 working days. 	signee. Items in Section B mark			ndatory.
A. Clinical center, participant, and visit identification	B. Physical exam			
1. Clinical center ID:	*7. Blood Pressure			
2. Participant ID:	a. Systolic:			mmHg
3. Name code:	b. Diastolic:			-
4. Date completed:				mmHg
day mon year	*8. Heart Rate:	C ⁰F		beats/min
5. Visit ID:	*9. Temperature: ((1) (1) (1)		•
6. Form version date:	*10. Respiration Rate:			breaths/min
$ \underbrace{1}_{\text{day}} \underbrace{0}_{\text{-}} \underbrace{M}_{\text{mon}} \underbrace{A}_{\text{mon}} \underbrace{Y}_{\text{-}} \underbrace{1}_{\text{year}} \underbrace{0}_{\text{year}} $				
* 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	Not Examined (3)
19. Other (<i>specify</i>):		Normal $\begin{pmatrix} 1 \end{pmatrix}$	Abnormal $\begin{pmatrix} 2 \end{pmatrix}$	Not Examined $\begin{pmatrix} & & \\ & & \\ & & \end{pmatrix}$

20. Is examiner a SOYA certified study physician:



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:



- 24. Clinic Coordinator PIN:
- **25.** Clinic Coordinator signature:

Purpose: To record results of pulmonary function tests. When: Visits 1, 2, 4-9.			
Instructions: Test must be performed with a KoKo spiror als.org/alaacrc within 10 working days.	neter. Key into SOYA data system at w	ww.cctri-	
A. Clinical center, participant and visit identification	10. Did participant take any of the medications before visit	-	
1. Clinical center ID:	a. Short-acting bronchodilator within last 4 hours:	/ \ /	。 2)
2. Participant ID:	b. Long-acting bronchodilator within last 12 hours:		2) 2)
 3. Name code: 4. Date completed: 	11. Mini-Wright peak flow measur <i>(highest of 3 at clinic):</i>		-
day mon year		Liters/min	
5. Visit ID: (Indicate "N" as visit ID if testing is not associated with a particular visit)	C. Pre-bronchodilator data Note: Items 14, 15, 18 and 19 using the online calculator.) can be calculate	ed
6. Form version date:	12. Pre-bronchodilator FVC:	• Liters	
<u> </u>	13. Pre-bronchodilator FEV ₁ :	Liters	
B. General PFT data7. Height (measured; enter only a or b)	14. Predicted FEV ₁ (from Manual calculated online at www.cctr		
a. In inches:		Liters	
b. In centimeters:	15. Percent predicted pre-bronchoor FEV ₁ :	dilator	
8. Weight (measured; enter only a or b)		%	
a. In pounds:	Calculation: (100 x pre-B FEV1; ie, 100 x item 13/item 1		ed
b. In kilograms:kg			
9. Choose one dominant race category as identified by participant (<i>used to calculate predicted values</i>):			
White (1)			
Black (2)			
Latino (₂)			

_ ___ __ __

D. Post-bronchodilator data

E. Reversibility data

18. Percent predicted post-bronchodilator FEV₁:

%

Calculation: (100 x post-BD FEV₁/predicted FEV₁); ie, (100 x item 17/item 14)

19. Percent reversibility:

%

Calculation: [(post-BD FEV1 - pre-BD FEV1)/pre-BD FEV1] 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:

Reference #:

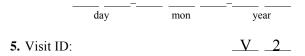
Randomization Form

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:



6. Form version date:

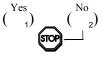


B. Inclusion criteria

7. Age 12 or older:



8. Physician diagnosed asthma:



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



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



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):



12. Percent predicted pre-bronchodilator FEV₁ greater than or equal to 50%:



- **13.** Bronchodilator reversibility
 - **a.** Participant demonstrated 12% or greater reversibility within the last 2 years:



b. Date reversibility demonstrated:

day mon year

- **14.** Methacholine PC₂₀
 - **a.** Participant demonstrated PC₂₀ less than 16 mg/mL within the last 2 years:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

b. Date PC₂₀ FEV₁ demonstrated:



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:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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

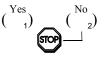
$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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:



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

$$\binom{\text{No}}{1}$$
 $\binom{\text{No}}{2}$

Y

Yes

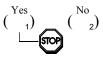
C. Exclusion criteria

21. Medication use

No

2)

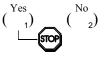
- a. Oral corticosteroid use within past 6 weeks:
- **b.** Current or previous use of tamoxifen:
- c. Use of any investigational treatments in previous 30 days: $\begin{pmatrix} 1 \\ 1 \end{pmatrix}$ $\begin{pmatrix} 2 \\ 2 \end{pmatrix}$
- **22.** Intake of soy, soy supplements or soy enriched foods four or more times within past 30 days:



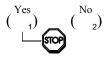
23. Previous adverse effects from genistein, other phytoestrogens or soy products:



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



25. Active thyroid disease:



26. History of endometrial, breast or ovarian cancer:



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)

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

Yes

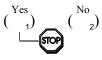
No



Not applicable

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:



30. Upper respiratory infection within past 2 weeks:



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

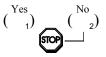
32. Change in diet over the past month or expected change in diet (eg, will initiate weight loss diet) during the study:



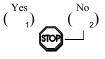
33. Able to swallow study tablets:



34. Accessible by telephone:



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



D. Procedures

36. Were the following baseline procedures completed or checked

-	Ŋ	les	N	ю
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)

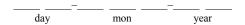
E. Peak flow from diary cards	42. Study physician		
38. Peak flow from diary cards for last 14	a. Study physician PIN:		
days of run-in period (participant must complete diary cards on at least 10 of last 14 days to be eligible)	b. Study physician signature (<i>do not key</i>):		
a. Day 1:	c. Date signed:		
b. Day 2:			
c. Day 3:	day mon year		
d. Day 4:	Note: • Print copy of treatment assignment from data system and attach to this		
e. Day 5:	form. • Affix tear-off portion of tablet bottle		
f. Day 6:	label on DD form item 12a.		
g. Day 7:	— H. Randomization data (generated by DCC		
h. Day 8:	data system)		
i. Day 9:	43. Asthma action plan values (<i>use values calculated by data system</i>)		
j. Day 10:	a. Personal best peak flow:		
k. Day 11:	b. Red zone: below		
l. Day 12:	c. Yellow zone:		
m. Day 13:	to [
n. Day 14:	d. Green zone: above		
F. Final check	Copy values to Asthma Action Plan card.		
39. Participant meets all eligibility criteria for randomization:	44. Kit ID (assigned by data system):		
$\binom{\text{Yes}}{1}$	Io 		
STOP	· L		

Participant ID:

_ ___ __ __

G. Administrative information

40. Date form reviewed:

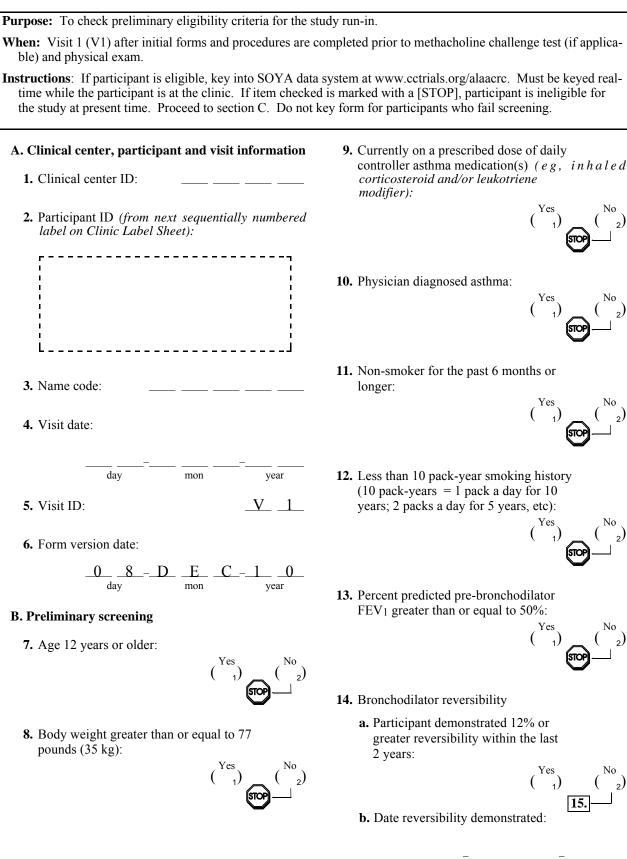


- 41. Clinic coordinator
 - a. Clinic coordinator PIN:
 - **b.** Clinic coordinator signature (*do not key*):

Screening Form

Reference #:

SOYA



year

mon

day

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

b. Date PC₂₀ FEV₁ demonstrated:



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:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

(

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

$$\binom{\text{No}}{1}$$
 $\binom{\text{No}}{2}$

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

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

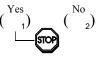
One of the above items 17-20 must be checked "Yes." If all items 16-20 are checked "No," then **STOP**; participant is ineligible for the study at this time. Proceed to section C.

21. Current or previous use of tamoxifen:

Participant ID:



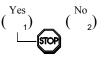
22. Previous adverse effects from genistein, other phytoestrogens, or soy products:



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



24. Active thyroid disease:



25. History of endometrial, breast or ovarian cancer:



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



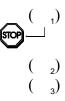
Not applicable

Not applicable

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

Yes

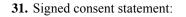
No



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



- **29.** Accessible by telephone:
- **30.** Intention to stay in the area for at least the next 6 months: (Yes (_____1)



32. Oral corticosteroid use within past 6 weeks:

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

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

(Yes (^{No}₂)

37. Unable to swallow study tablets:

$$\begin{pmatrix} \text{Yes} & \text{No} \\ 1 & 2 \end{pmatrix}$$

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

	У	les	N	ю
a. Non-skin cancer:	(1)	(2)
b. Endocrine disease including insulin-dependent diabetes	g	,	,	,
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:

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

 $\begin{pmatrix} \text{Yes} & \text{No} \\ 1 & \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

(

 $\binom{\text{Yes}}{1}$

(Yes

 $\binom{\text{Yes}}{1}$

 $\binom{\text{Yes}}{1}$

 $\begin{pmatrix} & & \\ & & 2 \end{pmatrix}$

(^{No}₂)

(No)

(^{No}₂)

(_____2)

Yes

C. Administrative information

40. Date form reviewed:

day mon year

_ _

- -

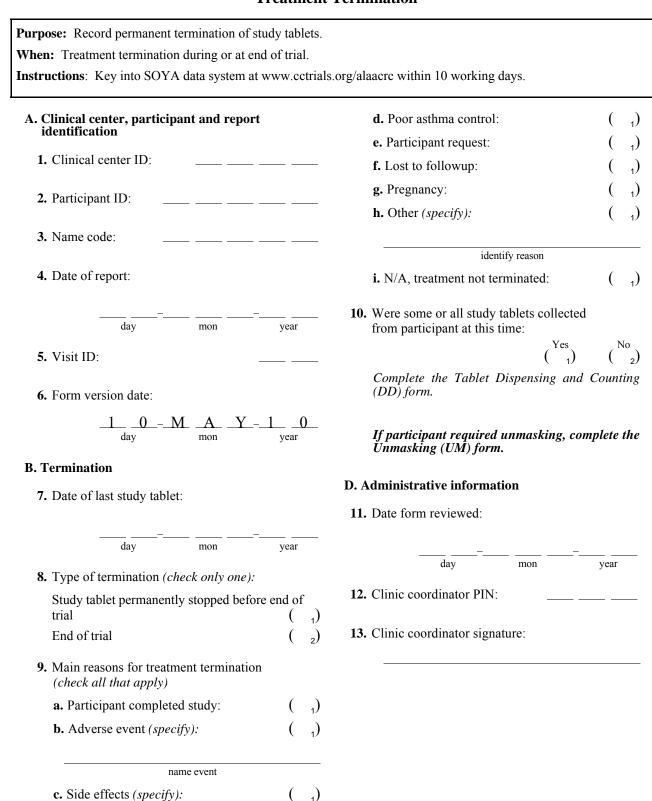
41. Clinic coordinator PIN: _____

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

Reference #:



SOYA

Reference #:

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 11. Treatment assignment revealed from identification (check only one): Standard unmasking envelope (_) 1. Clinical center ID: Tracking number on treatment unmasking 2. Participant ID: envelope: **3.** Name code: Web emergency unmasking site 2) (DCC 3) 4. Date of report: Other (specify) day mon year identify method 5. Visit ID: 12. Were any SOYA staff unmasked: Yes 6. Form version date: -M A Y - 1 0___0_ dav **13.** SOYA staff member(s) unmasked (*specify*): **B.** Unmasking 7. Randomization kit ID: Y _ 14. Was treatment terminated: 8. Date unmasked: If "Yes," fill out Treatment Termination (TT) form. If "No," explain reason(s) participant remains on day mon vear treatment. 9. Type of unmasking (check only one): Unscheduled unmasking (before Visit 9) (_) Scheduled unmasking at end of trial (at Visit 9) C. Administrative information 10. Reason for unscheduled unmasking 15. Date form reviewed: day mon year **16.** Clinic coordinator PIN: **17.** Clinic coordinator signature: