



LEEP

Losartan Effects on Emphysema Progression
American Lung Association Airways Clinical Research Centers (ALA-ACRC)
Pulmonary Trials Cooperative – NIH-NHLBI

Reference #:	_____
a) Site ID:	____ _
b) Participant ID:	<u> L </u> ____ _
c) Alpha ID code:	____ _
d) Date:	____ _ - ____ _ - ____ _ day month year
e) Visit ID:	<u> V </u> <u> 1 </u>
f) Form version date:	<u> 2 </u> <u> 3 </u> <u> J </u> <u> A </u> <u> N </u> <u> 2 </u> <u> 0 </u> <u> 1 </u> <u> 7 </u> day month year

ATS-DLD

RESPIRATORY QUESTIONNAIRE

When: V1.

Instructions: Coordinator should administer questionnaire to participant. Use the exact wording of each question. If the participant expresses doubt as to the meaning of the question, repeat it exactly. Emphasizing individual words or phrases often makes the meaning clear. Further explanation may be needed, but do not cross-examine the respondent. When after brief explanation doubt remains as to whether the answer should be “Yes” or “No”, the answer should be recorded as “No”. Key into LEEP data system at www.LEEPTrial.org within 10 working days.

ATS-DLD Respiratory Questionnaire**B. Cough**

Coordinator should say to participant: “These questions pertain mainly to your chest. Please answer ‘Yes’ or ‘No’ if possible. If a question does not appear to be applicable to you, you should say ‘does not apply.’ If you are in doubt as to whether your answer is ‘Yes’ or ‘No,’ say ‘No.’”

1. Do you usually have a cough (count a cough with first smoke or on first going out-of-doors; exclude clearing of throat):

Yes (1) No (2)
3. ←

2. Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week:

Yes (1) No (2)

3. Do you usually cough at all on getting up, or first thing in the morning:

Yes (1) No (2)

4. Do you usually cough at all during the rest of the day or at night:

Yes (1) No (2)

If “Yes” to any of items 1-4, complete items 5 and 6; if “No,” check “Does not apply” in item 5 and skip to item 7.

5. Do you usually cough like this on most days for 3 consecutive months or more during the year:

Yes (1)
 No (2)
 Does not apply (3)
7. ←

6. For how many years have you had this cough:

 # years

C. Phlegm

7. Do you usually bring up phlegm from your chest (count phlegm with the first smoke or on first going out-of-doors; exclude phlegm from the nose; count swallowed phlegm):

Yes (1) No (2)
9. ←

8. Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week:

Yes (1) No (2)

9. Do you usually bring up phlegm at all on getting up or first thing in the morning:

Yes (1) No (2)

10. Do you usually bring up phlegm at all during the rest of the day or at night:

Yes (1) No (2)

If “Yes” to any of items 7-10, complete items 11 and 12; if “No,” check “Does not apply” in item 11 and skip to item 13.

11. Do you bring up phlegm like this on most days for 3 consecutive months or more during the year:

Yes (1)
 No (2)
 Does not apply (3)
13. ←

12. For how many years have you had trouble with phlegm:

 # years

D. Episodes of cough and phlegm

- 13.** Have you had periods or episodes of (increased*) cough and phlegm lasting for 3 weeks or more each year:

**For individuals who usually have cough and/or phlegm.*

Yes No
(1) (2)

15. ◀

- 14.** For how long have you had at least 1 such episode per year:

years

E. Wheezing

15. Does your chest ever sound wheezy or whistling

- a.** When you have a cold:

Yes () No ()

- b.** Occasionally apart from colds:

Yes (1) No (2)

- c. Most days or nights:**

Yes No
(1) (2)

If “No” to all items 15a-c, skip to item 17.

- 16.** For how many years has this been present:

years

- 17. Have you ever had an ATTACK of wheezing that has made you feel short of breath:**

Yes ()
No ()

21. ◀

- 18.** How old were you when you had your first such attack:

age in years

- 19.** Have you had 2 or more such episodes:

Yes No
(1) (2)

- 20.** Have you ever required medicine or treatment for the(se) attack(s):

Yes No
(1) (2)

F. Breathlessness

- 21. Disabled from walking**

- a.** Are you disabled from walking by any condition other than heart or lung disease:

Yes No
(1) (2)

If "Yes," please specify below and skip to item 23:

nature of condition(s)

22. Dyspnea scale (check only one):

I only get breathless with strenuous exercise (*Grade 0*) (0)

I get short of breath when hurrying on the level or walking up a slight hill (*Grade 1*) (1)

I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level (*Grade 2*) (2)

I stop for breath after walking about 100 yards or after a few minutes on the level (*Grade 3*) (3)

I am too breathless to leave the house or I am breathless when dressing (*Grade 4*) (4)

G. Chest colds and chest illness

23. If you get a cold, does it usually go to your chest (*usually means more than ½ the time*):

Yes (1)
No (2)
Don't get colds (3)

24. During the past 3 years, have you had any chest illnesses that have kept you off work, indoors at home, or in bed:

Yes (1) No (2)
27. ←

25. Did you produce phlegm with any of these chest illnesses:

Yes (1) No (2)

26. In the last 3 years, how many such illnesses, with (increased) phlegm, did you have which lasted a week or more:

illnesses

H. Past illnesses

27. Did you have any lung trouble before the age of 16:

Yes (1) No (2)

28. Attacks of bronchitis

a. Have you ever had attacks of bronchitis:

Yes (1) No (2)

29. ←

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age was your first attack:

age in years

29. Pneumonia (*include bronchopneumonia*)

a. Have you ever had pneumonia:

Yes (1) No (2)

30. ←

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age did you first have it:

age in years

30. Hayfever

a. Have you ever had hayfever:

Yes (1) No (2)

31. ←

b. Was it confirmed by a doctor:

Yes (1) No (2)

c. At what age did it start:

age in years

31. Chronic bronchitis

- a.**
- Have you ever had chronic bronchitis:

Yes	No
(1)	(2)

32. ←

- b.**
- Do you still have it:

Yes	No
(1)	(2)

- c.**
- Was it confirmed by a doctor:

Yes	No
(1)	(2)

- d.**
- At what age did it start:
-
-
-
- age in years

32. Emphysema

- a.**
- Have you ever had emphysema:

Yes	No
(1)	(2)

33. ←

- b.**
- Do you still have it:

Yes	No
(1)	(2)

- c.**
- Was it confirmed by a doctor:

Yes	No
(1)	(2)

- d.**
- At what age did it start:
-
-
-
- age in years

33. Asthma

- a.**
- Have you ever had asthma:

Yes	No
(1)	(2)

34. ←

- b.**
- Do you still have it:

Yes	No
(1)	(2)

- c.**
- Was it confirmed by a doctor:

Yes	No
(1)	(2)

- d.**
- At what age did it start:
-
-
-
- age in years

- e.**
- If you no longer have it, at what age did it stop:

age in years**34. Have you ever had**

- a.**
- Any other chest illness:

Yes	No
(1)	(2)

*If "Yes", please specify:*_____

- b.**
- Any chest operations:

Yes	No
(1)	(2)

*If "Yes", please specify:*_____

- c.**
- Any chest injuries:

Yes	No
(1)	(2)

*If "Yes", please specify:*_____

35. Has a doctor ever told you that you had heart trouble:

Yes (1) No (2)

37. ←

36. Have you ever had treatment for heart trouble in the past 10 years:

Yes (1) No (2)

37. Has a doctor ever told you that you have high blood pressure:

Yes (1) No (2)

39. ←

38. Have you had any treatment for high blood pressure (hypertension) in the past 10 years:

Yes (1) No (2)

I. Occupational history

39. Have you ever worked full time (30 hours per week or more) for 6 months or more:

Yes (1) No (2)

49. ←

40. Have you ever worked for a year or more in any dusty job:

Yes (1) No (2)

44. ←

41. Specify job/industry:

_____ job/industry

42. Total years worked:

_____ # years

43. Was dust exposure:

Mild (1)
Moderate (2)
Severe (3)

44. Have you ever been exposed to gas or chemical fumes in your work

Yes (1) No (2)

48. ←

45. Specify job/industry:

_____ job/industry

46. Total years worked:

_____ # years

47. Was fume exposure:

Mild (1)
Moderate (2)
Severe (3)

48. What has been your usual occupation or job (the one you have worked the longest)

- a. Specify job/occupation:

_____ job/occupation

- b. Number of years employed in this occupation:

_____ # years

- c. Position/job title:

_____ position/job title

- d. Business, field or industry:

_____ business/field/industry

J. Tobacco smoking

49. Have you ever smoked cigarettes ("No" means less than 20 packs of cigarettes or 12 oz of tobacco in a lifetime or less than 1 cigarette a day for a year):

Yes (1) No (2)

57. ←

50. Do you now smoke cigarettes (as of 1 month ago):

Yes (1) No (2)

51. How old were you when you first started regular cigarette smoking:

age in years

52. If you have stopped smoking cigarettes completely, how old were you when you stopped (*if not leave blank*):

age in years

53. How many cigarettes do you smoke per day now:

cigarettes/day

54. On the average of the entire time you smoked, how many cigarettes did you smoke per day:

cigarettes/day

55. For how many years in total did you regularly smoke cigarettes:

years

56. Do or did you inhale the cigarette smoke (*check only one*):

Not at all (1)
Slightly (2)
Moderately (3)
Deeply (4)

57. Have you ever smoked a pipe regularly (*"Yes" means more than 12 oz tobacco in a lifetime*):

Yes (1) No (2)

63. ←

58. How old were you when you started to smoke a pipe regularly:

age in years

59. If you have stopped smoking a pipe completely, how old were you when you stopped (*if not leave blank*):

age in years

60. On the average of the entire time you smoked a pipe, how much pipe tobacco did you smoke per week (*a standard pouch of tobacco = 1 ½ oz*):

oz per week

61. How much pipe tobacco are you smoking per week now:

oz per week

62. Do or did you inhale the pipe smoke:

Not at all (1)
Slightly (2)
Moderately (3)
Deeply (4)

63. Have you ever smoked cigars regularly (*"Yes" means more than 1 cigar a week for a year*):

Yes (1) No (2)

69. ←

64. How old were you when you started smoking cigars regularly:

age in years

65. If you have stopped smoking cigars completely, how old were you when you stopped (*if not leave blank*):

age in years

66. On the average over the entire time you smoked cigars, how many cigars did you smoke per week:

cigars/week

67. How many cigars are you smoking per week now:

cigars/week

68. Do or did you inhale the cigar smoke:

Not at all (1)
Slightly (2)
Moderately (3)
Deeply (4)

E-cigarette smoking history

69. Have you ever used an electronic cigarette or e-cigarette:

Yes (1) No (2)

74. ←

70. When did you start using e-cigarettes (month/year):

____ month ____ - ____ year ____

71. Currently, how often are you using e-cigarettes:

Every day (1)
Some days (2)
Not at all (3)

73. ←

72. Does the e-cigarette you use contain nicotine:

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

73. When did you last use an e-cigarette (month/year):

____ month ____ - ____ year ____

K. Family history

74. Was your **father** ever told by a doctor that he had a chronic lung condition such as

- a. Chronic bronchitis:

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

- b. Emphysema:

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

- c. Asthma:

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

- d. Lung cancer:

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

- e. Other chest condition:

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

75. Is your **father** currently alive:

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

78. ←

76. Please specify age if living or age at death (enter only a or b):

- a. Age if living:

____ age in years

- b. Age at death:

____ age in years

77. Please specify cause of death (if living, leave blank):

____ cause of death

L. Administration information (for clinical use only)

82. Form completed by PIN:

83. Signature (do not key):

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

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

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

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

a. Age if living: _____
age in years

b. Age at death: _____ age in years

cause of death



Biospecimen Collection Form

Purpose: To document information about specimen collection of packed cells, plasma, serum and urine for storage.

When: V2, V5, and V7.

Instructions: In section B, indicate "Yes" if specimens were stored OR indicate "No" if specimens were not stored. If "Yes" is indicated, apply matching barcodes for all stored aliquots. Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant, and visit identification

1. Site ID: **Clinic**
2. Participant ID: L **ID**
3. Alpha ID code: **NameCode**
4. Date form completed: **VisitDate**
 day - month - year
5. Visit ID: **VisitID**
(If not associated with a particular study visit, record as "N")
6. Form version date: **BC106**
 0 day - 7 month - J year

B. Specimen collection for storage (collected at V2, V5, and V7)

- BC107** 7. Did participant consent to banking specimens for future research:

Yes (1) No (2)


If participant did not consent to banking specimens, this form is not required.

8. Plasma

- a. Was plasma stored:

Yes (1) No (2)

9

BC108a

- b. Aliquot 1 stored:

BC108b

Plasma Aliquot 1
barcode here **BC108bs**

- c. Aliquot 2 stored:

BC108c

Plasma Aliquot 2
barcode here **BC108cs**

- d. Aliquot 3 stored:

BC108d

Plasma Aliquot 3
barcode here **BC108ds**

- e. Aliquot 4 stored:

BC108e

Plasma Aliquot 4
barcode here **BC108es**

9. Serum

BC109a

a. Was serum stored:

Yes No
(1) (2)

10

BC109b

b. Aliquot 1 stored:

Serum Aliquot 1
barcode here BC109bs

BC109c

c. Aliquot 2 stored:

Serum Aliquot 2
barcode here BC109cs

BC109d

d. Aliquot 3 stored:

Serum Aliquot 3
barcode here BC109ds

BC109e

e. Aliquot 4 stored:

Serum Aliquot 4
barcode here BC109es

10. Urine

a. Was urine stored:

Yes No
(1) (2)

11

BC110a

b. Aliquot 1 stored:

BC110b

Urine Aliquot 1
barcode here BC110bs

c. Aliquot 2 stored:

BC110c

Urine Aliquot 2
barcode here BC110cs

d. Aliquot 3 stored:

BC110d

Urine Aliquot 3
barcode here BC110ds

e. Aliquot 4 stored:

BC110e

Urine Aliquot 4
barcode here BC110es

f. Aliquot 5 stored:

BC110f

Urine Aliquot 5
barcode here BC110fs

g. Aliquot 6 stored:

BC110g

Urine Aliquot 6
barcode here BC110gs

BC110h h. Aliquot 7 stored:

Urine Aliquot 7
barcode here **BC110hs**

BC110i i. Aliquot 8 stored:

Urine Aliquot 8
barcode here **BC110is**

BC110j j. Aliquot 9 stored:

Urine Aliquot 9
barcode here **BC110js**

BC110k k. Aliquot 10 stored:

Urine Aliquot 10
barcode here **BC110ks**

11. Packed cells for DNA (*collected at V2*):

BC111a a. Did participant consent to DNA collection
(*check “No” if DNA has already been collected*):

Yes No
 (1) (2)

12

BC111b b. Vacutainer #1 stored:

Packed Cells barcode here
BC111bs

BC111c c. *If Needed*: Vacutainer #2 stored:

Spare barcode here
BC111cs

C. Administrative information

12. Form completed by PIN:

BC112

13. Signature (*do not key*):

BC113

**LEEP**

Losartan Effects on Emphysema Progression (LEEP)
 American Lung Association Airways Clinical Research Centers (ALA-ACRC)
 Pulmonary Trials Cooperative -- NIH-NHLBI

Reference #: _____

Baseline History Form

Purpose: To document general health status and demographics.

When: To be completed at V1.

Instructions: Form is to be completed by certified LEEP coordinator, if response is marked  then the participant is ineligible. Stop and complete Screening Form (SC). For all eligible participants key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant, and visit identification1. Site ID: Clinic2. Participant ID: L ID3. Alpha ID code: NameCode

4. Date baseline history collected: **VisitDate**
 _____ day _____ month _____ year

5. Visit ID: **VisitID** V 1

6. Form version date: **BH106**
2 3 - J A N - 2 0 1 7
 day month year

B. Demographic information**BH107** 7. Sex (*check only one*):

Male (1)

Female (2)

BH108 8. Hispanic ethnicity:

Yes No
 (1) (2)

9. Race (*check all that apply*)**BH109_a** a. American Indian/Alaska Native: (1)**BH109_b** b. Asian: (1)**BH109_c** c. Native Hawaiian or other Pacific Islander: (1)**BH109_d** d. Black or African American (1)**BH109_e** e. Caucasian: (1)**BH109_f** f. Other (*specify*): (1)**BH109_fs***race*10. If multiple races are indicated, please check what is considered to be the primary race (*check only one*):

American Indian/Alaska Native (1)

Asian (2)

Native Hawaiian or other Pacific Islander (3)

Black or African American (4)

Caucasian (5)

Other (*specify*) (6)**BH110s***race*11. Age: _____ years **BH111**

12. Date of birth: _____ day _____ month _____ year **BH112**

C. COPD

13. How old were you when you were diagnosed with COPD:

_____ age **BH113**

14. Have you had any flare-up of your COPD (emphysema or chronic bronchitis) that have required treatment (*such as antibiotics, corticosteroids*) in the past six weeks:

Yes No
 (1) (2)



BH115 15. In the past 12 months, how many times have you had flare-ups of your COPD (emphysema or chronic bronchitis) that has required treatment (*such as antibiotics, corticosteroids; check only one*):

Three or more (1)

One or two (2)

None (3)

BH116 16. In the past 12 months, have you been hospitalized for COPD (*admitted for inpatient stay of 24 hours or more*):

Yes No
(1) (2)

BH117 17. Are you currently in a pulmonary rehabilitation program:

Yes No
(1) (2)

BH118 18. Do you currently use supplemental oxygen:

Yes No
(1) (2)

20

19. Do you currently use oxygen

BH119a a. At rest:

Yes No
(1) (2)

19c

BH119b b. At what flow rate:

____ • ____
L/min

BH119c c. During sleep:

Yes No
(1) (2)

19e

BH119d d. At what flow rate:

____ • ____
L/min

BH119e e. With exertion:

Yes No
(1) (2)

20

BH119f f. At what flow rate:

____ • ____
L/min

20. Which of the following medications are you currently taking for COPD (*check all that apply*)

a. Short-acting beta-agonist (SABA) (e.g., Albuterol, Proventil®, Ventolin®, Xopenex®): (1) **BH120_a**

b. Short-acting muscarinic antagonist (SAMA) (e.g., Ipratropium): (1) **BH120_b**

c. Combination SABA/SAMA (e.g., Combivent®, DuoNeb®): (1) **BH120_c**

d. Long-acting beta-agonist (LABA) (e.g., Salmeterol, Formoterol, Arformoterol): (1) **BH120_d**

e. Long-acting muscarinic antagonist (LAMA) (e.g., Tiotropium, Acridinium, Umeclidinium): (1) **BH120_e**

f. Combination LABA/LAMA (e.g., Anoro Ellipta®, Stiolto Respimat®, Utibron®): (1) **BH120_f**

g. Inhaled corticosteroids (ICS) (e.g., Fluticasone, Budesonide, Flunisolide, Mometasone): (1) **BH120_g**

h. Combination LABA/ICS (e.g., Advair®, Symbicort®, Dulera®, Breo Ellipta®): (1) **BH120_h**

i. Methylxanthines (e.g., Theophylline): (1) **BH120_i**

j. Systemic corticosteroids (e.g., Prednisone, Methylprednisolone, Dexamethasone): (1) **BH120_j**

k. PDE inhibitor (e.g., Roflumilast): (1) **BH120_k**

l. Other (*specify*): (1) **BH120_l**

BH120_Is

specify

m. None: (1) **BH120_m**

D. General medical history**21.** Has a doctor ever told you that you have any of the following conditions

		Yes	No
BH121a	a. Anemia:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121b	b. Connective tissue diseases (<i>rheumatoid arthritis, lupus, polymyalgia, scleroderma</i>):	(<u> 1 </u>)	(<u> 2 </u>)
BH121c	c. Coronary heart disease (<i>MI, heart attack, angina</i>):	(<u> 1 </u>)	(<u> 2 </u>)
BH121d	d. Diabetes:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121e	e. GERD (<i>gastroesophageal reflux disease</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121f	f. Hayfever:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121g	g. Heart failure or congestive heart failure:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121h	h. High cholesterol:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121i	i. HIV or AIDS:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121j	j. High blood pressure, hypertension:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121k	k. Kidney disease:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121l	l. Liver disease (<i>hepatitis, liver failure, cirrhosis</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121m	m. Lung cancer:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121n	n. Lymphoma or leukemia:.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121o	o. Other cancer (<i>excluding non-basal cell carcinoma</i>):...	(<u> 1 </u>)	(<u> 2 </u>)
BH121p	p. Neurological disease (<i>multiple sclerosis, Parkinson's, epilepsy, Alzheimer's</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121q	q. Osteoarthritis:	(<u> 1 </u>)	(<u> 2 </u>)
BH121r	r. Osteoporosis:	(<u> 1 </u>)	(<u> 2 </u>)
BH121s	s. Peripheral vascular disease (<i>blood clot, pulmonary embolism, phlebitis</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121t	t. Psychiatric disease (<i>depression, anxiety, bipolar disorder, schizophrenia</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
BH121u	u. Stroke:	(<u> 1 </u>)	(<u> 2 </u>)
BH121v	v. Stomach ulcers:	(<u> 1 </u>)	(<u> 2 </u>)
BH121w	w. Sleep apnea:	(<u> 1 </u>)	(<u> 2 </u>)
BH121x	x. Other condition #1 (<i>specify</i>):.....	(<u> 1 </u>)	(<u> 2 </u>)
	BH121xs		
	condition		
BH121y	y. Other condition #2 (<i>specify</i>):	(<u> 1 </u>)	(<u> 2 </u>)
	BH121ys		
	condition		
BH121z	z. Other condition #3 (<i>specify</i>):	(<u> 1 </u>)	(<u> 2 </u>)
	BH121zs		
	condition		

- Severe:** Prevents activities or participant seeks medical care.

Baseline History Form
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- BH123** 23. Have you had a flu shot (for influenza) in the past 12 months:

Yes (1) No (2)

25

- BH124** 24. Date of most recent flu shot:

____ month ____ - ____ year ____

- BH125** 25. When did you last have a pneumonia vaccine (check only one):

In the past year (1)

1-5 years ago (2)

More than 5 years ago (3)

Never (4)

- BH126** 26. Do you take medication(s) for high blood pressure:

Yes (1) No (2)

28

If "Yes," specify:

BH126s _____

BH126t _____

27. Classify blood pressure medication(s) by category based on reference card (check all that apply)

- BH127_a** a. Angiotensin converting enzyme (ACE) inhibitor: (1)



- BH127_b** b. Angiotensin II receptor blocker (ARB): (1)



- BH127_c** c. Potassium sparing diuretic (e.g., Spirolactone, Amiloride Hydrochloride, Triamterene): (1)



- BH127_d** d. Does not contain a, b, or c: (1)

28. Do you take any of the following medications (check all that apply)

- a. Lithium: (1) **BH128_a**



- b. Potassium supplement: (1) **BH128_b**



- c. Neither a or b: (1) **BH128_c**

29. Do you take non-steroidal anti-inflammatory medications such as Ibuprofen (e.g., Advil, Motrin) or naproxen (e.g., Aleve, Naprosyn) on a daily or frequent basis (> 5 times per week for more than 1 month): **BH129**

Yes (1) No (2)

STOP

Note: Regular use of NSAIDs is a contraindication for Losartan, occasional use is acceptable.

E. Socioeconomic data

Provide cue cards to participant for items 30-35.

30. What is your current marital status (check only one) **BH130**

A - Single (1)

B - Married (2)

C - Divorced (3)

D - Widowed (4)

E - Domestic partner (5)

Declined to answer (6)

31. What best describes your yearly household income (including all members and sources; check only one): **BH131**

A - \$30,000 or less (1)

B - \$30,001 - 50,000 (2)

C - \$50,001 - 75,000 (3)

D - Over \$75,000 (4)

E - Unknown (5)

Declined to answer (6)

- BH132 32.** Educational attainment. Ask the participant:
“What is the highest level of education you have
COMPLETED?” (*check only one*):
- A - Some high school/less (1)
- B - High school graduate/GED (2)
- C - Vocational/some college (3)
- D - College degree (4)
- E - Professional or graduate degree (5)
- Declined to answer (6)

- BH133 33.** What is your source of health insurance
(*check only one*):
- A - Private insurance (e.g., Blue
Cross/Blue Shield or other insurance
purchased by you or your employer) (1)
- B - Public insurance (e.g., Medicaid,
Medicare, paid for by government) (2)
- C - No health insurance (3)
- D - Unknown (4)
- E - Other (*specify*) (5)

BH133s*source of insurance*

Declined to answer (6)

- BH134 34.** How do you pay for your prescription drugs (*check
only one*):
- A - Out of pocket (pay entire amount
with own money) (1)
- B - Co-pay (insurance pays some
and family pays the rest) (2)
- C - Pay nothing (insurance pays for all
cost of prescriptions) (3)
- D - Unknown (4)
- E - Other (*specify*) (5)

BH134s*prescription payment*

Declined to answer (6)

- 35.** Which of the following best describes your daily
work schedule (*check only one*): **BH135**
- A - Full-time employment (1)
- B - Part-time employment (2)
- C - Student (3)
- D - Household work (4)
- E - Disabled (5)
- F - Retired (6)
- G - Not working (7)
- H - Other (*specify*) (8)

BH135s*daily work schedule*

Declined to answer (9)

F. Administrative information

- 36.** Form completed by PIN: **BH136**
- _____

- 37.** Signature (*do not key*): **BH137**
- _____

Reminder: Participant's current medications to be
recorded on both:

- () Pulmonary Medications Log (CP)
- () Non-Pulmonary Medications Log (CM)



LEEP

Losartan Effects on Emphysema Progression
American Lung Association Airways Clinical Research Centers (ALA-ACRC)
Pulmonary Trials Cooperative – NIH-NHLBI

Reference #:	_____
a) Site ID:	_____ Clinic _____
b) Participant ID:	_____ L _____ ID _____
c) Alpha ID code:	_____ NameCode _____
d) Date:	_____ VisitDate _____ day month year
e) Visit ID:	_____ VisitID _____ _____ CA100f _____
f) Form version date:	_____ 0 _____ 8 _____ N _____ O _____ V _____ 2 _____ 0 _____ 1 _____ 6 _____ day month year

COPD ASSESSMENT TEST™ (CAT)

(12 years and older)

Purpose: To collect data to determine COPD score.

When: V1, V2, V4-V7.

Completed by: Participant with coordinator assistance if needed.

Instructions: Please answer all items. For each item, please select the response that best describes your answer by marking the appropriate box. Coordinator should verify total score, the sum of all eight questions. Key into LEEP data system within 10 working days.

Your name:

Leave Blank

Today's date:

Leave Blank



How is your COPD? Take the COPD Assessment Test™ (CAT™)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy

0 ☒ 1 2 3 4 5

I am very sad

SCORE

- | | | | | |
|----|---|-------------|--|-------|
| 1. | I never cough | 0 1 2 3 4 5 | I cough all the time | CA101 |
| 2. | I have no phlegm (mucus) in my chest at all | 0 1 2 3 4 5 | My chest is completely full of phlegm (mucus) | CA102 |
| 3. | My chest does not feel tight at all | 0 1 2 3 4 5 | My chest feels very tight | CA103 |
| 4. | When I walk up a hill or one flight of stairs I am not breathless | 0 1 2 3 4 5 | When I walk up a hill or one flight of stairs I am very breathless | CA104 |
| 5. | I am not limited doing any activities at home | 0 1 2 3 4 5 | I am very limited doing activities at home | CA105 |
| 6. | I am confident leaving my home despite my lung condition | 0 1 2 3 4 5 | I am not at all confident leaving my home because of my lung condition | CA106 |
| 7. | I sleep soundly | 0 1 2 3 4 5 | I don't sleep soundly because of my lung condition | CA107 |
| 8. | I have lots of energy | 0 1 2 3 4 5 | I have no energy at all | CA108 |

The COPD Assessment Test was developed by a multi-disciplinary group of international experts in COPD supported by GSK. GSK activities with respect to the COPD Assessment Test are overseen by a governance board that includes independent external experts, one of whom chairs the board.

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**TOTAL
SCORE**

CA109

To be completed by a member of clinical center staff:

CA110 | 10. Form completed by PIN: _____

CA111 | 11. Signature (*do not key*): _____

CA112	12.	Who administered the questionnaire (<i>check only one</i>):	
		Participant	(1)
		Clinic coordinator	(2)
		Other (<i>specify</i>)	(3)

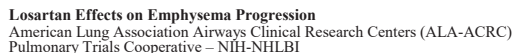
CA112s

relationship to participant

CA113	a	13. Who responded to the questionnaire (<i>check all that apply</i>):	
CA113	b	a. Participant	(1)
		b. Other (<i>specify</i>)	(1)

CA113_bs

relationship to participant



Non-Pulmonary Medications Log

<u>Code</u> M300	<u>Category</u> Antimicrobials - Antibiotics, antivirals, antifungals
M400	Pain and inflammation - Analgesic, anti-inflammatory, antipyretic - Muscle relaxants - Corticosteroids (not including ICS) - Immunosuppressives
M500	Psychiatric - Anti-anxiety, anti-depressants and antipsychotics
M600	Nutriceuticals - Vitamins and herbal remedies
M700	Other

	<i>Example:</i>		b. V1	c. V2	d. V3	e. V4	f. V5	g. V6	h. V7
10.	Medication(s) were reviewed at visit:		Yes (☒ 1) No (2)	Yes (☒ 1) No (2)	Yes (1) No (☒ 2)	Yes (☒ 1) No (2)	Yes (☒ 1) No (2)	Yes (☒ 1) No (2)	Yes (☒ 1) No (2)
	Medication name: Enter each drug one time (include generic and name brand when known; do not key)	a. Med. code (page 1)							
Ex.	<i>Atenolol, Tenormin</i>	<i>M100</i>	Yes (☒ 1) No (2)	Yes (☒ 1) No (2)	Yes (1) No (2)	Yes (☒ 1) No (2)	Yes (☒ 1) No (2)	Yes (1) No (☒ 2)	Yes (1) No (☒ 2)



Non-Pulmonary Medications Log

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: _____ **L** _____ **IDD** _____

3. Alpha ID code: _____ **NameCode..** _____

4. Date log started: _____ - _____ - **VisitDate** _____
day month year

5. Visit ID: _____ **VisitID** **IV** 7

6. Form version date: 3 - 0 - A **CM106**
day month year 2 0 1 7

B. Administrative information (end of study)

7. Date log closed: _____ - **CM1077** - _____
day month year

8. PIN: _____ **CM108** _____

9. Signature (*do not key*): _____ **CM1099** _____

C. Medications

Medications			CM110b	CM110c	CM110d	CM110e	CM110f	CM110g	CM110h
	CM110join		b. V1	c. V2	d. V3	e. V4	f. V5	g. V6	h. V7
10.	Medication(s) were reviewed at visit:		Yes No () ()	Yes No () ()	Yes No () ()	Yes No () ()	Yes No () ()	Yes No () ()	Yes No () ()
	Medication name: Enter each drug one time (<i>include generic and name brand when known; do not key</i>)	a. Med. code (page 1)							
11.	CM111join	CM111a	CM111b Yes No () ()	CM111c Yes No () ()	CM111d Yes No () ()	CM111e Yes No () ()	CM111f Yes No () ()	CM111g Yes No () ()	CM111h Yes No () ()
12.	CM112join	CM112a	CM112b Yes No () ()	CM112c Yes No () ()	CM112d Yes No () ()	CM112e Yes No () ()	CM112f Yes No () ()	CM112g Yes No () ()	CM112h Yes No () ()
13.	CM113join	CM113a	CM113b Yes No () ()	CM113c Yes No () ()	CM113d Yes No () ()	CM113e Yes No () ()	CM113f Yes No () ()	CM113g Yes No () ()	CM113h Yes No () ()
14.	CM114join	CM114a	CM114b Yes No () ()	CM114c Yes No () ()	CM114d Yes No () ()	CM114e Yes No () ()	CM114f Yes No () ()	CM114g Yes No () ()	CM114h Yes No () ()
15.	CM115join	CM115a	CM115b Yes No () ()	CM115c Yes No () ()	CM115d Yes No () ()	CM115e Yes No () ()	CM115f Yes No () ()	CM115g Yes No () ()	CM115h Yes No () ()

	Medication name: Enter each drug one time (include generic and name brand when known; do not key)	a. Med. code (page 1)	b. V1	c. V2	d. V3	e. V4	f. V5	g. V6	h. V7
16.	CM116join	CM116a	CM116b Yes No (1) (2)	CM116c Yes No (1) (2)	CM116d Yes No (1) (2)	CM116e Yes No (1) (2)	CM116f Yes No (1) (2)	CM116g Yes No (1) (2)	CM116h Yes No (1) (2)
17.	CM117join	CM117a	CM117b Yes No (1) (2)	CM117c Yes No (1) (2)	CM117d Yes No (1) (2)	CM117e Yes No (1) (2)	CM117f Yes No (1) (2)	CM117g Yes No (1) (2)	CM117h Yes No (1) (2)
18.	CM118join	CM118a	CM118b Yes No (1) (2)	CM118c Yes No (1) (2)	CM118d Yes No (1) (2)	CM118e Yes No (1) (2)	CM118f Yes No (1) (2)	CM118g Yes No (1) (2)	CM118h Yes No (1) (2)
19.	CM119join	CM119a	CM119b Yes No (1) (2)	CM119c Yes No (1) (2)	CM119d Yes No (1) (2)	CM119e Yes No (1) (2)	CM119f Yes No (1) (2)	CM119g Yes No (1) (2)	CM119h Yes No (1) (2)
20.	CM120join	CM120a	CM120b Yes No (1) (2)	CM120c Yes No (1) (2)	CM120d Yes No (1) (2)	CM120e Yes No (1) (2)	CM120f Yes No (1) (2)	CM120g Yes No (1) (2)	CM120h Yes No (1) (2)
21.	CM121join	CM121a	CM121b Yes No (1) (2)	CM121c Yes No (1) (2)	CM121d Yes No (1) (2)	CM121e Yes No (1) (2)	CM121f Yes No (1) (2)	CM121g Yes No (1) (2)	CM121h Yes No (1) (2)
22.	CM122join	CM122a	CM122b Yes No (1) (2)	CM122c Yes No (1) (2)	CM122d Yes No (1) (2)	CM122e Yes No (1) (2)	CM122f Yes No (1) (2)	CM122g Yes No (1) (2)	CM122h Yes No (1) (2)
23.	CM123join	CM123a	CM123b Yes No (1) (2)	CM123c Yes No (1) (2)	CM123d Yes No (1) (2)	CM123e Yes No (1) (2)	CM123f Yes No (1) (2)	CM123g Yes No (1) (2)	CM123h Yes No (1) (2)
24.	CM124join	CM124a	CM124b Yes No (1) (2)	CM124c Yes No (1) (2)	CM124d Yes No (1) (2)	CM124e Yes No (1) (2)	CM124f Yes No (1) (2)	CM124g Yes No (1) (2)	CM124h Yes No (1) (2)
25.	CM125join	CM125a	CM125b Yes No (1) (2)	CM125c Yes No (1) (2)	CM125d Yes No (1) (2)	CM125e Yes No (1) (2)	CM125f Yes No (1) (2)	CM125g Yes No (1) (2)	CM125h Yes No (1) (2)
26.	CM126join	CM126a	CM126b Yes No (1) (2)	CM126c Yes No (1) (2)	CM126d Yes No (1) (2)	CM126e Yes No (1) (2)	CM126f Yes No (1) (2)	CM126g Yes No (1) (2)	CM126h Yes No (1) (2)
27.	CM127join	CM127a	CM127b Yes No (1) (2)	CM127c Yes No (1) (2)	CM127d Yes No (1) (2)	CM127e Yes No (1) (2)	CM127f Yes No (1) (2)	CM127g Yes No (1) (2)	CM127h Yes No (1) (2)
28.	CM128join	CM128a	CM128b Yes No (1) (2)	CM128c Yes No (1) (2)	CM128d Yes No (1) (2)	CM128e Yes No (1) (2)	CM128f Yes No (1) (2)	CM128g Yes No (1) (2)	CM128h Yes No (1) (2)
29.	CM129join	CM129a	CM129b Yes No (1) (2)	CM129c Yes No (1) (2)	CM129d Yes No (1) (2)	CM129e Yes No (1) (2)	CM129f Yes No (1) (2)	CM129g Yes No (1) (2)	CM129h Yes No (1) (2)
30.	CM130join	CM130a	CM130b Yes No (1) (2)	CM130c Yes No (1) (2)	CM130d Yes No (1) (2)	CM130e Yes No (1) (2)	CM130f Yes No (1) (2)	CM130g Yes No (1) (2)	CM130h Yes No (1) (2)

	Medication name: Enter each drug one time (include generic and name brand when known; do not key)	a. Med. code (page 1)	b. V1	c. V2	d. V3	e. V4	f. V5	g. V6	h. V7
31.	CM131join	CM131a	CM131b Yes No (1) (2)	CM131c Yes No (1) (2)	CM131d Yes No (1) (2)	CM131e Yes No (1) (2)	CM131f Yes No (1) (2)	CM131g Yes No (1) (2)	CM131h Yes No (1) (2)
32.	CM132join	CM132a	CM132b Yes No (1) (2)	CM132c Yes No (1) (2)	CM132d Yes No (1) (2)	CM132e Yes No (1) (2)	CM132e Yes No (1) (2)	CM132g Yes No (1) (2)	CM132h Yes No (1) (2)
33.	CM133join	CM133a	CM133b Yes No (1) (2)	CM133c Yes No (1) (2)	CM133d Yes No (1) (2)	CM133e Yes No (1) (2)	CM133f Yes No (1) (2)	CM133g Yes No (1) (2)	CM133h Yes No (1) (2)
34.	CM134join	CM134a	CM134b Yes No (1) (2)	CM134c Yes No (1) (2)	CM134d Yes No (1) (2)	CM134e Yes No (1) (2)	CM134f Yes No (1) (2)	CM134g Yes No (1) (2)	CM134h Yes No (1) (2)
35.	CM135join	CM135a	CM135b Yes No (1) (2)	CM135c Yes No (1) (2)	CM135d Yes No (1) (2)	CM135e Yes No (1) (2)	CM135f Yes No (1) (2)	CM135g Yes No (1) (2)	CM135h Yes No (1) (2)
36.	CM136join	CM136a	CM136b Yes No (1) (2)	CM136c Yes No (1) (2)	CM136d Yes No (1) (2)	CM136e Yes No (1) (2)	CM136f Yes No (1) (2)	CM136g Yes No (1) (2)	CM136h Yes No (1) (2)
37.	CM137join	CM137a	CM137b Yes No (1) (2)	CM137c Yes No (1) (2)	CM137d Yes No (1) (2)	CM137e Yes No (1) (2)	CM137f Yes No (1) (2)	CM137g Yes No (1) (2)	CM137h Yes No (1) (2)
38.	CM138join	CM138a	CM138b Yes No (1) (2)	CM138c Yes No (1) (2)	CM138d Yes No (1) (2)	CM138e Yes No (1) (2)	CM138f Yes No (1) (2)	CM138g Yes No (1) (2)	CM138h Yes No (1) (2)
39.	CM139join	CM139a	CM139b Yes No (1) (2)	CM139c Yes No (1) (2)	CM139d Yes No (1) (2)	CM139e Yes No (1) (2)	CM139f Yes No (1) (2)	CM139g Yes No (1) (2)	CM139h Yes No (1) (2)
40.	CM140join	CM140a	CM140b Yes No (1) (2)	CM140c Yes No (1) (2)	CM140d Yes No (1) (2)	CM140e Yes No (1) (2)	CM140f Yes No (1) (2)	CM140g Yes No (1) (2)	CM140h Yes No (1) (2)
41.	CM141join	CM141a	CM141b Yes No (1) (2)	CM141c Yes No (1) (2)	CM141d Yes No (1) (2)	CM141e Yes No (1) (2)	CM141f Yes No (1) (2)	CM141g Yes No (1) (2)	CM141h Yes No (1) (2)
42.	CM142join	CM142a	CM142b Yes No (1) (2)	CM142c Yes No (1) (2)	CM142d Yes No (1) (2)	CM142e Yes No (1) (2)	CM142f Yes No (1) (2)	CM142g Yes No (1) (2)	CM142h Yes No (1) (2)
43.	CM143join	CM143a	CM143b Yes No (1) (2)	CM143c Yes No (1) (2)	CM143d Yes No (1) (2)	CM143e Yes No (1) (2)	CM143f Yes No (1) (2)	CM143g Yes No (1) (2)	CM143h Yes No (1) (2)
44.	CM144join	CM144a	CM144b Yes No (1) (2)	CM144c Yes No (1) (2)	CM144d Yes No (1) (2)	CM144e Yes No (1) (2)	CM144f Yes No (1) (2)	CM144g Yes No (1) (2)	CM144h Yes No (1) (2)
45.	CM145join	CM145a	CM145b Yes No (1) (2)	CM145c Yes No (1) (2)	CM145d Yes No (1) (2)	CM145e Yes No (1) (2)	CM145f Yes No (1) (2)	CM145g Yes No (1) (2)	CM145h Yes No (1) (2)

	Medication name: Enter each drug one time (include generic and name brand when known; do not key)	a. Med. code (page 1)	b. V1	c. V2	d. V3	e. V4	f. V5	g. V6	h. V7
46.	CM146join	CM146a	CM146b Yes No () ()	CM146c Yes No () ()	CM146d Yes No () ()	CM146e Yes No () ()	CM146f Yes No () ()	CM146g Yes No () ()	CM146h Yes No () ()
47.	CM147join	CM147a	CM147b Yes No () ()	CM147c Yes No () ()	CM147d Yes No () ()	CM147e Yes No () ()	CM147e Yes No () ()	CM147g Yes No () ()	CM147h Yes No () ()
48.	CM148join	CM148a	CM148b Yes No () ()	CM148c Yes No () ()	CM148d Yes No () ()	CM148e Yes No () ()	CM148f Yes No () ()	CM148g Yes No () ()	CM148h Yes No () ()
49.	CM149join	CM149a	CM149b Yes No () ()	CM149c Yes No () ()	CM149d Yes No () ()	CM149e Yes No () ()	CM149f Yes No () ()	CM149g Yes No () ()	CM149h Yes No () ()
50.	CM150join	CM150a	CM150b Yes No () ()	CM150c Yes No () ()	CM150d Yes No () ()	CM150e Yes No () ()	CM150f Yes No () ()	CM150g Yes No () ()	CM149h Yes No () ()
51.	CM151join	CM151a	CM151b Yes No () ()	CM151c Yes No () ()	CM151d Yes No () ()	CM151e Yes No () ()	CM151f Yes No () ()	CM150g Yes No () ()	CM150h Yes No () ()
52.	CM152join	CM152a	CM152b Yes No () ()	CM152c Yes No () ()	CM152d Yes No () ()	CM152e Yes No () ()	CM152f Yes No () ()	CM152g Yes No () ()	CM151h Yes No () ()
53.	CM153join	CM153a	CM153b Yes No () ()	CM153c Yes No () ()	CM153d Yes No () ()	CM153e Yes No () ()	CM153f Yes No () ()	CM153g Yes No () ()	CM152h Yes No () ()
54.	CM154join	CM154a	CM154b Yes No () ()	CM154c Yes No () ()	CM154d Yes No () ()	CM154e Yes No () ()	CM154f Yes No () ()	CM154g Yes No () ()	CM153h Yes No () ()
55.	CM155join	CM155a	CM155b Yes No () ()	CM155c Yes No () ()	CM155d Yes No () ()	CM155e Yes No () ()	CM155f Yes No () ()	CM155g Yes No () ()	CM154h Yes No () ()
56.	CM156join	CM156a	CM156b Yes No () ()	CM156c Yes No () ()	CM156d Yes No () ()	CM156e Yes No () ()	CM156f Yes No () ()	CM156g Yes No () ()	CM156h Yes No () ()
57.	CM157join	CM157a	CM157b Yes No () ()	CM157c Yes No () ()	CM157d Yes No () ()	CM157e Yes No () ()	CM157f Yes No () ()	CM157g Yes No () ()	CM157h Yes No () ()
58.	CM158join	CM158a	CM158b Yes No () ()	CM158c Yes No () ()	CM158d Yes No () ()	CM158e Yes No () ()	CM158f Yes No () ()	CM158g Yes No () ()	CM158h Yes No () ()
59.	CM159join	CM159a	CM159b Yes No () ()	CM159c Yes No () ()	CM159d Yes No () ()	CM159e Yes No () ()	CM159f Yes No () ()	CM159g Yes No () ()	CM159h Yes No () ()
60.	CM160join	CM160a	CM160b Yes No () ()	CM160c Yes No () ()	CM160d Yes No () ()	CM160e Yes No () ()	CM160f Yes No () ()	CM160g Yes No () ()	CM160h Yes No () ()



Pulmonary Medications Log

Purpose: Record of all **COPD specific medications** used by participant during LEEP. Pulmonary medications will be data entered using medication names **and** medication category code (e.g., *column a* - “Ventolin, albuterol”, and *column b* - “P101”).

When: Log is started at V1 and updated at every clinic visit.

Instructions: *Row 10* - Indicate if medications reviewed at visit. *Column a* - Each medication should be written one time; record generic name and brand name if known. *Column b* - Indicate Medication Category using code from list below:

- V1 - Drug list is started. Record name of each medication currently in use. Check “Yes” for each medication in use at V1 (*column c*).
- V2 - V7:
 - Ask if participant is currently taking each medication listed; indicate response with “Yes” or “No” in column corresponding to visit (*columns d-i*).
 - Ask if participant is taking any new medications; add each new medication to list and check “Yes” for corresponding visit.
- **After final visit key into LEEP data system** at www.LEEPTrial.org. Form will only be data entered one time.

Medication categories and codes

Code Category

Inhaled - Single medication

- P101 Short-acting beta-agonist (SABA); eg Albuterol, Proventil®, Xopenex®
- P102 Short-acting muscarinic antagonist (SAMA); eg Ipratropium
- P103 Long-acting beta-agonist (LABA); eg Salmeterol, Formoterol, Arformoterol
- P104 Long-acting muscarinic antagonist (LAMA); eg Tiotropium, Aclidinium, Umeclidinium
- P105 Inhaled corticosteroid (ICS); eg Fluticasone, Budesonide, Flunisolide, Mometasone

Code Category

Inhaled - Combination therapy

- P201 LABA/LAMA; eg Anoro Ellipta®, Stiolto Respimat®
- P202 LABA/ICS; eg Advair®, Symbicort®, Dulera®, Breo® Ellipta
- P203 SABA/SAMA; eg Combivent®, DuoNeb®

Systemic therapy

- P301 Oral PDE inhibitor; eg Roflumilast
- P302 Oral antibiotics
- P303 Oral steroids
- P304 Theophylline
- P401 IV or injected antibiotic
- P402 IV or injected steroids
- P500 Other pulmonary medication

	<i>Example:</i>		c. V1	d. V2	e. V3	f. V4	g. V5	h. V6	i. V7	
			Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂
10.	Medication(s) were reviewed at visit:									
	a. COPD medication names: Enter each drug one time (include generic and name brand when known; do not key)	b. Med. code (page 1)								
Ex.	<i>Umeclidinium, Vilanterol, Anoro Ellipta</i>	<i>P201</i>	Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂	Yes (✓ ₁)	No () ₂



Pulmonary Medications Log

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: _____ **L** _____ **IDD** _____

3. Alpha ID code: _____ **NameCode..** _____

4. Date log started: _____ - _____ - **VisitDate** _____
day month year

5. Visit ID: _____ **VisitID** **IV** 7

6. Form version date: 3 - 0 - A **CP106**
day month year

B. Administrative information (end of study)

7. Date log closed: _____ - **CP1077** - _____
day month year

8. PIN: **CP108** _____

9. Signature (*do not key*): **CP109** _____

C. Pulmonary Medications

CP110c			CP110d	CP110e	CP110f	CP110g	CP110h	CP110i	
CP110join			c. V1	d. V2	e. V3	f. V4	g. V5	h. V6	i. V7
			Yes No (1) (2)	Yes No (1) (2)	Yes No (1) (2)	Yes No (1) (2)	Yes No (1) (2)	Yes No (1) (2)	Yes No (1) (2)
10.	Medication(s) were reviewed at visit:								
	a. COPD medication names: Enter each drug one time (<i>include generic and name brand when known</i>)	b. Med. code (page 1)							
11.	CP111a (CP111join)	CP111b	CP111c Yes No (1) (2)	CP111d Yes No (1) (2)	CP111e Yes No (1) (2)	CP111f Yes No (1) (2)	CP111g Yes No (1) (2)	CP111h Yes No (1) (2)	CP111i Yes No (1) (2)
12.	CP112a (CP112join)	CP112b	CP112c Yes No (1) (2)	CP112d Yes No (1) (2)	CP112e Yes No (1) (2)	CP112f Yes No (1) (2)	CP112g Yes No (1) (2)	CP112h Yes No (1) (2)	CP112i Yes No (1) (2)
13.	CP113a (CP113join)	CP113b	CP113c Yes No (1) (2)	CP113d Yes No (1) (2)	CP113e Yes No (1) (2)	CP113f Yes No (1) (2)	CP113g Yes No (1) (2)	CP113h Yes No (1) (2)	CP113i Yes No (1) (2)
14.	CP114a (CP114join)	CP113b	CP114c Yes No (1) (2)	CP114d Yes No (1) (2)	CP114e Yes No (1) (2)	CP114f Yes No (1) (2)	CP115g Yes No (1) (2)	CP114h Yes No (1) (2)	CP114i Yes No (1) (2)

	a. COPD medication names: Enter each drug one time (include generic and name brand when known)	b. Med. code (page 1)	c. V1	d. V2	e. V3	f. V4	g. V5	h. V6	i. V7
15.	CP115a (CP115join)	CP115b	CP115c Yes No (1) (2)	CP115d Yes No (1) (2)	CP115e Yes No (1) (2)	CP115f Yes No (1) (2)	CP115g Yes No (1) (2)	CP115h Yes No (1) (2)	CP115i Yes No (1) (2)
16.	CP116a (CP116join)	CP116b	CP116c Yes No (1) (2)	CP116d Yes No (1) (2)	CP116e Yes No (1) (2)	CP116f Yes No (1) (2)	CP116g Yes No (1) (2)	CP116h Yes No (1) (2)	CP116i Yes No (1) (2)
17.	CP117a (CP117join)	CP117b	CP117c Yes No (1) (2)	CP117d Yes No (1) (2)	CP117e Yes No (1) (2)	CP117f Yes No (1) (2)	CP117g Yes No (1) (2)	CP117h Yes No (1) (2)	CP117i Yes No (1) (2)
18.	CP118a (CP118join)	CP118b	CP118c Yes No (1) (2)	CP118d Yes No (1) (2)	CP118e Yes No (1) (2)	CP118f Yes No (1) (2)	CP118g Yes No (1) (2)	CP118h Yes No (1) (2)	CP118i Yes No (1) (2)
19.	CP119a (CP119join)	CP119b	CP119c Yes No (1) (2)	CP119d Yes No (1) (2)	CP119e Yes No (1) (2)	CP119f Yes No (1) (2)	CP119g Yes No (1) (2)	CP119h Yes No (1) (2)	CP119i Yes No (1) (2)
20.	CP120a (CP120join)	CP120b	CP120c Yes No (1) (2)	CP120d Yes No (1) (2)	CP120e Yes No (1) (2)	CP120f Yes No (1) (2)	CP120g Yes No (1) (2)	CP120h Yes No (1) (2)	CP120i Yes No (1) (2)
21.	CP121a (CP121join)	CP121b	CP121c Yes No (1) (2)	CP121d Yes No (1) (2)	CP121e Yes No (1) (2)	CP121f Yes No (1) (2)	CP121g Yes No (1) (2)	CP121h Yes No (1) (2)	CP121i Yes No (1) (2)
22.	CP122a (CP122join)	CP122b	CP122c Yes No (1) (2)	CP122d Yes No (1) (2)	CP122e Yes No (1) (2)	CP122f Yes No (1) (2)	CP122g Yes No (1) (2)	CP122h Yes No (1) (2)	CP122i Yes No (1) (2)
23.	CP123a (CP123join)	CP123b	CP123c Yes No (1) (2)	CP123d Yes No (1) (2)	CP123e Yes No (1) (2)	CP123f Yes No (1) (2)	CP123g Yes No (1) (2)	CP123h Yes No (1) (2)	CP123i Yes No (1) (2)
24.	CP124a (CP124join)	CP124b	CP124c Yes No (1) (2)	CP124d Yes No (1) (2)	CP124e Yes No (1) (2)	CP124f Yes No (1) (2)	CP124g Yes No (1) (2)	CP124h Yes No (1) (2)	CP124i Yes No (1) (2)
25.	CP125a (CP125join)	CP125b	CP125c Yes No (1) (2)	CP125d Yes No (1) (2)	CP125e Yes No (1) (2)	CP125f Yes No (1) (2)	CP125g Yes No (1) (2)	CP125h Yes No (1) (2)	CP125i Yes No (1) (2)
26.	CP126a (CP126join)	CP126b	CP126c Yes No (1) (2)	CP126d Yes No (1) (2)	CP126e Yes No (1) (2)	CP126f Yes No (1) (2)	CP126g Yes No (1) (2)	CP126h Yes No (1) (2)	CP126i Yes No (1) (2)
27.	CP127a (CP127join)	CP127b	CP127c Yes No (1) (2)	CP127d Yes No (1) (2)	CP127e Yes No (1) (2)	CP127f Yes No (1) (2)	CP127g Yes No (1) (2)	CP127h Yes No (1) (2)	CP127i Yes No (1) (2)
28.	CP128a (CP119join)	CP128b	CP128c Yes No (1) (2)	CP128d Yes No (1) (2)	CP128e Yes No (1) (2)	CP128f Yes No (1) (2)	CP128g Yes No (1) (2)	CP128h Yes No (1) (2)	CP128i Yes No (1) (2)



Clinic Visit Form

Purpose: To record interval medical history (e.g., COPD exacerbations, healthcare utilizations, symptoms) and study procedures.

When: V2, V3, V4, V5, V6 and V7.

Instructions: Form to be completed by certified LEEP coordinator during clinic visit. Key into LEEP data system at <http://LEEPTrial.org> within 10 working days.

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date of visit: _____ **VisitDate** _____
 _____ day _____ month _____ year

5. Visit ID: _____ **VisitID** _____

6. Form version date: _____ **CV106** _____
2 3 - J A N - 2 0 1 7
 day month year

B. Interval history

CV107 7. Current smoking status (tobacco):

Current smoker ()

Quit since last study visit ()

9

Former smoker ()

9

CV108 8. On average, number of cigarettes smoked per day since last study visit: _____

9. Since the last study visit have you received

Yes No

a. Influenza vaccine (e.g., flu shot): () () **CV109a**

b. Pneumonia vaccine: () () **CV109b**

10. Since the last study visit have you been diagnosed with any of the following (*check all that apply*)

a. Flu (influenza): () **CV110_a**

b. Pneumonia: () **CV110_b**

c. Sinusitis: () **CV110_c**

d. Angioedema: () **CV110_d**

e. Heart attack: () **CV110_e**

f. Heart palpitations (requiring treatment): () **CV110_f**

g. Stroke (including TIA): () **CV110_g**

h. Kidney disease: () **CV110_h**

i. Hypertension: () **CV110_i**

j. Hypoglycemia: () **CV110_j**

k. Hypotension: () **CV110_k**

l. Broken bone: () **CV110_l**

m. Other (*specify*): () **CV110_m**

CV110_ms

n. None: () **CV110_n**

11. Since your last study visit, ask the participant to rate the severity of the following symptoms (*ask about ALL symptoms listed*):

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
CV111a	a. Headache/head pain:.....	(0)	(1)	(2)	(3)
CV111b	b. Dizziness/lightheadedness:.....	(0)	(1)	(2)	(3)
CV111c	c. Congestion/runny nose:.....	(0)	(1)	(2)	(3)
CV111d	d. Sore throat:	(0)	(1)	(2)	(3)
CV111e	e. Chest pain:	(0)	(1)	(2)	(3)
CV111f	f. Dry cough:.....	(0)	(1)	(2)	(3)
CV111g	g. Back pain:.....	(0)	(1)	(2)	(3)
CV111h	h. Heartburn/indigestion:.....	(0)	(1)	(2)	(3)
CV111i	i. Nausea/vomiting:.....	(0)	(1)	(2)	(3)
CV111j	j. Diarrhea:.....	(0)	(1)	(2)	(3)
CV111k	k. Musculoskeletal pain:.....	(0)	(1)	(2)	(3)
CV111l	l. Muscle cramps:.....	(0)	(1)	(2)	(3)
CV111m	m. Weakness:.....	(0)	(1)	(2)	(3)
CV111n	n. Fatigue:.....	(0)	(1)	(2)	(3)
CV111o	o. Fever:.....	(0)	(1)	(2)	(3)
CV111p	p. Edema (<i>e.g., swelling, "water retention"</i>):	(0)	(1)	(2)	(3)
CV111q	q. Skin rash or hives:.....	(0)	(1)	(2)	(3)
CV111r	r. Sleep problems:.....	(0)	(1)	(2)	(3)
CV111s	s. Other symptom #1 (<i>specify</i>):.....	(0)	(1)	(2)	(3)
	<u>CV111ss</u>				
	<i>symptom</i>				
CV111t	t. Other symptom #2 (<i>specify</i>):.....	(0)	(1)	(2)	(3)
	<u>CV111ts</u>				
	<i>symptom</i>				
CV111u	u. Other symptom #3 (<i>specify</i>):.....	(0)	(1)	(2)	(3)
	<u>CV111us</u>				
	<i>symptom</i>				

CV112 12. Did participant have a COPD flare/exacerbation* since last visit:

Yes No
 (1) (2)
☒ 14 ☐

**Use worksheet below to determine number and severity of COPD flares/exacerbations. Each flare/exacerbation must meet the following criteria:*

- 2 or more new or worsening symptoms lasting 3 or more consecutive days and
- Requires a new prescribed treatment.

13. Number of COPD flare(s)/exacerbation(s) calculated from worksheet below:

a. Number of mild: _____ **CV113a**

b. Number of moderate: _____ **CV113b**

c. Number of severe: _____ **CV113c**

COPD flare/exacerbation worksheet (complete data for each event; do not key):

	New COPD flare/exacerbation event # (events since last clinic visit)						Totals
	1	2	3	4	5	6	
Symptoms: Check all new or worsening symptoms that lasted 3 or more consecutive days since last study visit							
Short of breath:							
Sputum production:							
Purulent sputum:							
Cough:							
Wheeze:							
Chest tightness:							
Were 2 or more symptoms checked above (if "Yes", check box):							
Treatment: Check to indicate all treatment(s) prescribed for specific COPD flare/exacerbation; include both new and additional medications (must have at least 1)							
Antibiotic(s):							
Systemic steroid:							
Additional COPD medication:							
Other medication:							
Was additional treatment (new or increased dose) prescribed (if "Yes", check box):							
Severity of event: Severity for COPD flare/exacerbation is on highest level of treatment required to treat:							
Mild = Change in COPD medication (eg, change in dose or additional medication)							
Moderate = New prescription for steroid and/or antibiotic							
Severe = hospitalization for COPD							
Resolved: Indicate if event resolved. Note: COPD flare/exacerbations must have at least a 2 week separation (from start of treatment to start of next exacerbation)							

- CV114** 14. Since your last clinic visit have you been seen by a healthcare provider for any reason (*other than a scheduled visit for this study*):

Yes No
 (1) (2)
☒ 17 ☐

15. How many times did you visit an outpatient facility for treatment of a

CV115a a. COPD exacerbation: _____

CV115b b. Pulmonary condition: _____

CV115c c. Non-pulmonary condition: _____

16. How many times did you visit an Emergency Room (ED or ER) for treatment of a

CV116a a. COPD exacerbation: _____

CV116b b. Pulmonary condition: _____

CV116c c. Non-pulmonary condition: _____

- CV117** 17. Since your last study visit were you admitted to the hospital for an inpatient stay of 24 hours or more:

Yes No
 (1) (2)
☒ 24 ☐

18. Number(s) of inpatient hospital stays for

CV118a a. COPD exacerbation: _____

CV118b b. Pulmonary condition: _____

CV118c c. Non-pulmonary condition: _____

For each hospitalization since the last study visit provide reason and length of stay.

19. Hospitalization 1:

CV119a a. Reason: _____

CV119b b. Length of stay (*in days*): _____

20. Hospitalization 2:

CV120a a. Reason: _____

CV120b b. Length of stay (*in days*): _____

21. Hospitalization 3:

a. Reason: **CV121a**

b. Length of stay (*in days*): _____ **CV121b**

22. Hospitalization 4:

a. Reason: **CV122a**

b. Length of stay (*in days*): _____ **CV122b**

23. Hospitalization 5:

a. Reason: **CV123a**

b. Length of stay (*in days*): _____ **CV123b**

C. Review of medications

24. Have you been prescribed a new blood pressure medication: **CV124**

Yes No
 (1) (2)
☒ 26 ☐

If yes, specify new blood pressure medication(s):

CV124s

medication name(s)

medication name(s)

25. Indicate all applicable drug categories for new blood pressure medication(s) (**refer to LEEP contraindicated medications list**)

a. Angiotensin converting enzyme (ACE) inhibitor: **CV125_a** (1)

b. Angiotensin II receptor blocker (ARB): **CV125_b** (1)

c. Potassium sparing diuretic: **CV125_c** (1)

d. Something other than a, b, or c: **CV125_d** (1)

Note: PI must be notified if new medication(s) contain an ACE inhibitor or ARB or if a potassium diuretic has been prescribed as all are contraindicated for use with Losartan.

CV126 26. Pulmonary Medications Log (CP) completed:

Yes	No
(1)	(2)

CV127 27. Non-Pulmonary Medications Log (CM) completed:

Yes	No
(1)	(2)

D. Serious Adverse events**CV128** 28. Since the last study visit did the participant have a serious adverse event (e.g., hospitalization, life threatening event):

Yes	No
(1)	(2)

For hospitalizations or any other serious adverse event complete a Serious Adverse Event (SR) report and submit to the DCC. Refer to MOP for guidelines on expedited reporting requirements.

CV129 29. Any other significant medical events since the last study visit:

Yes	No
(1)	(2)

If yes, specify event:

CV129s

Any event that is unanticipated and could be related to study participation or study drug must be reported on a UP form. Refer to MOP.

E. Study procedures**30.** Pregnancy test result:**CV130**Positive (*complete UP form*) (1)

Negative (2)

Female participant, not of childbearing potential (not done) (3)

Not applicable, participant is male (4)

Missed (5)

If required test is missed, submit a Protocol Deviation (PD) form.

31. Specimens for safety labs collected and sent for analysis:**CV131**

Yes	No
(1)	(2)

Safety labs (CBC with differential and CMP) to be done at V4 and V7, if not drawn at V4 or V7 report as a protocol deviation.

Biospecimens for future studies are recorded on BC form.

F. Administrative information**32.** Form completed by PIN:**CV132**

33. Signature (*do not key*):**CV133**



Drug Assignment and Dispensing

Purpose: To document treatment assignment and distribution of study drug and provide time sensitive tracking of study drug supply.

When: At the time study drug is dispensed.

Instructions: This form should be filled out by a certified LEEP Clinic Coordinator, Study Physician or PI. Key into LEEP data system at www.LEEPTrial.org **at the time of the visit.**

A. Site, participant, and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____

4. Date study drug dispensed: _____ **VisitDate**

_____ day - _____ month - _____ year

5. Visit ID: _____ **VisitID** _____

(If not associated with a particular study visit, record as "N")

6. Form version date: _____ **DA106**

2 9 - M A R - 2 0 1 7
 day month year

B. Medication details

DA107 7. Treatment assignment from data system:

L _____
 bottle ID#

Note: *Bottle ID assignment is to be printed and stored in participant's record.*

DA108 8. Tear off label from dispensed bottle:



Affix bottle label here

Bottle ID number to be keyed at data entry.

Note: *Label to be affixed to form at the time bottle given to participant.*

9. Expiration date of dispensed bottle:

DA109

_____ day - _____ month - _____ year

10. Study drug bottle dispensed for following reason
(check all that apply)

a. Scheduled visit: () **DA110_a**

b. Replacement of "lost" drug: () **DA110_b**

c. Other *(specify)*: () **DA110_c**

DA110_cs

reason

C. Administrative information

11. Form completed by PIN:

DA111

12. Signature *(do not key)*:

DA112



Drug Dose

Purpose: Record any change of study drug dose. Note: Permanent stop recorded on Treatment Termination (TT) form.

When: At V3 and anytime a change of dose is communicated to participant after V2 and before V7.

Instructions: Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant, and visit identification

1. Site ID: Clinic

2. Participant ID: L ID

3. Alpha ID code: NameCode

4. Date completed: VisitDate
 _____ day _____ month _____ year

5. Visit ID: VisitID
(If not associated with a particular study visit, record as "N")

6. Form version date: DD106
2 5 - J A N - 2 0 1 7
 day month year

B. V3 dose titration

DD106 7. Is this V3:

Yes No
 (1) (2)
☒ 10

8. Was dose increased to 2 capsules per day:

Yes No
 (1) (2)
☒ 13

9. Reason dose not escalated (*check all that apply*)

a. Seated blood pressure low: (☐) **DD109_a**

b. Orthostatic blood pressure low: (☐) **DD109_b**

c. Dizzy/light headed: (☐) **DD109_c**

d. Other side effects (*specify*): (☐) **DD109_d**

DD109_ds

e. Contraindicated medication prescribed: (☐) **DD109_e**

f. Pregnancy: (☐) **DD109_f**



**Complete Treatment Termination (TT) form
 for permanent stop of treatment.**

g. Other (*specify*): (☐) **DD109_g**

DD109_gs

reason

If V3 skip to Section D.

C. Dose Change

10. Date participant instructed to change dose: **DD110**

_____ day _____ month _____ year

11. Participant instructed to (*check only one*): **DD111**

Take one capsule per day (☐)

Take two capsules per day (☐)

Stop taking study drug - temporary hold (☐)

Stop taking treatment permanently (☐)



**Complete Treatment Termination (TT) form for
 permanent stop of treatment.**

12. Reason for dose change (*check all that apply*)

DD112_a a. Seated blood pressure low: ()

DD112_b b. Orthostatic blood pressure low: ()

DD112_c c. Dizzy/light headed: ()

DD112_d d. Other side effects (*specify*): ()DD112_ds*specify (eg, symptom, diagnosis)*

DD112_e e. Contraindicated medication prescribed: ()

DD112_f f. Abnormal lab result (*specify*): ()DD112_fs*test (eg, serum K+)*

DD112_g g. Pregnancy: ()

***Complete Treatment Termination (TT) form
for permanent stop of treatment.***

DD112_h h. Restart drug after temporary hold: ()

DD112_i i. Increase after temporary lower dose: ()

DD112_j j. Other (*specify*): ()DD112_js*specify***D. Administrative information**

DD113 13. Form completed by PIN:

DD114 14. Signature (*do not key*):

**LEEP**

Losartan Effects on Emphysema Progression (LEEP)
 American Lung Association Airways Clinical Research Centers (ALA-ACRC)
 Pulmonary Trials Cooperative -- NIH-NHLBI

Reference #: _____

Drug Return/Adherence/Capsule Count Form

Purpose: To document adherence with study drug and return of study drug bottle. If more than 2 bottles are returned complete a second form using visit ID "N".

When: V4, V5, V6, and V7.

Instructions: This form should be completed by certified LEEP Clinic Coordinator. Key into LEEP data system at www.LeePTrial.org within 10 working days.

A. Site, participant, and visit identification1. Site ID: _____ **Clinic** _____2. Participant ID: L _____ **ID** _____3. Alpha ID code: _____ **NameCode** _____

4. Date study drug returned: **VisitDate**
 _____ day - _____ month - _____ year

5. Visit ID: **VisitID** _____
(If not associated with a particular study visit or if a 2nd form needed at a visit, record as "N")

6. Form version date: **DR106**
2 9 - M A R - 2 0 1 7
 day month year

B. Medication details**DR107** 7. Bottle ID #1: L _____

DR108 8. Date bottle dispensed:
 _____ day - _____ month - _____ year

DR109 9. Number of capsules remaining: _____ capsule(s)
If no other bottles returned, skip to item 13.

DR110 10. Bottle ID #2: L _____

DR111 11. Date bottle dispensed:
 _____ day - _____ month - _____ year

12. Number of capsules remaining: _____ **DR112**
capsule(s)13. Participant taking drug (*check only one*): **DR113**
As expected (1)**15**

More than expected
 (too few capsules returned) (2)

Less than expected
 (too many capsules returned) (3)

Note: Review medication adherence importance and strategies as needed. Pay attention to prescribed dose.

14. What reason(s) did participant give for not taking expected doses (*check all that apply*)a. Forgot to take medicine: (1) **DR114_a**b. Ran out of capsules: (1) **DR114_b**c. Unable to tolerate them: (1) **DR114_c**d. Lost bottle: (1) **DR114_d**e. Participant's decision to change dosing: (1) **DR114_e**f. Other (*specify*): (1) **DR114_f****DR114_fs**

reason

C. Administrative information15. Form completed by PIN: **DR115**16. Signature (*do not key*): **DR116**



mMRC (modified Medical Research Council) Dyspnea Scale

Purpose: To document information about COPD symptoms.

When: V2, V4-V7.

Completed by: Participant with coordinator assistance as needed.

Instructions: Participant to answer question 7 with assistance from coordinator as needed. Key into LEEP data system within 10 working days.

A. Site, participant, and visit identification

1. Site ID: **Clinic** _____

2. Participant ID:
_____ **L** _____ **ID** _____

3. Alpha ID code: **NameCode** _____

4. Date form completed: **VisitDate**
____ day ____ month ____ year

5. Visit ID: **VisitID** _____

6. Form version date: **DS106**
____ day ____ month ____ year

B. Dyspnea scale

7. Breathlessness scale (*check only one*): **DS107**

I only get breathless with strenuous exercise (*Grade 0*) (0)

I get short of breath when hurrying on the level or walking up a slight hill (*Grade 1*) (1)

I walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level (*Grade 2*) (2)

I stop for breath after walking about 100 yards or after a few minutes on the level (*Grade 3*) (3)

I am too breathless to leave the house or I am breathless when dressing (*Grade 4*) (4)

C. Administrative information

8. Form completed by PIN: **DS108**

9. Signature (*do not key*): **DS109**



Early Study Exit Form

Purpose: To document reason for participant **exit, prior to V7**, from study; these include such reasons as participant withdrawal of consent, ineligibility for randomization (e.g., lab or HRCT results), and loss to follow-up.

When: At the time study participation ends (prior to or after randomization).

Instructions: This form is to be completed for any participant who is **eligible based on Screening Form (SC)**.
 Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant, and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date withdrawal reported: _____ **VisitDate** _____
 _____ day - _____ month - _____ year

5. Visit ID: _____ **VisitID** _____
If not associated with a particular study visit record as "N".

6. Form version date: _____ **EE106** _____
2 3 - J A N - 2 0 1 7
 day month year

B. Exit before randomization

EE107 7. Did participation in LEEP end before randomization:

Yes No
 (1) (2)

11

EE108 8. Date of withdrawal:

_____ day - _____ month - _____ year

EE109 9. **Primary** reason for withdrawal (*check only one*):

Consented and declined to enroll (1)

Consented and ineligible (2)

Consented and not randomized for other reason (3)

10. Indicate all reasons for participant's withdrawal from LEEP prior to randomization (*check all that apply*)

a. Creatinine clearance was insufficient (GFR < 30 mL/min): (1) **EE110_a**

b. Potassium 5 mEq/dL or greater: (1) **EE110_b**

c. AST or ATL greater than 2.5 times the upper limit of normal: (1) **EE110_c**

d. HRCT with percentage of voxels of density < -950 HU outside of eligibility range of 5-35% range: (1) **EE110_d**

e. Unable to have HRCT: (1) **EE110_e**

f. Pregnancy: (1) **EE110_f**

g. COPD exacerbation between V1 and randomization: (1) **EE110_g**

h. New contraindicated medication (e.g., ACE, ARB; not noted at V1 or started after V1): (1) **EE110_h**

i. New diagnosis that would interfere with study participation: (1) **EE110_i**

j. Missed visits or appointments: (1) **EE110_j**

k. Participant withdrawal of consent: (1) **EE110_k**

l. Move out of area: (1) **EE110_l**

m. Physician decision (*specify*): (1) **EE110_m**

EE110_ms

reason

n. Lost to follow up (*unable to reach participant over 4 weeks using multiple attempts and multiple methods, refer to MOP*): (1) **EE110_n**

o. Death: (1) **EE110_o**

p. Research burden: (1) **EE110_p**

q. Other reason not listed above (*specify*): (1) **EE110_q**

EE110_qs

reason

Skip to item 14

C. Exit after V2 but prior to V7**EE111** 11. Primary reason for early withdrawal from LEEP (*check only one*):

Research burden (1)

Participant moved out of area (2)

Participant withdrew consent (3)

Lost to follow up (*to be completed after V7 window closes and participant still cannot be contacted*) (4)PI/Study Physician decision (*specify*) (5)**EE111s1***reason*

Death (6)

Other reason not listed above (*specify*): (7)**EE111s2***reason*12. Indicate any reasons for participant's withdrawal that are **study related** (e.g., related to the study design, procedures, visits, etc):**EE112_a** a. HRCT: (1)**EE112_b** b. Frequency or length of visits: (1)**EE112_c** c. Study treatment/placebo: (1)**EE112_d** d. Blood draws: (1)**EE112_e** e. Spirometry: (1)**EE112_f** f. Other reason not listed above (*specify*): (1)**EE112_fs***reason***EE112_g** g. Not applicable, reason for withdrawal not related to study design, schedule or procedures: (1)**EE113** 13. Date of withdrawal: - month - year **D. Administrative information**

14. Form completed by PIN:

EE11415. Signature: (*do not key*):**EE115**



Yes No
(1) (2)

 ☐

- EL123** 23. Evidence of interstitial, occupational or chronic infectious lung disease:

Yes No
(1) (2)


- EL124** 24. Any changes to chest (event or procedure) that would make V7 HRCT not interpretable (*e.g., metallic objects in the chest such as shrapnel or pacemaker leads*):

Yes No
(1) (2)


- EL125** 25. For women of child bearing potential: currently pregnant, lactating, or unwilling to practice effective contraception for the duration of the study:

Yes (1)

No (2)
Not applicable (3)

- EL125** 26. Major chronic illnesses which in the judgment of the study physician would interfere with participation in the study (*e.g., including but not limited to cardiac, renal, hepatic (LFTs more than 2.5x normal upper limit), neurological, psychiatric, endocrine or neoplastic diseases, uncontrolled diabetes, uncontrolled HIV infection or other immune system disorder, hyperthyroidism, seizure disorders, non-skin cancer, rheumatic diseases*):

Yes No
(1) (2)


- EL127** 27. Intention to leave area within 12 months:

Yes No
(1) (2)


- EL128** 28. Failed to keep appointments or other indicators of noncompliance:

Yes No
(1) (2)


D. Final check

29. Participant meets all eligibility criteria for randomization:

EL128

Yes No
(1) (2)


E. Administrative information

30. Form completed by PIN:

EL130

31. Signature (*do not key*):

EL131

32. Study physician PIN:

EL132

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

EL133

34. Date study physician signed:

EL134

_____ - _____ - _____
day month year

After data entering this EL form, return to LEEP Data System Main Menu and select LEEP Treatment Assignment link to complete randomization process.

Note:

Print treatment assignment from data system and store in participant's record.

F. Randomization data (generated by LEEP data system)

35. Treatment assignment:

 L - _____
Bottle ID



Laboratory Data Form

Purpose: To document laboratory data for CBC with differential and CMP.

When: To be filled by the coordinator after clinic receives lab results for collections at V1, V4, V7, or as needed.

Instructions: Transfer results from lab report to this form. If in doubt regarding reporting values or conversions, please contact the DCC. Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant and visit identification

1. Site ID: Clinic _____

2. Participant ID: ID
L _____

3. Alpha ID code: NameCode _____

4. Date completed: VisitDate
____ day ____ month ____ year

5. Visit ID: VisitID _____
If not associated with a particular study visit, record as "N".

6. Form version date: LD106
2 5 - A U G - 2 0 1 7
day month year

B. Specimen results

LD107 7. Date of blood collection:
____ day ____ month ____ year

C. CMP

For items 8-11, mmol = mEq.

LD108 8. Sodium: _____ mEq/L

LD109 9. Potassium: _____ mEq/L

LD110 10. Chloride: _____ mEq/L

LD111 11. Bicarbonate (CO₂) _____ mEq/L

LD112 12. BUN: _____ mg/dL

13. Creatinine (enter only a or b)

a. In mg/dL: _____ mg/dL **LD113a**

b. In μmol/L: _____ μmol/L **LD113b**

14. Glucose: _____ mg/dL **LD114**

15. Calcium (enter only a or b)

a. In mg/dL: _____ mg/dL **LD115a**

b. In mmol/L: _____ mmol/L **LD115b**

16. Total Protein: _____ g/dL **LD116**

17. Albumin: _____ g/dL **LD117**

18. Total Bilirubin: _____ mg/dL **LD118**

19. AST: _____ IU **LD119**

20. ALT: _____ IU **LD120**

21. Alkaline Phosphatase: _____ IU **LD121**

D. CBC with differential

Note: mm³ = cumm = μL = mL

22. RBC count (enter only a or b)

a. x 10¹²/L: _____ x 10¹²/L **LD122a**

b. x 10⁶/μL: _____ x 10⁶/μL **LD122b**



Missed Data

Purpose: Record information about missed study data.

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

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

A. Site, participant, and visit identification

1. Site ID: **Clinic**

2. Participant ID: L **ID**

3. Alpha ID code: **NameCode**

4. Date form completed: **VisitDate**

 - -
day month year

5. Visit ID: **VisitID**

6. Form version date: **MD106**

 2 3 - J A N - 2 0 1 7
day month year

B. Missed visit information

MD107 7. Was a visit missed completely:

Yes No
(1) (2)

8. Forms missed [expected at visit] (*check all that apply*)

MD108_a a. CV (Clinic Visit Form) [V2-V7]: (1)

MD108_b b. DA (Drug Assignment and Dispensing) [V2-V6]: (1)

MD108_c c. DD (Drug Dose) [V3]: (1)

MD108_d d. DR (Drug Return/Adherence Capsule Count) [V4-V7]: (1)

MD108_e e. LD (Laboratory Data Form) [V2, V4, V7]: (1)

MD108_f f. PE (Physical Exam) [V1, V5, V7]: (1)

MD108_g g. PF (Pulmonary Function Testing) [V1, V5, V7]: (1)

MD108_h h. PM (Physical Measurements Form) [V1-V7]: (1)

i. RR (HRCT Radiologist Review) **MD108_i**
[V1, V7]: (1)

j. RT (HRCT Scan Acquisition Form) **MD108_j**
[V1, V7]: (1)

k. SL (Study Closeout Form) **MD108_k**
[V7 or when treatment terminated]: (1)

l. SV (Study Evaluation) **MD108_l**
[V7 or when treatment terminated]: (1)

m. UM (Unmasking) [V7]: (1) **MD108_m**

n. N/A, none missed: (1) **MD108_n**

9. Questionnaires missed [expected at visit]
(*check all that apply*)

a. AT (ATS-DLD Respiratory Questionnaire) [V1]: (1) **MD109_a**

b. CA (COPD Assessment Test) [V1, V2, V4-V7]: (1) **MD109_b**

c. DS (mMRC) [V1, V2, V4-V7]: (1) **MD109_c**

d. PQ (PROMIS-20a) [V1, V2, V4-V7]: (1) **MD109_d**

e. SG (SGRQ-C) [V1, V2, V4-V7]: (1) **MD109_e**

f. N/A, none missed: (1) **MD109_f**

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

a. Participant was ill: (1) **MD110_a**

b. Participant was temporarily away from area: (1) **MD110_b**

c. Participant refused: (1) **MD110_c**

d. Participant has permanently moved from area: (1) **MD110_d**

e. Unable to contact participant: (1) **MD110_e**

f. Participant forgot: (1) **MD110_f**

g. Unable to reschedule within visit window: (1) **MD110_g**

h. Participant withdrawn: (1) **MD110_h**

i. Other (*specify*): (1) **MD110_i**

MD110_is

MD111 **11.** Additional notes/explanations:

C. Administrative information

MD112 **12.** Form completed by PIN:

MD113 **13.** Signature (*do not key*):



Physical Exam

Purpose: To record information about a participant's health.

When: V1, V5, V7.

Instructions: Completed by certified study physician or designee. Items marked with an "*" are mandatory. Note abnormalities and briefly describe; use extra sheets if necessary. Key into LEEP data system within 10 working days.

A. Site, participant and visit identification

1. Site ID: Clinic _____

2. Participant ID: L ID _____

3. Alpha ID code: NameCode _____

4. Date of exam: VisitDate

____ day ____ month ____ year ____

5. Visit ID: VisitID _____

6. Form version date: PE106

1 0 - N O V - 2 0 1 6
day month year

B. Physical exam

*7.	General appearance: <u>PE107t</u>	Normal (1)	Abnormal (2)	PE107
*8.	Chest/respiratory: <u>PE108t</u>	Normal (1)	Abnormal (2)	PE108
*9.	Heart: <u>PE109t</u>	Normal (1)	Abnormal (2)	PE109
*10.	HEENT/Neck: <u>PE110t</u>	Normal (1)	Abnormal (2)	PE110
*11.	Abdomen: <u>PE111t</u>	Normal (1)	Abnormal (2)	PE111
*12.	Extremities: <u>PE112t</u>	Normal (1)	Abnormal (2)	PE112
13.	Skin: <u>PE113t</u>	Normal (1)	Abnormal (2)	PE113
14.	Neurological: <u>PE114t</u>	Normal (1)	Abnormal (2)	Not Examined (3) PE114

15. Other (specify): **PE115t**Normal
(1)Abnormal
(2)Not
Examined
(3)**PE115***Physical measurements including vital signs recorded on Physical Measurements (PM) form.***C. Physician signature****D. Administrative information****PE116** 16. Is examiner a LEEP certified study physician:Yes
(1)No
(2)**18.***If No, then form must be countersigned by
overseeing LEEP certified Study Physician.*

17. Examiner

19. Form completed by PIN:

PE119

20. Signature (do not key):

PE120**PE117a** a. Examiner signature:

PE117b b. Examiner name (print):

PE117c c. Date form reviewed:____ - ____ - ____
day month year

18. LEEP certified study physician

PE118a a. Date form reviewed:____ - ____ - ____
day month year**PE118b** b. LEEP certified study physician PIN:

PE118c c. LEEP certified study physician signature:

**LEEP**

Losartan Effects on Emphysema Progression (LEEP)
 American Lung Association Airways Clinical Research Centers (ALA-ACRC)
 Pulmonary Trials Cooperative -- NIH-NHLBI

Reference #: _____

Pulmonary Function Testing

Purpose: To record results of pulmonary function tests.

When: V1, V5 and V7.

Instructions: Record the best FEV₁ and the best FVC after examining all of the acceptable curves, even if they do not come from the same curve. Key into LEEP data system at <http://www.LEEPtrial.org> within 10 working days.

A. Site, participant and visit identification

1. Site ID: **Clinic** _____

2. Participant ID: _____

L _____ **ID** _____

3. Alpha ID code: **NameCode** _____

4. Date of spirometry test: **VisitDate**

____ day - ____ month - ____ year

5. Visit ID: **VisitID** _____

6. Form version date: **PF106**

2 7 - J A N - 2 0 1 7
 day month year

B. General PFT data

PF107 7. Choose one predominant ethnicity category as identified by participant (*used to calculate predicted values*):

Caucasian (1)

African-American (2)

Latino/Hispanic (3)

Asian (4)

Other (*specify*) (5)

PF107s _____

specify

8. Did the participant take a short-acting bronchodilator **PF108** in the past 4 hours (*Atrovent, Combivent, albuterol, ipratropium, Ventolin, Proventil*):

Yes No
 (1) (2)

If "Yes," perform post-bronchodilator testing only.

9. Did the participant take a long-acting (twice/day) **PF109** bronchodilator in the past 12 hours (*Serevent, Advair, salmeterol, theophylline, Dulera, Symbicort*):

Yes No
 (1) (2)

10. Did the participant take a longer acting (once/day) **PF110** bronchodilator in the past 24 hours (*tiotropium, Spiriva*):

Yes No
 (1) (2)

11. Did the participant smoke in the past 2 hours: **PF111**

Yes No
 (1) (2)

C. Pre-bronchodilator data

12. Start time:

PF112 : _____ **PF112u**
 hour minute (1) (2)
 am pm

13. Pre-bronchodilator FVC: _____ **PF113**
Liters

14. Pre-bronchodilator FEV₁: _____ **PF114**
Liters

15. Predicted FEV₁ (*using NHANES III predicted values*) **PF115**

Liters

PF116 16. Percent predicted pre-bronchodilator FEV₁: _____ %

17. Bronchodilator dosing time:

PF117 : _____
hour minute

PF117u
(1) (2)
am pm

The participant should also take any other regularly prescribed respiratory medications at this time.

D. Post-bronchodilator data (15-30 minutes after albuterol)

18. Start time:

PF118 : _____
hour minute

PF118u (1) (2)
am pm

PF119 19. Post-bronchodilator FVC: _____ $\frac{\bullet}{\text{Liters}}$ _____

PF120 20. Post-bronchodilator FEV₁:

_____ • _____
Liters

PF121 21. Post bronchodilator FEV₁ / FVC ratio:

Calculation: (post-bronchodilator FEV₁ / post-bronchodilator FVC; i.e., item 20/item 19)

PF122 22. Percent predicted post-bronchodilator FEV₁: _____ %

E. Examiner information

PF123 23. Spirometry tester PIN:

PF124 24. *If performed by a non-LEEP certified spirometry tester:* Name of person performing test:

Note: Complete the LEEP Signature List and Delegation of Authority Log (SD) form and a Protocol Deviation (PD) form.

F. Administrative information

25. Form completed by PIN: PF125

26. Signature (*do not key*): **PF126**

signature

**LEEP**

Losartan Effects on Emphysema Progression (LEEP)
 American Lung Association Airways Clinical Research Centers (ALA-ACRC)
 Pulmonary Trials Cooperative -- NIH-NHLBI

Reference #: _____

Physical Measurements Form

Purpose: To record anthropometrics, vital signs, SpO₂ and orthostatic blood pressure.

When: All clinic visits.

Instructions: Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date of exam: _____ **VisitDate** _____

____ day - ____ month - ____ year

5. Visit ID: _____ **VisitID** _____

6. Form version date: _____ **PM106** _____

1 day - 0 month - N year - 2 0 1 6

B. Height, weight and vital signs

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

PM107a a. Inches: _____ inches _____

PM107b b. Centimeters: _____ cm _____

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

PM108a a. In pounds: _____ lbs _____

PM108b b. Kilograms: _____ kg _____

PM109 9. Heart rate: _____ beats/min _____

PM110 10. Oxygen saturation on room air: _____ % _____

C. Orthostatic blood pressure

At dose initiation or escalation, items 11 and 12 must be completed prior to dose administration.

11. Sitting blood pressure

a. Systolic: _____ mmHg **PM111a**

b. Diastolic: _____ mmHg **PM111b**

12. Standing blood pressure (*after 3 minutes standing*)

a. Systolic: _____ mmHg **PM112a**

b. Diastolic: _____ mmHg **PM112a**

13. Is the participant's dose being started or escalated **PM113** at this visit:

Yes No
 (1) (2)
 16

D. Orthostatic blood pressure after administering drug

(At V2 assess 2 hours after administration; at V3 or any other dose increase, assess 1 hour after administration.)

14. Sitting blood pressure

a. Systolic: _____ mmHg **PM114a**

b. Diastolic: _____ mmHg **PM114b**

15. Standing blood pressure (*after 3 minutes standing*)

a. Systolic: _____ mmHg **PM115a**

b. Diastolic: _____ mmHg **PM115a**

E. Administrative information

16. Form completed by PIN: _____ **PM116**

17. Signature (*do not key*): _____ **PM117**



LEEP

Losartan Effects on Emphysema Progression
American Lung Association Airways Clinical Research Centers (ALA-ACRC)
Pulmonary Trials Cooperative – NIH-NHLBI

Reference #:	_____
a) Site ID:	_____ Clinic _____
b) Participant ID:	_____ L _____ ID _____
c) Alpha ID code:	_____ NameCode _____
d) Date:	_____ VisitDate _____ day month year
e) Visit ID:	_____ VisitID _____
f) Form version date:	_____ PQ100f _____ day month year

PROMIS-20a

Patient-Reported Outcomes Measurement Information

System: Physical Functioning Short-Form 20a

Purpose: To document information about physical functioning.

When: V1, V2, V4-V7.

Completed by: Participant.

Instructions: Clinic coordinator should review the completed questionnaire for missing responses and resolve any problems before the participant leaves the clinic. Key into LEEP data system within 10 working days.

Patient-Reported Outcomes Measurement Information System: Physical Functioning Short-Form 20a

Please respond to each item by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PQ101	1. Are you able to do chores such as vacuuming or yard work:	(5)	(4)	(3)	(2)	(1)
PQ102	2. Are you able to push open a heavy door:	(5)	(4)	(3)	(2)	(1)
PQ103	3. Are you able to dress yourself, including tying shoelaces and doing buttons:	(5)	(4)	(3)	(2)	(1)
PQ104	4. Are you able to wash your back:	(5)	(4)	(3)	(2)	(1)
PQ105	5. Are you able to dry your back with a towel:	(5)	(4)	(3)	(2)	(1)
PQ106	6. Are you able to sit on the edge of a bed:	(5)	(4)	(3)	(2)	(1)
PQ107	7. Are you able to wash and dry your body:	(5)	(4)	(3)	(2)	(1)
PQ108	8. Are you able to get in and out of a car:	(5)	(4)	(3)	(2)	(1)
PQ109	9. Are you able to squeeze a new tube of toothpaste:	(5)	(4)	(3)	(2)	(1)
PQ110	10. Are you able to hold a plate full of food:	(5)	(4)	(3)	(2)	(1)
PQ111	11. Are you able to run a short distance, such as to catch a bus:	(5)	(4)	(3)	(2)	(1)
PQ112	12. Are you able to shampoo your hair:	(5)	(4)	(3)	(2)	(1)
PQ113	13. Are you able to get on and off the toilet:	(5)	(4)	(3)	(2)	(1)
PQ114	14. Are you able to transfer from a bed to a chair and back:	(5)	(4)	(3)	(2)	(1)

		Not at all	Very little	Somewhat	Quite a lot	Cannot do
PQ115	15. Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports:	(5)	(4)	(3)	(2)	(1)
PQ116	16. Does your health now limit you in bending, kneeling, or stooping:	(5)	(4)	(3)	(2)	(1)
PQ117	17. Does your health now limit you in lifting or carrying groceries:	(5)	(4)	(3)	(2)	(1)
PQ118	18. Does your health now limit you in doing two hours of physical labor:	(5)	(4)	(3)	(2)	(1)
PQ119	19. Does your health now limit you in walking more than a mile:	(5)	(4)	(3)	(2)	(1)
PQ120	20. Does your health now limit you in climbing one flight of stairs:	(5)	(4)	(3)	(2)	(1)

To be completed by a member of clinical center staff:

PQ121 21. Form completed by PIN: _____

PQ122 22. Signature (*do not key*): _____

PQ123 23. Who administered the questionnaire (*check only one*)

Participant (*self-administered*) ()

Clinic coordinator	()
--------------------	-----

Other (specify) ()

PQ123s

relationship to participant

24. Who responded to the questionnaire (*check all that apply*)

PQ124 a **a.** Participant: _____ ()

PQ124 b. Other (*specify*): ()

PQ124_bs

relationship to participant



HRCT Radiologist Review

Purpose: To document review of participant's HRCT image by center's local radiologist and indicate if clinically significant incidental findings were noted.

When: V1, V7.

Completed by: Clinic coordinator after review by LEEP study physician.

Instructions: Complete this form for each HRCT visit. Radiologist should review scans within 24 hours and clinic coordinator and study physician should review radiologist report in a timely manner. Key into LEEP data system at www.LEEPTrial.org within 10 days of HRCT scan. Radiologist's report and this form to be stored in participant's study binder.

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: _____ **L** _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date form completed: _____ **VisitDate** _____
_____ day _____ month _____ year

5. Visit ID (V1, V7): _____ **VisitID** _____

6. Form version date: _____ **RR106** _____
_____ day _____ month _____ year

B. Radiologist reports

RR107 7. Report on HRCT scan reviewed: Yes (1) No (2)

RR108 8. Were clinically significant incidental findings noted by radiologist: Yes (1) No (2)

RR109 9. Is urgent action needed based on radiologist's report: Yes (1) No (2)

If "Yes," complete Unanticipated Problem (UP) form or Serious Adverse Event Report (SR) form as appropriate.

10. LEEP certified study physician review by PIN: _____ **RR110**

11. LEEP certified study physician signature (do not key): _____ **RR111**

12. Date of LEEP study physician signature: _____ **RR112**
_____ day _____ month _____ year

C. Administrative information

13. Form completed by PIN: _____ **RR113**

14. Signature (do not key): _____ **RR114**



HRCT Scan Acquisition Form

Purpose: To evaluate participant for HRCT scan and record collection of scan for the LEEP eligibility and primary outcome.

When: V1, V7.

Instructions: Coordinator to complete all sections except E. CT technologist to complete section E. Key into LEEP data system at www.LEEPTrial.org within **2 working days**.

A. Site, participant and visit identification

1. Site ID: Clinic _____

2. Participant ID: L _____ ID _____ ID _____

3. Alpha ID code: NameCode _____ NameCode _____

4. Date form completed: **Visit** Date _____
_____ day _____ month _____ year

5. Visit ID *V1 or V7*: **Visit** ID _____

6. Form version date: **RT106**
1 8 - M A Y - 2 0 1 7
day month year

B. Contraindications

RT107 7. Did the participant have a positive pregnancy test:

Yes No N/A
1 2 3


A pregnancy test is required before each HRCT (the day of) scan unless the participant is not of child-bearing potential. If required pregnancy testing is not performed, do not perform HRCT scan.

RT108 8. Has participant had a COPD exacerbation in the past 2 weeks *required steroids or antibiotics*:

Yes No
1 2


If "Yes," the HRCT scan must be rescheduled.

C. Medications

COPD medications are to be taken on day of HRCT scan. Participant should be in "usual state of health."

9. Indicate if participant used short-acting bronchodilator *eg, albuterol, Ventolin, Proair, Proventil, Xopenex, isoproterenol, metaproterenol*): **RT109**

At clinic visit 1
Prior to visit, but within 6 hours of scan 2

10. Indicate if participant used long-acting COPD medication(s) *eg, long-acting beta agonist, long-acting muscarinic, or combination LABA/LAMA, LABA/ICS, etc*): **RT110**

At clinic visit 1
Prior to visit as prescribed (took most recent scheduled dose) 2
Prior to visit but missed most recent dose (e.g. more than 12 hours since last dose of 2x/day medication) 3
Participant does not use long-acting COPD medication(s) 4

BMI Worksheet

LEEP Coordinator to determine prior to HRCT visit. BMI to be calculated using online calculator at www.LEEPTrial.org. Enter for item 22.

BMI based on V1 data:

Participant's height: _____
cm or inches

Participant's weight: _____
kg or lbs

BMI calculated: _____ kg/m²

Note: Same BMI used for V1 and V7 dose calculations.

D. Prior to HRCT scan

Confirm that the CT technologist is using appropriate settings according to the LEEP HRCT scan protocol before scans performed.

11. Scanner used for HRCT scans for V1 and V7 to be done on same machine.)

RT111a

- a. Brand/manufacturer *check only one*):
- | | |
|----------------------------------|---|
| Siemens | 1 |
| GE | 2 |
| Philips | 3 |
| Toshiba | 4 |
| Other <i>specify</i>) | 5 |

RT111as

brand

RT111b

- b. Scanner model:**

RT111c

- c. Scanner serial number:

12. Is the scanner indicated above certified for use in LEEP *phantom scan done and approved*):

Yes	No
1	2

If "No," phantom to be scanned as soon as possible and scan and PT form submitted.

13. I have verified that the CT technologist's settings for this HRCT scan acquisition match those for LEEP HRCT protocol *determine **prior** to participant's scan*):

- a. Coordinator PIN:** **RT113a**

- b. Coordinator signature** *do not key*): **RT113b**

E. HRCT scan acquisition *to be completed by CT technologist)*

14. Acquisition date: RT114

_____ - _____ - _____
day month year

15. Acquisition time:
- RT115**

_____ : _____ () ()
hour min am pm

16. Recon algorithm s) selected *check one or two based on LEEP scanner specific protocol; refer to MOP Appendix B)*:

- a.** B35: 1 RT116_a
- b.** B30: 1 RT116_b
- c.** B31: 1 RT116_c
- d.** B: 1 RT116_d
- e.** YB: 1 RT116_e
- f.** Standard: 1 RT116_f
- g.** Detail: 1 RT116_g
- h.** None: 1 RT116_h
- i.** Other (*specify*): 1 RT116_i

RT116_is

recon algorithm

F. HRCT scan acquisition information

27. Indicate status of HRCT scan *check only one*) **RT127**

Scan successful: 1

Scan unsuccessful, participant unable
to perform:

Other *specify*): 3

G. Administrative information

28. Form completed by PIN: **RT128**

29. Signature *do not key*): RT129

Followup checklist:

-) Scan archived
-) Scan sent to Radiologist for over reading
-) Scan burned to disk
-) Scan uploaded to NEMO
-) Radiologist Review (RR) form completed within 2 days of scan)

) Radiologist Review (RR) form completed within 2 days of scan)



LEEP

Losartan Effects on Emphysema Progression (LEEP)
American Lung Association Airways Clinical Research Centers (ALA-ACRC)
Pulmonary Trials Cooperative -- NIH-NHLBI

Reference #: _____

Screening Form

Purpose: To document screening visit.

When: V1, after informed consent is signed. Must be completed **before** HRCT scan.

Instructions: Certified LEEP coordinator to administer and complete form for everyone who signs a consent. If any response is marked with **Elig** participant is ineligible, go to section E. **ALL** Screening Forms (regardless of eligibility) are to be keyed into LEEP data system at www.LEEPTrial.org **within 2 days**.

Note: This revision corresponds to protocol version 2.2 or later. If your IRB has not approved this protocol, please use the previous SC form revision (10Aug17).

A. Site, participant, and visit identification

1. Site ID: _____

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

Affix label here

3. Alpha ID code: _____

4. Date of screening:
____ day - ____ month - ____ year

5. Visit ID: V 1

6. Form version date:
2 7 - J U N - 2 0 1 8
day month year

10. Current or former smoker - Greater than or equal to 10 pack-year history of smoking
(10 pack-years = 1 pack a day for 10 years;
2 packs a day for 5 years, etc):

Yes (1) No (2)
Elig

Pack year history:

Average packs/day x number of years smoked

____ x ____ = ____

Example: 1/2 pack/day x 10 years = 5 pack years

11. Can you hold your breath for at least 15 seconds:

Yes (1) No (2)
Elig

12. Can you lie flat for at least 10 minutes:

Yes (1) No (2)
Elig

13. Would you be claustrophobic in CT scanner:

Yes (1) No (2)
Elig

14. Do you have metal objects (e.g., shrapnel, pacemaker lead) in your chest (Note: These changes preclude adequate HRCT imaging):

Yes (1) No (2)
Elig

B. Inclusion criteria

7. Participant has signed informed consent:
Yes (1) No (2)
Elig

8. Age at screening: _____ years

9. 40 years of age or older:
Yes (1) No (2)
Elig

C. Exclusion criteria

15. Current treatment with angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB):

Yes No
(1) (2)
└─▶ 

16. Known intolerance to ACE inhibitor or ARB:

Yes No
(1) (2)
└─▶ 

17. History of angioedema (*repetitive episodes of rapid swelling; usually of face, lips, tongue, limbs, genitals*):

Yes No
(1) (2)
└─▶ 

18. Pre-existing condition for which an ACE inhibitor or ARB is indicated (*e.g., history of myocardial infarction, known cardiomyopathy, heart failure*):

Yes No
(1) (2)
└─▶ 

19. Current regular use of NSAIDs (*e.g., Advil, Motrin, Ibuprofen, naproxen, Aleve*) defined as daily use 5 or more days of the week for more than one month:

Yes No
(1) (2)
└─▶ 

20. Currently taking potassium supplement:

Yes No
(1) (2)
└─▶ 

21. Current treatment with a potassium sparing diuretic (*e.g., spironolactone, amiloride triamterene*):

Yes No
(1) (2)
└─▶ 

22. COPD exacerbation requiring treatment (*e.g., systemic steroids, antibiotics*) within 6 weeks of V1:

Yes No
(1) (2)
└─▶ 

23. Chronic systemic corticosteroid use (more than 10mg/day of prednisone):

Yes No
(1) (2)
└─▶ 

24. Resting SpO₂ < 89% on 2L nasal cannula continuous flow or , if at altitude > 4,000 feet, resting SpO₂ < 89% on 4L NC continuous flow:

Yes No
(1) (2)
└─▶ 

25. Known unilateral or bilateral renal artery stenosis more than 70%:

Yes No
(1) (2)
└─▶ 

26. Previous lung resection surgery:

Yes No
(1) (2)
└─▶ 

27. Evidence of interstitial, occupational or chronic infectious lung disease:

Yes No
(1) (2)
└─▶ 

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

Yes (1)
 └─▶
No (2)
Not applicable (3)

29. Major chronic illnesses which in the judgment of the study physician would interfere with participation in the study (*e.g., including but not limited to: cardiac, renal, hepatic (LFTs more than 2.5x normal upper limit), neurological, psychiatric, endocrine or neoplastic diseases, uncontrolled diabetes, uncontrolled HIV infection or other immune system disorder, hyperthyroidism, seizure disorders, non-skin cancer, rheumatic diseases*):

Yes No
(1) (2)
└─▶ ~~Elig~~

- 30. Intention to leave area within 12 months:**

Yes No
(1) (2)
└─▶ ~~Elig~~

D. Clinical criteria

- ### 31. Spirometry - post-bronchodilator (post-BD)

Refer to Pulmonary Function Testing (PF) form.

- a. Post-BD FEV₁ % predicted: _____ %

- b. Post-BD FEV₁ % predicted between 20-80%:**

Yes No
(1) (2)


- c. Post-BD FEV₁ / FVC ratio:**

0.

- d. Is FEV₁ / FVC ratio less than or equal to 0.70:**

Yes No
(1) (2)


- 32. Hypertension - systolic BP greater than 140 mm Hg and/or diastolic BP greater than 90 mm Hg:**

Yes No
(1) (2)
└─▶ ~~Elig~~

- 33.** Hypotension (seated or standing), systolic BP less than 90 mm Hg or diastolic BP less than 60 mm Hg:

Yes No
(1) (2)
└─▶ ~~Elig~~

- 34.** Blood collected for CBC and CMP:

Yes (1) No (2)

- 34a.** Is the participant enrolled in COPD Genetic Epidemiology (COPDGene) currently or in the past:

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

E. Eligibility

Before completing item 35, verify that no response indicates ineligible (~~Fig~~).

- 35.** Is this participant eligible:

Yes No
(1) (2)

37

- 36.** Is participant willing to continue screening:

Yes No
(1) (2)

Note: If participant declines to participate complete Early Study Exit (EE) form.

F. Administrative information

37. Form completed by PIN:

- 38. Signature (do not key):**

HRCT scan to be completed only if participant meets all eligibility criteria to continue including

- Lab results acceptable (CBC: CMP) and GFR 30 mL/min or higher by Cockcroft-Gault calculation
- Not pregnant (day of HRCT scan)

**LEEP**

Losartan Effects on Emphysema Progression
American Lung Association Airways Clinical Research Centers (ALA-ACRC)
Pulmonary Trials Cooperative – NIH-NHLBI

Reference #:	_____
a) Site ID:	_____ Clinic _____
b) Participant ID:	_____ L _____ ID _____
c) Alpha ID code:	_____ NameCode _____
d) Date:	_____ VisitDate _____ day month year
e) Visit ID:	_____ VisitID _____
f) Form version date:	_____ SG100f _____ day month year

ST. GEORGE'S

RESPIRATORY QUESTIONNAIRE

FOR COPD PATIENTS (SGRQ-C)

When: V1, V2, V4-V7.

Completed by: Participant with coordinator assistance if needed.

Instructions: Clinic coordinator should review the completed assessment for missing responses and resolve any problems before the participant leaves the clinic. Key into LEEP data system within 10 working days.

The St. George's Respiratory Questionnaire

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Questions about how much respiratory trouble you have (*check only one*).

SG101 **1.** I cough:

Most days a week (1)

Several days a week (2)

Only with respiratory infections (3)

Not at all (4)

SG102 **2.** I bring up phlegm (sputum):

Most days a week (1)

Several days a week (2)

Only with respiratory infections (3)

Not at all (4)

SG103 **3.** I have shortness of breath:

Most days a week (1)

Several days a week (2)

Not at all (3)

SG104 **4.** I have attacks of wheezing:

Most days a week (1)

Several days a week (2)

A few days a month (3)

Only with respiratory infections (4)

Not at all (5)

SG105 **5.** How many respiratory attacks did you have in the last year:

3 or more attacks (1)

1 or 2 attacks (2)

None (3)

SG106 **6.** How often do you have good days (with few respiratory problems):

No good days (1)

A few good days (2)

Most days are good (3)

Every day is good (4)

SG107 **7.** If you wheeze, is it worse when you get up in the morning:

Yes (1)

No (2)

Respiratory Condition**SG108 8.** How would you describe your respiratory problem:

Causes me a lot of problems or is the most important physical problem I have (1)

Causes me a few problems (2)

Causes me no problem (3)

Activities that usually make you feel breathless these days

	True	False
SG109 9. Washing or dressing yourself:	(1)	(2)
SG110 10. Walking around the house:	(1)	(2)
SG111 11. Walking outside on level ground:	(1)	(2)
SG112 12. Walking up a flight of stairs:	(1)	(2)
SG113 13. Walking up hills:	(1)	(2)

Questions about your cough and breathlessness these days

	True	False
SG114 14. Coughing hurts:	(1)	(2)
SG115 15. Coughing makes me tired:	(1)	(2)
SG116 16. I am short of breath when I talk:	(1)	(2)
SG117 17. I am short of breath when I bend over:	(1)	(2)
SG118 18. My coughing or breathing disturbs my sleep:	(1)	(2)
SG119 19. I get exhausted easily:	(1)	(2)

Questions about other effects that your respiratory problems may have on you these days

		True	False
SG120	20. My cough or breathing is embarrassing in public:	(☐ 1)	(☐ 2)
SG121	21. My respiratory problems are a nuisance to my family, friends, or neighbors:	(☐ 1)	(☐ 2)
SG122	22. I get afraid or panic when I cannot catch my breath:	(☐ 1)	(☐ 2)
SG123	23. I feel that I am not in control of my respiratory problems:	(☐ 1)	(☐ 2)
SG124	24. I have become frail or an invalid because of my respiratory problems:	(☐ 1)	(☐ 2)
SG125	25. Exercise is not safe for me:	(☐ 1)	(☐ 2)
SG126	26. Everything seems too much of an effort:	(☐ 1)	(☐ 2)

Questions about how your activities might be affected by your respiratory problems

		True	False
SG127	27. I take a long time to get washed or dressed:	(☐ 1)	(☐ 2)
SG128	28. I cannot take a bath or shower, or I take a long time to do it:	(☐ 1)	(☐ 2)
SG129	29. I walk slower than other people of my age or I stop to rest:	(☐ 1)	(☐ 2)
SG130	30. Jobs such as household chores take a long time or I have to stop to rest:	(☐ 1)	(☐ 2)
SG131	31. If I walk up one flight of stairs, I have to go slowly or stop:	(☐ 1)	(☐ 2)
SG132	32. If I hurry or walk fast, I have to stop or slow down:	(☐ 1)	(☐ 2)
SG133	33. My breathing makes it difficult to do things such as walk up hills, carry things up stairs, light gardening such as weeding, dance, bowl, or play golf:	(☐ 1)	(☐ 2)
SG134	34. My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim:	(☐ 1)	(☐ 2)

Questions about how your respiratory problems usually affect your daily life

		True	False
SG135	35. I cannot play sports or do other physical activities:	(☐ ₁)	(☐ ₂)
SG136	36. I cannot go out for entertainment or recreation:	(☐ ₁)	(☐ ₂)
SG137	37. I cannot go out of the house to do the shopping:	(☐ ₁)	(☐ ₂)
SG138	38. I cannot do household chores:	(☐ ₁)	(☐ ₂)
SG139	39. I cannot move far from my bed or chair:	(☐ ₁)	(☐ ₂)
SG140	40. Please check the box (one only) that you think best describes how your respiratory problems affect you:		
	They do not stop me doing anything I would like to do	(☐ ₁)	
	They stop me doing one or two things I would like to do	(☐ ₂)	
	They stop me doing most of the things I would like to do	(☐ ₃)	
	They stop me doing everything I would like to do	(☐ ₄)	

Thank you for completing this questionnaire. Before you finish, would you please make sure that you have answered all questions?

For Clinic Staff use only:

SG141 | **41.** Form completed by PIN: _____

SG142 **42.** Signature (*do not key*): _____

SG143 | 43. Who administered the questionnaire (*check only one*)

Participant (*self-administered*) (1)

Clinic coordinator (2)

Other (specify) (3)

SG143s

relationship to participant

44. Who responded to the questionnaire (*check all that apply*)

SG144_a **a.** Participant: ()

SG144 b	b. Other (<i>specify</i>):	() ()
----------------	------------------------------	--------------------

SG144_bs

relationship to participant



Study Closeout

Purpose: To evaluate study staff's experience in LEEP and record distribution of exit materials.

When: V7 or earlier as needed.

Respondent: Study coordinator and study physician.

Instructions: Conduct interview at the end of V7 or earlier visit if participant terminates earlier. Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant, and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date of exit interview: _____ **VisitDate** _____
 _____ day - _____ month - _____ year

5. Visit ID (if not associated with a particular study visit, record as "N"):

VisitID _____

6. Form version date: _____ **SL106** _____
 2 5 - J A N - 2 0 1 7
 day month year

C. Exit procedures

9. Exit materials distributed

	Yes	No	
a. Exit letter:	(<u> 1 </u>)	(<u> 2 </u>)	SL109a
b. Final spirometry test results:	(<u> 1 </u>)	(<u> 2 </u>)	SL109b
c. Treatment unmasking envelope:	(<u> 1 </u>)	(<u> 2 </u>)	SL109c

D. Administrative information

10. Form completed by PIN: _____ **SL110**

11. Signature (do not key): _____ **SL111**

B. Exit questions for study staff

SL107 7. *For Study Coordinator:* Do you have any idea which study medication was assigned (check only one):

Losartan (1)

Placebo (2)

Don't know (3)

SL108 8. *For Study Physician:* Do you have any idea which study medication was assigned (check only one):

Losartan (1)

Placebo (2)

Don't know (3)



Serious Adverse Event Report

Purpose: To report a serious adverse event (SAE).

Definition of SAE: Any event that results in any of the following outcomes:

- death
- life threatening (i.e., places a participant at immediate risk of death)
- hospitalization (inpatient stay; initial or prolonged)
- persistent or significant disability/incapacity
- congenital anomaly/birth defect

Important medical events that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An event may also be classified as “unexpected.” This is any event, the specificity (nature or frequency) or severity of which is not consistent with the risk information described in the protocol, consent, or package insert.

Examples of events to be reported as an SAE:

- Allergic bronchospasm (e.g., anaphylaxis) **requiring intensive medical treatment** in an emergency room
- A medical event **requiring medical or surgical intervention** to prevent one of the serious outcomes listed above:
 - Blood dyscrasia (e.g., leukemia) requiring outpatient treatment
 - Cerebrovascular accident (i.e., stroke) requiring intervention
 - Drug overdose

When: Submit report within 24 hours of a clinical center learning of a serious adverse event, even if some information is missing.

Respondent: Participant, family member (spouse) or both.

Instructions: Form is submitted to the DCC when it has been keyed into the LEEP data system. In addition the site must:

- Email the DCC if receipt of this report is not confirmed within 24 hours, at JHSPH.LEEP@jhu.edu; indicate Serious Adverse Event in subject line and indicate high priority.
- Submit as much information as is known with initial submission (within 24 hours).
- Submit new information and/or follow-up information by editing the form, including resolution of event (items 20-22).

For emergencies, the PI or study physician should contact the DCC central office at (443) 287-3170 during office hours; during non-office hours, contact Robert Wise, MD at (410) 905-5688.

A. Site, participant, and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date event reported to site: _____ **VisitDate** _____
 _____ day - _____ month - _____ year

5. Visit ID: _____ **VisitID** _____

If not associated with a particular study visit, record as “N”.

6. Form version date: _____ **SR106** _____

_____ day - _____ month - _____ year
 2 5 - J A N - 2 0 1 7

7. Sequential number of this SR form: _____
*Sequence number is 01 unless more than one SAE is reported on the **same day for the same participant**; then number additional forms sequentially (e.g., 02, 03).*

B. Participant information

SR108 8. Age: _____
years

SR109 9. Sex: _____
Male Female
(1) (2)

10. Height (from last study visit; complete **only a or b**)

SR110a a. Inches: _____
inches

SR110b b. Centimeters: _____
cm

11. Weight (from last study visit; complete **only a or b**)

SR111a a. Pounds: _____
lbs

SR111b b. Kilograms: _____
kg

C. Event information

SR112 12. Date of event onset: _____
day - month - year

SR113 13. Event (e.g., COPD exacerbation, heart attack):

14. Event criteria (check all that apply)

SR114_a a. Death: ()

SR114_b b. Life threatening event
(immediate risk of death): ()

SR114_c c. Medically significant, requiring
hospitalization (inpatient stay;
initial or prolonged): ()

SR114_d d. Severely or permanently disabling: ()

SR114_e e. Medically significant but not
requiring hospitalization: ()

SR114_f f. Congenital anomaly: ()

SR114_g g. Event requiring medical or
surgical intervention: ()

SR114_h h. Other (specify): ()

SR114_hs

specify

15. Was adverse event unexpected (check only one): **SR115**

Yes (1)

No (2)

16. Relationship of adverse event to study as determined by study PI/physician (check only one): **SR116**

Not related (1)

Possibly (2)

Probably (3)

Definitely (4)

17. Which of the following body systems are involved
(check all that apply)

a. Cardiovascular: () **SR117_a**

b. Dermatological: () **SR117_b**

c. Gastrointestinal: () **SR117_c**

d. Hematological: () **SR117_d**

e. Metabolic: () **SR117_e**

f. Musculoskeletal: () **SR117_f**

g. Neurological: () **SR117_g**

h. Psychological: () **SR117_h**

i. Pulmonary/Respiratory: () **SR117_i**

j. Renal/Urologic: () **SR117_j**

k. Hepatobiliary: () **SR117_k**

l. Other (specify): () **SR117_l**

18. What action was taken (check all that apply)

a. None: () **SR118_a**

b. Hospitalization/prolonged
hospitalization: () **SR118_b**

c. Remedial therapy:
non-pharmacological: () **SR118_c**

d. Remedial therapy: pharmacological: () **SR118_d**

e. Study drug stopped: () **SR118_e**

f. Study exit: () **SR118_f**

19. Hospitalization**SR119a****a.** Was the participant hospitalized (*for inpatient overnight stay*):

Yes No
 (1) (2)
☐ ☒ **20**

SR119b**b.** Reason for hospitalization:

SR119c**c.** Date admitted:

____ day ____ month ____ year ____

SR119d**d.** Date discharged:

____ day ____ month ____ year ____

SR120 **20.** Current status of the adverse event (*check only one*):

Ongoing

(1)
☐ ☒ **23**

Resolved without sequelae
(*complete item 22*)

(2)
☐ ☒ **22**

Resolved with sequelae
(*complete items 22 and 36f*)

(3)
☐ ☒ **22**

Death (*complete item 21*)

(4)

21. Death information**SR121a****a.** Date of death:

____ day ____ month ____ year ____

SR121b**b.** Was autopsy performed:

Yes No
 (1) (2)

SR121c**c.** Probable cause of death:

 Skip to item 23.

22. Date resolved:

____ day ____ month ____ year ____

D. Study drug and procedures**23.** Was participant on a study drug at the onset of the adverse event: **SR123**

Yes No
 (1) (2)
☐ ☒ **30**

24. Dose at time of event: _____ **SR124**
mg/day**25.** Date started on study drug: **SR125**

____ day ____ month ____ year ____

26. Change in study drug due to event (*check only one*): **SR126**

No change

(1)
☐ ☒ **30**

Temporarily stopped

(2)
If study drug temporarily stopped, fill out Drug Dose (DD) form.

Permanently stopped

(3)
If study drug permanently stopped, fill out Treatment Termination (TT) form.

27. Date study drug stopped: **SR127**

____ day ____ month ____ year ____

28. Was study drug restarted: **SR128**

Yes No
 (1) (2)
☐ ☒

29. Date study drug restarted: **SR129**

____ day ____ month ____ year ____

Please complete description of serious adverse event in section G.

I have reviewed the SR form and verify that all information is complete.

SR130 30. PI PIN: _____

SR131 31. PI signature (*do not key*):

SR132 32. Date signed: _____
 _____ - _____ - _____
 day month year

F. Administrative information

This SR form must be data entered within 24 hours of receipt of information.

SR133 33. Form completed by PIN:

SR134 34. Signature (*do not key*):

SR135 35. Date reported to DCC:

_____ - _____ - _____
day month year

G. Adverse event narrative**36.** Description of serious adverse event**SR136a** a. General description of event:**SR136b** b. Current medications at time of event (*from logs*):**SR136** c. Symptoms:**SR136d** d. Course/duration:**SR136e** e. Treatments/procedures:**SR136f** f. Sequelae:**SR136g** g. Relevant lab/diagnostic tests:

H. Update on status of adverse event

37. Follow-up #1

SR137a a. Date of current status:

_____ - _____ - _____
day month year

SR137b **b. Narrative:**

--

38. Follow-up #2

SR138a a. Date of current status:

_____ - _____ - _____
day month year

SR138b **b. Narrative:**

--

39. Follow-up #3

SR139a a. Date of current status:

_____ - _____ - _____
day month year

SR139a **b. Narrative:**

--



Reference #:	_____
a) Site ID:	_____ Clinic _____
b) Participant ID:	_____ ID _____
c) Alpha ID code:	_____ NameCode _____
d) Date:	_____ VisitDate _____ day month year
e) Visit ID:	_____ VisitID _____
f) Form version date:	_____ SV100f _____ day month year

STUDY EVALUATION

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

When: V7 or earlier visit as needed.

Respondent: Participant with coordinator assistance if needed.

Instructions: Administer evaluation at the end of V7 or earlier visit if participant leaves study earlier. Key into LEEP data system at www.LEEPTrial.org within 10 working days.

Study Evaluation

- 1.** Why did you participate in the study
(*check all that apply*)

- SV101_a** **a.** Hoped it would improve
 my COPD: (1)
- SV101_b** **b.** Free medication: (1)
- SV101_c** **c.** Compensation: (1)
- SV101_d** **d.** Medical care: (1)
- SV101_e** **e.** Contribution to science: (1)
- SV101_f** **f.** Other (*specify*): (1)

SV100s

- SV102** **2.** How would you rate your experience as
a participant in the study (*check only*
one)

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

- SV103** **3.** What did you like about the study:

- 4.** How could we have improved the
study:

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

- Losartan (1)
- Placebo (2)
- Don't know (3)

- 6.** Would you want to continue with this
treatment:

- Yes No
- (1) (2)

- 7.** Do you think your COPD has improved
since starting the study (*check only*
one):

- Yes (1)
- No (2)
- Unsure (3)

SV104**SV105****SV106****SV107**



Instructions: Key into LEEP data system at www.LEEPTrial.org within 10 working days.

Treatment Termination
1 of 1



Unmasking

Purpose: Record unmasking of study treatment.

When: V7 or when study treatment is unmasked.

Instructions: Key into LEEP data system at www.LEEPTrial.org within 10 working days.

A. Site, participant and visit identification

1. Site ID: _____ **Clinic** _____

2. Participant ID: L _____ **ID** _____

3. Alpha ID code: _____ **NameCode** _____

4. Date of report: _____ **VisitDate** _____

____ day - ____ month - ____ year

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

6. Form version date: _____ **UM106** _____

0 6 - J U L - 2 0 1 7
 day month year

10. Treatment assignment revealed from (check only one) **UM110**

Standard unmasking envelope
 (complete item 11) (1)

DCC (2)

Emergency unmasking (3)

Other (specify) (4)

identify method

11. Unmasking envelope

a. Envelope ID: _____ **UM111a**

b. Verification code: U _____ **UM111b**

12. Were any LEEP staff unmasked: **UM112**

Yes No
 (1) (2)
 14

13. LEEP staff member(s) unmasked (specify) **UM113**

B. Unmasking

UM107 7. Date unmasked:

____ day - ____ month - ____ year

UM108 8. Type of unmasking (check only one):

Unscheduled unmasking (before V7) (1)

Scheduled unmasking at end of trial
 (at V7) (2)

10

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

UM109 9. Reason for unscheduled unmasking (specify):

C. Administrative information

14. Form completed by PIN: **UM114**

15. Signature (do not key): **UM115**



Unanticipated Problem Report

Purpose: To report an unanticipated problem (UP), an event that meets the following 3 criteria:

- Is unexpected **and**
- Places participant(s) at greater risk of harm (physical or psychological) **and**
- Is at least possibly related to the research study

Note:

- *SAEs are reported on the Serious Adverse Event Report (SR) form*
- *Protocol deviations that do not meet all 3 criteria noted above are reported on the Protocol Deviation (PD) form*

When: Form is to be completed and submitted to the DCC **within 24 hours** of event being reported to or identified by the site.

Instructions: Form is submitted to the DCC when it has been keyed into the LEEP data system.

In addition the site must:

- E-mail DCC if receipt of this report is not confirmed within 24 hours. Email JHSPH.LEEP@jhu.edu; indicate Unanticipated Problem in subject line and indicate high priority
- Submit as much information as is known with initial submission (within 24 hours)
- Submit new information and/or follow-up information by editing this form, including resolution of event (items 12 and 13)

A. Site, participant, and visit identification

1. Site ID: Clinic _____

UP101a

a. Does event affect a single participant:

Yes (☐) No (☐)

4. ←

2. Participant ID: L ID _____

3. Alpha ID code: NameCode _____

4. Date deviation reported to or identified by site:

_____ **FormDate**
day - month - year

5. Visit ID: VisitID _____
If not associated with a particular study visit record as "N".

6. Form version date: **UP106**

2 5 - J A N - 2 0 1 7
day month year

7. Sequential number of this UP report: **SeqN** _____
Sequence number is 01 unless more than one UP reported on the same day for the same participant(s); then number sequentially (e.g., 02, 03).

B. Event

UP108 8. Did event involve multiple participants:

9.

If “Yes”, complete only a or b:

a. All participants at the site in date range:

i. **UP108ai** _____ - _____ to ii. **UP108aii** _____ - _____
 day month year day month year

b. Multiple participants:

<i>i.</i>	<u> L </u>	<u>UP108bi</u>	_____	<i>viii.</i>	<u> L </u>	<u>UP108bviii</u>	_____
<i>ii.</i>	<u> L </u>	<u>UP108bii</u>	_____	<i>ix.</i>	<u> L </u>	<u>UP108bvix</u>	_____
<i>iii.</i>	<u> L </u>	<u>UP108biii</u>	_____	<i>x.</i>	<u> L </u>	<u>UP108bvx</u>	_____
<i>iv.</i>	<u> L </u>	<u>UP108biv</u>	_____	<i>xi.</i>	<u> L </u>	<u>UP108bvxi</u>	_____
<i>v.</i>	<u> L </u>	<u>UP108bv</u>	_____	<i>xii.</i>	<u> L </u>	<u>UP108bvxi</u>	_____
<i>vi.</i>	<u> L </u>	<u>UP108bvi</u>	_____	<i>xiii.</i>	<u> L </u>	<u>UP108bvxi</u>	_____
<i>vii.</i>	<u> L </u>	<u>UP108bvii</u>	_____	<i>xiv.</i>	<u> L </u>	<u>UP108bvxi</u>	_____

UP109 9. Event:

UP110 10. Date of onset for event/unanticipated problem:

_____ - _____ - _____
day month year

11. Type of unanticipated problem (*check all that apply*)

UP111_a	a. Protocol deviation:	()
UP111_b	b. Noncompliance:	()
UP111_c	c. Unanticipated medical problem:	()
UP111_d	d. Other (<i>specify</i>):	()

UP111_ds

type of UP

12. Status of event (*check one*):

Ongoing ()

14. ←

Resolved without sequelae (2)
 Resolved with sequelae
(specify sequelae in narrative) (3)

13. Date resolved: **UP113**

_____ - _____ - _____
day month year

- 14.** Which of the following body systems are involved
(check all the apply)

UP114_a	a.	Cardiovascular:	()
UP114_b	b.	Dermatological:	()
UP114_c	c.	Gastrointestinal:	()
UP114_d	d.	Hematological:	()
UP114_e	e.	Metabolic:	()
UP114_f	f.	Musculoskeletal:	()
UP114_g	g.	Neurological:	()
UP114_h	h.	Psychological:	()
UP114_i	i.	Pulmonary/Respiratory:	()
UP114_j	j.	Renal/Urologic:	()
UP114_k	k.	Hepatobiliary:	()
UP114_l	l.	Other (<i>specify</i>):	()

UP114 Is

specify

UP114 m m. None/Not applicable: ()

C. Principal investigator to complete

- UP115 15.** Did/does the event place the participant(s) at greater risk of physical or psychological harm than previously known:

Yes () No ()

- UP116 16.** Was the event unexpected:

Yes () No ()

- UP117 17.** Was the event related to this research study
(check one):

Definitely related	(1)
Probably related	(2)
Possibly related	(3)
Not related	(4)

Reminder - by definition an unanticipated problem:

- increases risk of harm
- is unexpected
- is at least possibly related to the study

I have reviewed the UP form (including narrative)

18. PI PIN: **UP118**

19. PI signature (*do not key*): **UP119**

20. Date of signature: **UP120**

_____ - _____ - _____
day month year

D. Administrative information

- 21.** Form completed by PIN: **UP121**

22. Signature (*do not key*): **UP122**

- 23. Date reported to the DCC:** **UP123**

_____ - _____ - _____
day month year

Note: All UPs require narrative (item 24). Any UP which is a protocol deviation or non-compliance requires a Corrective Action Plan (item 25).

UP124 24. Description of event/unanticipated problem:

Note: report of an unanticipated medical event should include participant's age and sex as well as diagnosis, intervention(s), concomitant medications, and indicate if participant was on study treatment at the time of the event.

25. Corrective Action Plan *(required when protocol deviation or non-compliance reported)***UP125a** a. Date plan implemented:

 - -
day month year

UP125b b. Detailed plan:

26. Follow-up #1**UP126a** **a.** Date of current status:

 - -
day month year

UP126b **b.** Narrative:**27. Follow-up #2****UP127a** **a.** Date of current status:

 - -
day month year

UP127a **b.** Narrative: