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

ANTHROPOMETRY FORM

ID NUMBER:	BLINDID					FORM CODE: ANT VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #			

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ ANT0A 0b) Initials..... ☐☐☐

Instructions: *This form should be completed during the participant's visit. For numerical responses, enter the number so that the last digit appears in the rightmost box.*

1) Assessment of ability to stand (choose one):..... ☐ ANT01

Can stand erectly on both feet 1
Can stand on both feet, but posture not erect ... 2
Cannot stand on both feet..... 3 → **End**

2) Standing height (round to nearest cm):..... ☐☐☐ cm ANT02

3) Weight:..... ☐☐☐.☐ kg ANT03

4) BMI:..... ☐☐☐.☐ wt/ht^2 ANT04

5) Arm Span ..... ☐☐☐ cm ANT05

6) Girth (round to nearest cm)

a) Waist: ..... ☐☐☐ cm ANT06A

b) Hip: ..... ☐☐☐ cm ANT06B

c) Neck: ..... ☐☐☐ cm ANT06C

BRONCHOSCOPY SPECIMEN COLLECTION WORKSHEET

ID NUMBER: BLINDID

FORM CODE: **BCW**
VERSION: **2.0** 6/10/14

Visit Number VISIT

SEQ #

0a. Form Completion Date..... __ __ / __ __ / __ __ __ __ BCW0A 0b. Initials..... BCW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

[Check here if subject is Male ☐] BCW0C

VITAL SIGNS TAKEN PRIOR TO BRONCHOSOCPY

1. O_2 Saturation on room air:..... BCW1

HISTORY AND PHYSICAL

2a. Does your center require lab work prior to bronchoscopy? (Y/N)..... BCW2A

2b. If yes, please describe: BCW2B _____

2c. Were the results of the lab work abnormal? (Y/N) BCW2C

2d. Do the results of blood work described in 2b and 2c make the participant ineligible to proceed with a bronchoscopy? (Y/N)..... BCW2D

3a. Did the doctor perform a limited physical exam? (Y/N) BCW3A

3b. In the opinion of the investigator, are there any other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy substudy? (Y/N) BCW3B

3c. Please describe: BCW3C _____

Female Participants Only

4a. Is the participant of child-bearing potential? (Y/N)..... BCW4A

4b. If yes, what was the result of the pregnancy test..... BCW4B

Negative 0
Positive..... 1

ID NUMBER:									FORM CODE: BCW VERSION: **2.0** 6/10/14	Visit Number			SEQ #			

PRE-BRONCHOSCOPY PULMONARY FUNCTION

5. Pre-bronchodilator FEV_1 (reported/best): ..... ☐.☐☐ BCW5 L-BTPS

6. Post-bronchodilator (4 puffs albuterol) FEV_1 (reported/best): ..... ☐.☐☐ BCW6 L-BTPS

BLOOD COLLECTION:

7. Date of blood collection: ..... ☐☐/☐☐/☐☐☐☐ BCW7
   m m / d d / y y y y

8. Collection time: ..... BCW8 ☐☐:☐☐ AM / PM BCW8A
   h h : m m **(Circle One)**

9. Number of venipuncture attempts: ..... ☐ BCW9

10. Any blood drawing incidents or problems? (Y/N) ..... ☐ BCW10

11. Blood drawing incidents: Document problems with venipuncture below. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 8.

    a. Sample not drawn (Y/N) ..... ☐ BCW11A
    b. Partial sample drawn (Y/N) ..... ☐ BCW11B
    c. Tourniquet reapplied (Y/N) ..... ☐ BCW11C
    d. Fist clenching (Y/N) ..... ☐ BCW11D
    e. Needle movement(Y/N) ..... ☐ BCW11E
    f. Participant reclining(Y/N) ..... ☐ BCW11F
    g. Sample re-drawn(Y/N) ..... ☐ BCW11G

12. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here: BCW12
    _____
    _____

13. Phlebotomist's code number: ..... ☐☐☐ BCW13

ORAL RINSE

14. Was the tongue scraping collected? (Y/N) ..... ☐ BCW14

15. Collection time: ..... BCW15 ☐☐:☐☐ AM / PM BCW15A
    h h : m m **(Circle One)**

16. Was the oral rinse collected? (Y/N) ..... ☐ BCW16

17. Collection time: ..... BCW17 ☐☐:☐☐ AM / PM BCW17A
h h : m m **(Circle One)**

18a. Was the time between oral rinse and bronchoscopy more than 60 minutes? (Y/N) .. ☐ BCW18A

18b. If yes, was an additional tongue scraping collected? (Y/N) ..... ☐ BCW18B

PROCEDURES:

BRONCHOSCOPY

19. Saline Control Samples

a. Sterile Saline Sample Collected? (Y/N)..... ☐ BCW19A_V2

b. Scope Saline Sample Collected? (Y/N)..... ☐ BCW19B_V2

20. Protected Brush Specimen (X3 in lower lobe):

a. Lobe BCW19A _____

b. Number collected ..... ☐ BCW19B

21. Airway wash (Combined data for first and second wash)

a. Lobe: BCW20A _____

b. Infused: ☐☐ mL BCW20B c. Return: ☐☐.☐ mL BCW20C

22. Bronchial alveolar lavage (Combined data on both BALs)

a. Lobe: BCW21A _____

b. Infused: ☐☐☐ mL BCW21B c. Return: ☐☐☐.☐ mL BCW21C

d.Collection time:..... BCW21D ☐☐:☐☐ AM / PM BCW21E
h h : m m **(Circle One)**

NOTE: If less than 15cc of fluid is returned from the combined volume of the 20cc wash and the 2x40cc lavage, then the 1x50cc lavage should not be performed.

23. Cytological brushings (X3 in ipsilateral lower lobe)

a. Lobe: BCW22A _____

b. Number of brushes collected: ..... ☐ BCW22B

24. Small airway epithelial brushings (optional)

a. Small airways brush samples collected? (Y/N) ..... ☐ BCW24A_V2

b. Lobe: BCW24B_V2 _____

c. Number of brushes collected: ..... ☐ BCW24C_V2

Endobronchial biopsy collected (X8 in contralateral lung, using all lobes if possible)

25. Side ..... ☐ BCW23 (if collected on V1)

Left 0
Right 1

BCW25_V2 (if collected on V2)

26. Biopsies:

a. Biopsy 1: Snap Freeze (Y/N) ..... ☐ BCW24A

b. Biopsy 2: Formalin (Y/N) ..... ☐ BCW24B

c. Biopsy 3: Formalin (Y/N) ..... ☐ BCW24C

d. Biopsy 4: Formalin (Y/N) ..... ☐ BCW24D

e. Biopsy 5: Formalin (Y/N) ..... ☐ BCW24E

f. Biopsy 6: Snap Freeze (Y/N) ..... ☐ BCW24F

g. Biopsy 7: Formalin (Y/N) ..... ☐ BCW24G

h. Biopsy 8: Formalin (Y/N) ..... ☐ BCW24H

27a. Lidocaine: 1% ☐☐☐ mg BCW25A b. 2% ☐☐☐ mg BCW25B c. 4% ☐☐☐ mg BCW25C

28. Comments: BCW26 _____

PRE-BRONCHOSCOPY PULMONARY FUNCTION

29. Pre-bronchodilator FEV_1 (reported/best): ..... ☐.☐☐ L-BTPS BCW27

30. Did you administer additional albuterol? (Y/N) ..... ☐ BCW28

31. How many micrograms? ..... ☐☐☐ ug BCW29

32. Post-bronchodilator (4 puffs albuterol) FEV_1 (reported/best) : ..... ☐.☐☐ L-BTPS BCW30

33. Did you administer additional albuterol? (Y/N) ..... ☐ BCW31

34. How many micrograms? ..... ☐☐☐ ug BCW32

35. Additional FEV_1 values after additional albuterol (reported/best) : .....☐.☐☐ L-BTPS BCW33

POST-BRONCHOSCOPY STATUS

36. Did the participant experience any adverse events during the bronchoscopy? (Y/N)..... ☐ BCW34

37. Did the participant need to be admitted for overnight observation post bronchoscopy? (Y/N)..... ☐ BCW35

38. CONDITION ON DISCHARGE:

a. No chest discomfort complaints (Y/N)..... ☐ BCW36A
b. Alert / responsive (Y/N)..... ☐ BCW36B
c. Oriented to time, person, place (Y/N)..... ☐ BCW36C
d. Heart rate < 100/min (Y/N) ..... ☐ BCW36D
e. Ambulate w/o difficulty (Y/N)..... ☐ BCW36E
f. Sips water w/o cough/difficulty (Y/N)..... ☐ BCW36F
g. FEV1 > 90% of the pre-BD baseline FEV1 (Y/N).. ☐ BCW36G

39. Comments: BCW37 _____

_____

40. Coordinator Signature and Date: _____

BRONCHOSCOPY SPECIMEN COLLECTION WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: **BCW** VERSION: **1.0** 2/22/12	Visit Number	VISIT	SEQ #

0a. Form Completion Date..... ☐☐/☐☐/☐☐☐☐ BCW0A 0b. Initials..... ☐☐☐ BCW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

[Check here if subject is Male ☐] BCW0C

VITAL SIGNS TAKEN PRIOR TO BRONCHOSOCPY

1. O_2 Saturation on room air:..... ☐☐☐ BCW1

HISTORY AND PHYSICAL

2a. Does your center require lab work prior to bronchoscopy? (Y/N) ..... ☐ BCW2A

2b. If yes, please describe: BCW2B _____

2c. Were the results of the lab work abnormal? (Y/N) ..... ☐ BCW2C

2d. Do the results of blood work described in 2b and 2c make the participant ineligible to proceed with a bronchoscopy? (Y/N)..... ☐ BCW2D

3a. Did the doctor perform a limited physical exam? (Y/N) ..... ☐ BCW3A

3b. In the opinion of the investigator, are there any other physical symptoms or conditions that make this participant ineligible for participation in the bronchoscopy substudy? (Y/N) ..... ☐ BCW3B

3c. Please describe: BCW3C _____

Female Participants Only

4a. Is the participant of child-bearing potential? (Y/N) ..... ☐ BCW4A

4b. If yes, what was the result of the pregnancy test ..... ☐ BCW4B

Negative 0
Positive..... 1

ID NUMBER:								

FORM CODE: BCW
VERSION: **1.0** 2/22/12

Visit Number ☐☐ SEQ # ☐☐☐

PRE-BRONCHOSCOPY PULMONARY FUNCTION

5. Pre-bronchodilator FEV_1 (reported/best): ..... ☐.☐☐ L-BTPS BCW5

6. Post-bronchodilator (4 puffs albuterol) FEV_1 (reported/best): ..... ☐.☐☐ L-BTPS BCW6

BLOOD COLLECTION:

7. Date of blood collection:..... ☐☐/☐☐/☐☐☐☐ BCW7
   m m / d d / y y y y

8. Collection time: ..... BCW8 ☐☐:☐☐ AM / PM BCW8A
   h h : m m **(Circle One)**

9. Number of venipuncture attempts: ..... ☐ BCW9

10. Any blood drawing incidents or problems? (Y/N)..... ☐ BCW10

11. Blood drawing incidents: Document problems with venipuncture below. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 8.

    a. Sample not drawn (Y/N) ..... ☐ BCW11A
    b. Partial sample drawn (Y/N)..... ☐ BCW11B
    c. Tourniquet reapplied (Y/N) ..... ☐ BCW11C
    d. Fist clenching (Y/N)..... ☐ BCW11D
    e. Needle movement(Y/N) ..... ☐ BCW11E
    f. Participant reclining(Y/N) ..... ☐ BCW11F
    g. Sample re-drawn(Y/N) ..... ☐ BCW11G

12. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here: BCW12
    _____
    _____

13. Phlebotomist's code number: ..... ☐☐☐ BCW13

ORAL RINSE

14. Was the tongue scraping collected? (Y/N) ..... ☐ BCW14

15. Collection time: ..... BCW15 ☐☐:☐☐ AM / PM BCW15A
    h h : m m **(Circle One)**

16. Was the oral rinse collected? (Y/N) ..... ☐ BCW16

17. Collection time: ..... BCW17 ☐☐:☐☐ AM / PM BCW17A
h h : m m **(Circle One)**

18a. Was the time between oral rinse and bronchoscopy more than 60 minutes? (Y/N) ... ☐ BCW18A

18b. If yes, was an additional tongue scraping collected? (Y/N) ..... ☐ BCW18B

PROCEDURES:

BRONCHOSCOPY

19. Protected Brush Specimen (X3 in lower lobe):
   a. Lobe BCW19A _____
   b. Number collected ..... ☐ BCW19B

20. Airway wash (Combined data for first and second wash)
   a. Lobe: BCW20A _____
   b. Infused: ☐☐ mL BCW20B c. Return: ☐☐.☐ mL BCW20C

21. Bronchial alveolar lavage (Combined data on both BALs)
   a. Lobe: BCW21A _____
   b. Infused: ☐☐☐ mL BCW21B c. Return: ☐☐☐.☐ mL BCW21C
   d.Collection time:..... BCW21D ☐☐:☐☐ AM / PM BCW21E
   h h : m m **(Circle One)**

22. Cytological brushings (X3 in ipsilateral lower lobe)
   a. Lobe: BCW22A _____
   b. Number of brushes collected: ..... ☐ BCW22B

Endobronchial biopsy collected (X8 in contralateral lung, using all lobes if possible)

23. Side..... ☐ BCW23
   Left 0
   Right 1

24. Biopsies:

a. Biopsy 1: Snap Freeze (Y/N) ..... ☐ BCW24A

b. Biopsy 2: Formalin (Y/N) ..... ☐ BCW24B

c. Biopsy 3: Formalin (Y/N) ..... ☐ BCW24C

d. Biopsy 4: Formalin (Y/N) ..... ☐ BCW24D

e. Biopsy 5: Formalin (Y/N) ..... ☐ BCW24E

f. Biopsy 6: Snap Freeze (Y/N) ..... ☐ BCW24F

g. Biopsy 7: Formalin (Y/N) ..... ☐ BCW24G

h. Biopsy 8: Formalin (Y/N) ..... ☐ BCW24H

25a. Lidocaine: 1% ☐☐☐ mg BCW25A b. 2% ☐☐☐ mg BCW25B c. 4% ☐☐☐ mg BCW25C

26. Comments: BCW26 _____

POST-BRONCHOSCOPY PULMONARY FUNCTION

27. Pre-bronchodilator FEV_1 (reported/best): ..... ☐.☐☐ L-BTPS BCW27

28. Did you administer additional albuterol? (Y/N) ..... ☐ BCW28

29. How many micrograms? ..... ☐☐☐ ug BCW29

30. Post-bronchodilator (4 puffs albuterol) FEV_1 (reported/best) : ..... ☐.☐☐ L-BTPS BCW30

31. Did you administer additional albuterol? (Y/N) ..... ☐ BCW31

32. How many micrograms? ..... ☐☐☐ ug BCW32

33. Additional FEV_1 values after additional albuterol (reported/best) : ..... ☐.☐☐ L-BTPS BCW33

POST-BRONCHOSCOPY STATUS

34. Did the participant experience any adverse events during the bronchoscopy? (Y/N) ..... ☐ BCW34

35. Did the participant need to be admitted for overnight observation post bronchoscopy? (Y/N) ..... ☐ BCW35

36. CONDITION ON DISCHARGE:

a. No chest discomfort complaints (Y/N) ..... ☐ BCW36A

b. Alert / responsive (Y/N) ..... ☐ BCW36B

c. Oriented to time, person, place (Y/N)..... ☐ BCW36C

d. Heart rate < 100/min (Y/N)..... ☐ BCW36D

e. Ambulate w/o difficulty (Y/N)..... ☐ BCW36E

f. Sips water w/o cough/difficulty (Y/N)..... ☐ BCW36F

g. FEV1 > 90% of the pre-BD baseline FEV1 (Y/N).. ☐ BCW36G

37. Comments: BCW37 _____

_____

38. Coordinator Signature and Date: _____

BASELINE EXACERBATION QUESTIONNAIRE

ID NUMBER:	BLINDID					FORM CODE: BEQ VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ BEQ0A 0b) Initials..... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Please read the questions exactly as written.*

1) Have you had an episode of breathing problems in the last 12 months? *(Y/N)* ..... ☐ BEQ01

If Yes

2) How many episodes of breathing problems have you had in the last 12 months? ..... ☐ BEQ02

How was/were the episode(s) of breathing problem(s) treated? Please answer for each episode (if more than one) by checking all relevant treatments given for each episode.

3) For the first episode of breathing problems you had in the last 12 months:

3a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ03A

3b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ03B

3c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N)..... ☐ BEQ03C

3d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ BEQ03D

3e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ BEQ03E

During that visit were you given (check all that apply):

3e1) An additional antibiotic ..... ☐ BEQ03E1

3e2) Additional steroids ..... ☐ BEQ03E2

3e3) Don't know ..... ☐ BEQ03E3

3e4) Don't remember..... ☐ BEQ03E4

3f) Were you evaluated in an Emergency Department? ..... ☐ BEQ03F

During that visit were you given (check all that apply):

3f1) An additional antibiotic ..... ☐ BEQ03F1

3f2) Additional steroids ..... ☐ BEQ03F2

3f3) Don't know ..... ☐ BEQ03F3

3f4) Don't remember ..... ☐ BEQ03F4

3g) Were you admitted to the hospital? ..... ☐ BEQ03G

4) (do not ask) Did the participant have a second episode? ..... ☐ → **If no, skip to end** BEQ04

5) For the second episode of breathing problems you had in the last 12 months:

5a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ05A

5b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ05B

5c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ BEQ05C

5d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) ..... ☐ BEQ05D

5e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ BEQ05E

During that visit were you given (check all that apply):

5e1) An additional antibiotic ..... ☐ BEQ05E1

5e2) Additional steroids ..... ☐ BEQ05E2

5e3) Don't know ..... ☐ BEQ05E3

5e4) Don't remember ..... ☐ BEQ05E4

5f) Were you evaluated in an Emergency Department? ..... ☐ BEQ05F

During that visit were you given (check all that apply):

5f1) An additional antibiotic ..... ☐ BEQ05F1

5f2) Additional steroids ..... ☐ BEQ05F2

5f3) Don't know ..... ☐ BEQ05F3

5f4) Don't remember ..... ☐ BEQ05F4

5g) Were you admitted to the hospital? ..... ☐ BEQ05G

6) (do not ask) Did the participant have a third episode? ..... ☐ → **If no, skip to end** BEQ06

7) For the third episode of breathing problems you had in the last 12 months:

7a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ07A

7b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ07B

7c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N)..... ☐ BEQ07C

7d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ BEQ07D

7e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ BEQ07E

During that visit were you given (check all that apply):

7e1) An additional antibiotic ..... ☐ BEQ07E1

7e2) Additional steroids ..... ☐ BEQ07E2

7e3) Don't know ..... ☐ BEQ07E3

7e4) Don't remember..... ☐ BEQ07E4

7f) Were you evaluated in an Emergency Department? ..... ☐ BEQ07F

During that visit were you given (check all that apply):

7f1) An additional antibiotic ..... ☐ BEQ07F1

7f2) Additional steroids ..... ☐ BEQ07F2

7f3) Don't know ..... ☐ BEQ07F3

7f4) Don't remember..... ☐ BEQ07F4

7g) Were you admitted to the hospital? ..... ☐ BEQ07G

8) (do not ask) Did the participant have a fourth episode?..... ☐ →**If no, skip to end** BEQ08

9) For the fourth episode of breathing problems you had in the last 12 months:

9a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ09A

9b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ09B

9c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ☐ BEQ09C

9d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) ☐ BEQ09D

9e) Were you evaluated in a physician's office or urgent care? (Y/N) ☐ BEQ09E

During that visit were you given (check all that apply):

9e1) An additional antibiotic ☐ BEQ09E1

9e2) Additional steroids ☐ BEQ09E2

9e3) Don't know ☐ BEQ09E3

9e4) Don't remember ☐ BEQ09E4

9f) Were you evaluated in an Emergency Department? ☐ BEQ09F

During that visit were you given (check all that apply):

9f1) An additional antibiotic ☐ BEQ09F1

9f2) Additional steroids ☐ BEQ09F2

9f3) Don't know ☐ BEQ09F3

9f4) Don't remember ☐ BEQ09F4

9g) Were you admitted to the hospital? ☐ BEQ09G

10) (do not ask) Did the participant have a fifth episode? ☐ → **If no, skip to end** BEQ10

11) For the fifth episode of breathing problems you had in the last 12 months:

11a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ☐ BEQ11A

11b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ☐ BEQ11B

11c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ☐ BEQ11C

11d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) ☐ BEQ11D

11e) Were you evaluated in a physician's office or urgent care? (Y/N) ☐ BEQ11E

During that visit were you given (check all that apply):

11e1) An additional antibiotic ..... ☐ BEQ11E1

11e2) Additional steroids ..... ☐ BEQ11E2

11e3) Don't know ..... ☐ BEQ11E3

11e4) Don't remember ..... ☐ BEQ11E4

11f) Were you evaluated in an Emergency Department? ..... ☐ BEQ11F

During that visit were you given (check all that apply):

11f1) An additional antibiotic ..... ☐ BEQ11F1

11f2) Additional steroids ..... ☐ BEQ11F2

11f3) Don't know ..... ☐ BEQ11F3

11f4) Don't remember ..... ☐ BEQ11F4

11g) Were you admitted to the hospital? ..... ☐ BEQ11G

12) (do not ask) Did the participant have a sixth episode?..... ☐ → **If no, skip to end** BEQ12

13) For the sixth episode of breathing problems you had in the last 12 months:

13a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ13A

13b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ BEQ13B

13c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N)..... ☐ BEQ13C

13d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ BEQ13D

13e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ BEQ13E

During that visit were you given (check all that apply):

13e1) An additional antibiotic ..... ☐ BEQ13E1

13e2) Additional steroids ..... ☐ BEQ13E2

13e3) Don't know ..... ☐ BEQ13E3

13e4) Don't remember ..... ☐ BEQ13E4

13f) Were you evaluated in an Emergency Department? ..... ☐ BEQ13F

During that visit were you given (check all that apply):

13f1) An additional antibiotic ..... ☐ BEQ13F1

13f2) Additional steroids ..... ☐ BEQ13F2

13f3) Don't know ..... ☐ BEQ13F3

13f4) Don't remember..... ☐ BEQ13F4

13g) Were you admitted to the hospital? ..... ☐ BEQ13G

BIOSPECIMEN COLLECTION FORM

ID NUMBER: BLINDID

FORM CODE: BIO
VERSION: 2.0 12/09/10

Visit Number VISIT

SEQ #

0a. Form Completion Date..... __ __ / __ __ / __ __ __ __ BIO0A 0b. Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

Fasting Blood Collection Information:

1. Did you fast before today's appointment? BIO01
   ☐ 1 Yes ☐ 0 No

2. At what time did you last eat? BIO02 : __ __ AM / PM BIO02_AMPM
   h h : m m **(Circle One)**

Blood Collection:

3. Date of blood collection:..... __ __ / __ __ / __ __ __ __ BIO03
   m m / d d / y y y y

4. Collection time:..... BIO04 : __ __ AM / PM BIO04_AMPM
   h h : m m **(Circle One)**

5. Number of venipuncture attempts:..... __ BIO05

6. Any blood drawing incidents or problems? ..... ☐ 1 Yes ☐ 0 No **If Yes, specify in Item 7 and/or Item 8** BIO06

7. Blood drawing incidents: Document problems with venipuncture below. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 8.

	Tube 1	2	3	4	5	6	7	8	9
a. Sample not drawn	BIO07A1	BIO07A2	BIO07A3	BIO07A4	BIO07A5	BIO07A6	BIO07A7	BIO07A8	BIO07A9
b. Partial sample drawn	BIO07B1	BIO07B2	BIO07B3	BIO07B4	BIO07B5	BIO07B6	BIO07B7	BIO07B8	BIO07B9
c. Tourniquet reapplied	BIO07C1	BIO07C2	BIO07C3	BIO07C4	BIO07C5	BIO07C6	BIO07C7	BIO07C8	BIO07C9
d. Fist clenching	BIO07D1	BIO07D2	BIO07D3	BIO07D4	BIO07D5	BIO07D6	BIO07D7	BIO07D8	BIO07D9
e. Needle movement	BIO07E1	BIO07E2	BIO07E3	BIO07E4	BIO07E5	BIO07E6	BIO07E7	BIO07E8	BIO07E9
f. Participant reclining	BIO07F1	BIO07F2	BIO07F3	BIO07F4	BIO07F5	BIO07F6	BIO07F7	BIO07F8	BIO07F9
f. Sample re-drawn	☐	☐	☐	☐	☐	☐	☐	☐	☐

Sample re-drawn not collected

8. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here:
   BIO08 _____
   _____

9. Phlebotomist's code number: __ __ __ BIO09

Blood Processing:

Indicate the time each tube was processed:

10. Tube 1 - Red Top 1 – Serum

a. Time Processed: BIO10A AM / PM **(Circle One)** BIO10A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO10B

- ☐ Broken Tube BIO10B1
- ☐ Sample re-centrifuged BIO10B2
- ☐ Clotted BIO10B3
- ☐ Hemolyzed BIO10B4
- ☐ Lipemic BIO10B5
- ☐ Other BIO10B6
  Specify:_____ BIO10B6A

c. Number of Aliquots: ☐ BIO10C

d. Volume in last aliquot: ☐☐☐ µL BIO10D

e. Freezer box number: ☐☐☐☐ BIO10E

f. Time aliquots placed in freezer BIO10F AM / PM **(Circle One)** BIO10F_AMPM

11. Tube 2 - Red Top 2 – Serum

a. Time Processed: BIO11A AM / PM **(Circle One)** BIO11A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO11B

- ☐ Broken Tube BIO11B1
- ☐ Sample re-centrifuged BIO11B2
- ☐ Clotted BIO11B3
- ☐ Hemolyzed BIO11B4
- ☐ Lipemic BIO11B5
- ☐ Other BIO11B6
  Specify:_____ BIO11B6A

c. Number of Aliquots: ☐ BIO11C

d. Volume in last aliquot: ☐☐☐ µL BIO11D

e. Freezer box number: ☐☐☐☐ BIO11E

f. Time aliquots placed in freezer BIO11F AM / PM **(Circle One)** BIO11F_AMPM

12. Tube 3 – Yellow Top 1 – Plasma-ACD

a. Time Processed: BIO12A AM / PM **(Circle One)** BIO12A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO12B

☐ Broken Tube BIO12B1
☐ Sample re-centrifuged BIO12B2
☐ Clotted BIO12B3
☐ Hemolyzed BIO12B4
☐ Lipemic BIO12B5
☐ Other BIO12B6
Specify:_____ BIO12B6A

c. Number of Aliquots: ☐ BIO12C

d. Volume in last aliquot: ☐☐☐ µL BIO12D

e. Freezer box number: ☐☐☐☐ BIO12E

f. Time aliquots placed in freezer BIO12F ☐☐ AM / PM **(Circle One)** BIO12F_AMPM

13. Tube 4 – Lavender Top 1 – Plasma-EDTA 10ml

a. Time Processed: BIO13A AM / PM **(Circle One)** BIO13A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO13B

☐ Broken Tube BIO13B1
☐ Sample re-centrifuged BIO13B2
☐ Clotted BIO13B3
☐ Hemolyzed BIO13B4
☐ Lipemic BIO13B5
☐ Other BIO13B6
Specify:_____ BIO13B6A

c. Number of Aliquots: ☐ BIO13C

d. Volume in last aliquot: ☐☐☐ µL BIO13D

e. Freezer box number: ☐☐☐☐ BIO13E

f. Time aliquots placed in freezer BIO13F ☐☐ AM / PM **(Circle One)** BIO13F_AMPM

14. Tube 5 – Lavender Top 2 – Plasma/cell lysate-EDTA 10ml

a. Time Processed: BIO14A AM / PM **(Circle One)** BIO14A_AMPM

b. Problems Processing? ☐1Yes ☐0No BIO14B

- ☐Broken Tube BIO14B1
- ☐Sample re-centrifuged BIO14B2
- ☐Clotted BIO14B3
- ☐Hemolyzed BIO14B4
- ☐Lipemic BIO14B5
- ☐Other BIO14B6

Specify:_____ BIO14B6A

c. Number of Aliquots: ☐ BIO14C

d. Volume in last aliquot: ☐☐☐ µL BIO14D

e. Freezer box number: ☐☐☐☐ BIO14E

f. Time aliquots placed in freezer BIO14F AM / PM **(Circle One)** BIO14F_AMPM

15. Tube 6 – Lavender Top 3 – EDTA 10ml

a. Time Processed: BIO15A AM / PM **(Circle One)** BIO15A_AMPM

b. Problems Processing? ☐1Yes ☐0No BIO15B

- ☐Broken Tube BIO15B1
- ☐Sample re-centrifuged BIO15B2
- ☐Clotted BIO15B3
- ☐Hemolyzed BIO15B4
- ☐Lipemic BIO15B5
- ☐Other BIO15B6

Specify:_____ BIO15B6A

c. Number of Aliquots: ☐ BIO15C

d. Volume in last aliquot: ☐☐☐ µL BIO15D

e. Freezer box number: ☐☐☐☐ BIO15E

f. Time aliquots placed in freezer BIO15F AM / PM **(Circle One)** BIO15F_AMPM

16. Tube 7 – Lavender Top 4 – CBC 4ml

a. Time sent to clinical center lab: BIO16A AM / PM **(Circle One)** BIO16A_AMPM

17. Tube 8 – P100 – Plasma P100

a. Time Processed: BIO17A AM / PM **(Circle One)** BIO17A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO17B

☐ Broken Tube BIO17B1
☐ Sample re-centrifuged BIO17B2
☐ Clotted BIO17B3
☐ Hemolyzed BIO17B4
☐ Lipemic BIO17B5
☐ Other BIO17B6
Specify:_____ BIO17B6A

c. Number of Aliquots: ☐ BIO17C

d. Volume in last aliquot: ☐☐☐ µL BIO17D

e. Freezer box number: ☐☐☐☐ BIO17E

f. Time aliquots placed in freezer BIO17F AM / PM **(Circle One)** BIO17F_AMPM

18. Tube 9 – PAX Gene – RNA

a. Date placed in freezer: ☐☐/☐☐/☐☐☐☐ BIO18A

b. Time placed in freezer: BIO18B AM / PM **(Circle One)** BIO18B_AMPM

c. Problems Processing? ☐[1]Yes ☐[0]No BIO18C

☐ Broken Tube BIO18C1
☐ Sample re-centrifuged BIO18C2
☐ Clotted BIO18C3
☐ Hemolyzed BIO18C4
☐ Lipemic BIO18C5
☐ Other BIO18C6
Specify:_____ BIO18C6A

d. Freezer box number: ☐☐☐☐ BIO18D

Urine Sample

19. Was a urine sample collected? ..... ☐1Yes ☐0No BIO19

20. Date of urine sample: ..... ☐☐/☐☐/☐☐☐☐ BIO20
m m / d d / y y y y

21. Time urine sample collected: ..... BIO21 ☐☐:☐☐ AM / PM BIO21_AMPM
h h : m m **(Circle One)**

22. Time urine sample was processed: ..... BIO22 ☐☐:☐☐ AM / PM BIO22_AMPM
h h : m m **(Circle One)**

23. Number of aliquots with preservative:..... ☐☐ BIO23

24. Number of aliquots without preservative:... ☐☐ BIO24

25. Time urine samples were placed in freezer: BIO24A ☐☐ AM / PM BIO24A_AMPM
h h : m m **(Circle One)**

26. Is this patient able to become pregnant?... ☐1Yes ☐0No **If yes, complete Item 27** BIO25

27. Pregnancy test requested? ..... ☐1Yes ☐0No BIO26

27a. Was the participant pregnant? ☐1Yes ☐0No BIO26A

28. Processor's code #:..... ☐☐☐ BIO27

29. Comments on blood processing, urine collection/processing, and CBC: BIO28

_____
_____
_____

BIOSPECIMEN COLLECTION FORM

ID NUMBER: BLINDID

FORM CODE: BIO
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a. Form Completion Date..... __ __ / __ __ / __ __ __ __ BIO0A 0b. Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

Fasting Blood Collection Information:

1. Did you fast before today's appointment? BIO01
   ☐ 1 Yes ☐ 0 No

2. At what time did you last eat? BIO02 : __ __ AM / PM BIO02_AMPM
   h h : m m **(Circle One)**

Blood Collection:

3. Date of blood collection:..... __ __ / __ __ / __ __ __ __ BIO03
   m m / d d / y y y y

4. Collection time:..... BIO04 : __ __ AM / PM BIO04_AMPM
   h h : m m **(Circle One)**

5. Number of venipuncture attempts:..... __ BIO05

6. Any blood drawing incidents or problems?..... ☐ 1 Yes ☐ 0 No **If Yes, specify in Item 7 and/or Item 8** BIO06

7. Blood drawing incidents: Document problems with venipuncture below. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 8.

	Tube 1	2	3	4	5	6	7	8	9
a. Sample not drawn	BIO07A1	BIO07A2	BIO07A3	BIO07A4	BIO07A5	BIO07A6	BIO07A7	BIO07A8	BIO07A9
b. Partial sample drawn	BIO07B1	BIO07B2	BIO07B3	BIO07B4	BIO07B5	BIO07B6	BIO07B7	BIO07B8	BIO07B9
c. Tourniquet reapplied	BIO07C1	BIO07C2	BIO07C3	BIO07C4	BIO07C5	BIO07C6	BIO07C7	BIO07C8	BIO07C9
d. Fist clenching	BIO07D1	BIO07D2	BIO07D3	BIO07D4	BIO07D5	BIO07D6	BIO07D7	BIO07D8	BIO07D9
e. Needle movement	BIO07E1	BIO07E2	BIO07E3	BIO07E4	BIO07E5	BIO07E6	BIO07E7	BIO07E8	BIO07E9
f. Participant reclining	BIO07F1	BIO07F2	BIO07F3	BIO07F4	BIO07F5	BIO07F6	BIO07F7	BIO07F8	BIO07F9

8. If any other blood drawing problems not listed above (e.g., fasting status, etc.), describe incident or problem here:
   BIO08 _____
   _____

9. Phlebotomist's code number: __ __ __ BIO09

Blood Processing:

Indicate the time each tube was processed:

10. Tube 1 - Red/Gray Top 1 – Serum-SST

a. Time Processed: ☐☐:☐☐ BIO10A AM / PM **(Circle One)** BIO10A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO10B

- ☐ Broken Tube BIO10B1
- ☐ Sample re-centrifuged BIO10B2
- ☐ Clotted BIO10B3
- ☐ Hemolyzed BIO10B4
- ☐ Lipemic BIO10B5
- ☐ Other BIO10B6 BIO10B6A
  Specify:_____

c. Number of Aliquots: ☐ BIO10C

d. Volume in last four aliquots: ☐☐☐ µL BIO10D

e. Freezer box number: ☐☐☐☐ BIO10E

f. Time aliquots placed in freezer ☐☐:☐☐ BIO10F AM / PM **(Circle One)** BIO10F_AMPM

11. Tube 2 - Red/Gray Top 2 – Serum-SST

a. Time Processed: ☐☐:☐☐ BIO11A AM / PM **(Circle One)** BIO11A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO11B

- ☐ Broken Tube BIO11B1
- ☐ Sample re-centrifuged BIO11B2
- ☐ Clotted BIO11B3
- ☐ Hemolyzed BIO11B4
- ☐ Lipemic BIO11B5
- ☐ Other BIO11B6
  Specify:_____ BIO11B6A

c. Number of Aliquots: ☐ BIO11C

d. Volume in last four aliquots: ☐☐☐ µL BIO11D

e. Freezer box number: ☐☐☐☐ BIO11E

f. Time aliquots placed in freezer ☐☐:☐☐ BIO11F AM / PM **(Circle One)** BIO11F_AMPM

12. Tube 3 – Yellow Top 1 – Plasma-ACD

a. Time Processed: BIO12A ☐☐:☐☐ AM / PM **(Circle One)** BIO12A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO12B

- ☐ Broken Tube BIO12B1
- ☐ Sample re-centrifuged BIO12B2
- ☐ Clotted BIO12B3
- ☐ Hemolyzed BIO12B4
- ☐ Lipemic BIO12B5
- ☐ Other BIO12B6

Specify:_____ BIO12B6A

c. Number of Aliquots: ☐ BIO12C

d. Volume in last four aliquots: ☐☐☐ µL BIO12D

e. Freezer box number: ☐☐☐☐ BIO12E

f. Time aliquots placed in freezer BIO12F ☐☐:☐☐ AM / PM **(Circle One)** BIO12F_AMPM

13. Tube 4 – Lavender Top 1 – Plasma-EDTA 10ml

a. Time Processed: BIO13A ☐☐:☐☐ AM / PM **(Circle One)** BIO13A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO13B

- ☐ Broken Tube BIO13B1
- ☐ Sample re-centrifuged BIO13B2
- ☐ Clotted BIO13B3
- ☐ Hemolyzed BIO13B4
- ☐ Lipemic BIO13B5
- ☐ Other BIO13B6

Specify:_____ BIO13B6A

c. Number of Aliquots: ☐ BIO13C

d. Volume in last four aliquots: ☐☐☐ µL BIO13D

e. Freezer box number: ☐☐☐☐ BIO13E

f. Time aliquots placed in freezer BIO13F ☐☐:☐☐ AM / PM **(Circle One)** BIO13F_AMPM

14. Tube 5 – Lavender Top 2 – Plasma/cell lysate-EDTA 10ml

a. Time Processed: BIO14A AM / PM **(Circle One)** BIO14A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO14B

- ☐ Broken Tube BIO14B1
- ☐ Sample re-centrifuged BIO14B2
- ☐ Clotted BIO14B3
- ☐ Hemolyzed BIO14B4
- ☐ Lipemic BIO14B5
- ☐ Other BIO14B6

Specify:_____ BIO14B6A

c. Number of Aliquots: BIO14C

d. Volume in last four aliquots: µL BIO14D

e. Freezer box number: BIO14E

f. Time aliquots placed in freezer BIO14F AM / PM **(Circle One)** BIO14F_AMPM

15. Tube 6 – Lavender Top 3 – EDTA 10ml

a. Time Processed: BIO15A AM / PM **(Circle One)** BIO15A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO15B

- ☐ Broken Tube BIO15B1
- ☐ Sample re-centrifuged BIO15B2
- ☐ Clotted BIO15B3
- ☐ Hemolyzed BIO15B4
- ☐ Lipemic BIO15B5
- ☐ Other BIO15B6

Specify:_____ BIO15B6A

c. Number of Aliquots: BIO15C

d. Volume in last four aliquots: µL BIO15D

e. Freezer box number: BIO15E

f. Time aliquots placed in freezer BIO15F AM / PM **(Circle One)** BIO15F_AMPM

16. Tube 7 – Lavender Top 4 – CBC 4ml

a. Time sent to clinical center lab: BIO16A AM / PM **(Circle One)** BIO16A_AMPM

17. Tube 8 – P100 – Plasma P100

a. Time Processed: BIO17A AM / PM **(Circle One)** BIO17A_AMPM

b. Problems Processing? ☐[1]Yes ☐[0]No BIO17B

- ☐ Broken Tube BIO17B1
- ☐ Sample re-centrifuged BIO17B2
- ☐ Clotted BIO17B3
- ☐ Hemolyzed BIO17B4
- ☐ Lipemic BIO17B5
- ☐ Other BIO17B6

Specify:_____ BIO17B6A

c. Number of Aliquots: ☐ BIO17C

d. Volume in last four aliquots: ☐☐☐ µL BIO17D

e. Freezer box number: ☐☐☐☐ BIO17E

f. Time aliquots placed in freezer BIO17F AM / PM **(Circle One)** BIO17F_AMPM

18. Tube 9 – PAX Gene – RNA

a. Date placed in freezer: ☐☐/☐☐/☐☐☐☐ BIO18A

b. Time placed in freezer: BIO18B AM / PM **(Circle One)** BIO18B_AMPM

c. Problems Processing? ☐[1]Yes ☐[0]No BIO18C

- ☐ Broken Tube BIO18C1
- ☐ Sample re-centrifuged BIO18C2
- ☐ Clotted BIO18C3
- ☐ Hemolyzed BIO18C4
- ☐ Lipemic BIO18C5
- ☐ Other BIO18C6

Specify:_____ BIO18C6A

d. Freezer box number: ☐☐☐☐ BIO18D

Urine Sample

19. Was a urine sample collected? ..... ☐[1]Yes ☐[0]No BIO19

20. Date of urine sample: ..... ☐☐/☐☐/☐☐☐☐ BIO20
m m / d d / y y y y

21. Time urine sample collected: ..... BIO21 : ☐☐ AM / PM BIO21_AMPM
h h : m m **(Circle One)**

22. Time urine sample was processed: ..... BIO22 : ☐☐ AM / PM BIO22_AMPM
h h : m m **(Circle One)**

23. Number of aliquots with preservative:..... ☐☐ BIO23

24. Number of aliquots without preservative:... ☐☐ BIO24

25. Is this patient able to become pregnant?... ☐[1]Yes ☐[0]No **If yes, complete Item 26** BIO25

26. Pregnancy test requested? ..... ☐[1]Yes ☐[0]No BIO26

26a. Was the participant pregnant? ☐[1]Yes ☐[0]No BIO26A

27. Processor's code #:..... ☐☐☐ BIO27

28. Comments on blood processing, urine collection/processing, and CBC: BIO28

_____

_____

_____

BRONCHITIS INDEX SCORING FORM

ID NUMBER:	BLINDID				

FORM CODE: **BIS**
VERSION: **1.0** 3/2/12

Visit Number VISIT

SEQ # ☐☐☐

0a) Form Date: ..... ☐☐/☐☐/☐☐☐☐ BIS0A

0b) Code ..... ☐☐☐ BIS0B

Instructions: *This form should be completed during the participant's visit.*

1) Erythema ..... ☐ BIS1

Normal 0
Light Red 1
Red 2
Beefy Red 3

2) Edema ..... ☐ BIS2

Normal airway 0
Blunting of bifurcations 1
Airway Narrowing 2
Airway occluded 3

3) Secretions ..... ☐ BIS3

Normal 0
Strands of clear mucus 1
Globules of mucus 2
Airway occluded 3

4) Friability ..... ☐ BIS4

Normal 0
Punctate submucosal hemorrhages 1
Linear submucosal hemorrhages 2
Frank bleeding 3

BASELINE MEDICAL HISTORY FORM

ID NUMBER:	BLINDID				

FORM CODE: **BMH**
VERSION: **2.0** 7/6/11

Visit Number VISIT

SEQ # ☐☐☐

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ 0b) Initials..... ☐☐☐

Instructions: *Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

This questionnaire includes a number of questions about your medical history. This will help us better understand how various medical conditions relate to COPD.

1) Have you had any hospitalizations with in the past 12 months? (Y/N) ..... ☐ BMH01

If **YES**:

1a) Describe: BMH01A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01A1

1b) Describe: BMH01B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01B1

1c) Describe: BMH01C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01C1

1d) Describe: BMH01D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01D1

1e) Describe: BMH01E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01E1

1f) Describe: BMH01F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01F1

1g) Describe: BMH01G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01G1

1h) Describe: BMH01H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01H1

2) Have you visited an emergency department or urgent care center in the past 12 months? (Y/N) ..... ☐ BMH02

If **YES**:

2a) Describe: BMH02A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02A1

2b) Describe: BMH02B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02B1

2c) Describe: BMH02C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02C1

2d) Describe: BMH02D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02D1

2e) Describe: BMH02E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02E1

2f) Describe: BMH02F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02F1

2g) Describe: BMH02G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02G1

2h) Describe: BMH02H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02H1

2i) Describe: BMH02I _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02I1

2j) Describe: BMH02J _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02J1

3) Have you ever had any surgeries (lung, heart, other)? (Y/N) ..... ☐ BMH03

If **YES**:

3a) Describe: BMH03A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03A1

3b) Describe: BMH03B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03B1

3c) Describe: BMH03C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03C1

3d) Describe: BMH03D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03D1

3e) Describe: BMH03E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03E1

3f) Describe: BMH03F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03F1

3g) Describe: BMH03G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03G1

3h) Describe: BMH03H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03H1

3i) Describe: BMH03I _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03I1

3j) Describe: BMH03J _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03J1

4) Do you get an influenza vaccination (flu shot) every year? BMH04

- ☐ Yes → **Go to 4b**
- ☐ I get a flu shot some years → **Go to 4b**
- ☐ I've never had a flu shot → **Go to 5**

4b) Did you get an influenza vaccination (flu shot) in the last 12 months? BMH04B

- ☐ Yes
- ☐ No

5) When was your most recent pneumonia vaccination? (Pneumovax) BMH05
   - ☐ Never had
   - ☐ Within past 5 years
   - ☐ More than 5 years ago

6) Have you been diagnosed with alpha-1 anti-trypsin deficiency? BMH06
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

Have you ever seen a physician or other medical provider for any of the following kinds of problems?

		Yes	No	Explain
7)	Eyes, ears, nose, throat			
a)	Vision problems BMH07A	☐	☐	BMH07A1
b)	Hearing problems BMH07B	☐	☐	BMH07B1
c)	Dizziness BMH07C	☐	☐	BMH07C1
d)	Ears ringing BMH07D	☐	☐	BMH07D1
e)	Sinusitis/rhinitis BMH07E	☐	☐	BMH07E1
f)	Other BMH07F	☐	☐	BMH07F1

		Yes	No	Explain
8)	Cardiovascular			
a)	High blood pressure BMH08A		☐	BMH08A1
b)	Coronary artery disease BMH08B		☐	BMH08B1
c)	Angina (chest pain) BMH08C	☐	☐	BMH08C1
d)	Heart attack BMH08D	☐	☐	BMH08D1
e)	Murmur BMH08E	☐	☐	BMH08E1
f)	Palpitations, irregular heartbeat BMH08F		☐	BMH08F1
g)	Valve disease BMH08G	☐	☐	BMH08G1
h)	Congestive heart failure BMH08H		☐	BMH08H1
i)	Blood clots BMH08I	☐	☐	BMH08I1
j)	Poor circulation (claudication) BMH08J	☐	☐	BMH08J1
k)	Other BMH08K	☐	☐	BMH08K1

9) Gastrointestinal	Yes	No	Explain
a) Esophageal condition or disease BMH09A	☐	☐	BMH09A1
b) Ulcers BMH09B	☐	☐	BMH09B1
c) Hepatitis or jaundice BMH09C	☐	☐	BMH09C1
d) Crohn's disease or colitis BMH09D	☐	☐	BMH09D1
e) Gallstones BMH09E	☐	☐	BMH09E1
f) Cirrhosis BMH09F	☐	☐	BMH09F1
g) GERD (heart burn) BMH09G	☐	☐	BMH09G1
h) Hiatal hernia BMH09H	☐	☐	BMH09H1
i) Other BMH09I	☐	☐	BMH09I1

10) Pulmonary/vascular	Yes	No	Explain
a) Intubation or respirator BMH10A	☐	☐	BMH10A1
b) Pneumothorax (collapsed lung) BMH10B	☐	☐	BMH10B1
c) Tuberculosis BMH10C	☐	☐	BMH10C1
d) Pulmonary fibrosis BMH10D	☐	☐	BMH10D1
e) Lung nodules BMH10E	☐	☐	BMH10E1
f) Pulmonary embolism BMH10F	☐	☐	BMH10F1
g) Other BMH10G	☐	☐	BMH10G1

11) Oncology/hematology	Yes	No	Explain
a) Cancer (except basal cell skin cancer) BMH11A	☐	☐	BMH11A1
b) Anemia BMH11B	☐	☐	BMH11BEXP
c) Other BMH11C	☐	☐	BMH11C1

12) Genitourinary and reproductive	Yes	No	Explain
a) Menstrual symptoms (women) BMH12A	☐	☐	BMH12A1
b) Enlarged prostate or BPH (men) BMH12B	☐	☐	BMH12B1
c) Bladder or kidney problems/ kidney stones BMH12C	☐	☐	BMH12C1
d) Other BMH12D	☐	☐	BMH12DEXP

13) Endocrine	Yes	No	Explain
a) Diabetes BMH13A	☐	☐	BMH13A1
b) Thyroid BMH13B	☐	☐	BMH13B1
c) Other BMH13C	☐	☐	BMH13CEXP

14) Neurology	Yes	No	Explain
a) Stroke BMH14A	☐	☐	BMH14A1
b) Headaches BMH14B	☐	☐	BMH14B1
c) Seizure BMH14C	☐	☐	BMH14C1
d) Other BMH14D	☐	☐	BMH14D1

15) Muscular/skeletal	Yes	No	Explain
a) Rheumatoid arthritis BMH15A		☐	BMH15A1
b) Gout BMH15B	☐	☐	BMH15B1
	Yes	No	Explain .....
c) Osteoporosis BMH15C	☐	☐	BMH15C1
d) Fractures BMH15D	☐	☐	BMH15D1
e) Joint pain BMH15E	☐	☐	BMH15E1
f) Osteoarthritis BMH15F	☐	☐	BMH15F1
g) Other BMH15G	☐	☐	BMH15G1

16) Dermatology	Yes	No	Explain
a) Rashes/hives/eczema BMH16A		☐	BMH16A1
b) Psoriasis BMH16B	☐	☐	BMH16BEXP
c) Shingles BMH16C	☐	☐	BMH16C1
d) Other BMH16D	☐	☐	BMH16D1

17) Infectious disease	Yes	No	Explain
a) Atypical mycobacteria (MAC, MAI) BMH17A		☐	BMH17A1
b) Fungal disease BMH17B	☐	☐	BMH17B1
c) Other BMH17C	☐	☐	BMH17C1

18) Psychiatric	Yes	No	Explain
a) Anxiety BMH18A	☐	☐	BMH18A1
b) Depression BMH18B	☐	☐	BMH18B1
c) Other BMH18C	☐	☐	BMH18C1

19) Other significant problems	Yes	No	
not reported in questions 2-18 BMH19		☐	a) BMH19A
			b) BMH19B
			c) BMH19C
			d) BMH19D
			e) BMH19E

These next questions refer to recent illnesses or problems you may have had.

20) In the last two weeks have you had any of the following:

20a) A fever, cold, flu, or sore throat? (Y/N) ..... ☐ BMH20A

20b) A urinary tract infection? (Y/N) ..... ☐ BMH20B

20c) Seasonal allergies? (Y/N) ..... ☐ BMH20C

20d) A sinus infection or sinusitis? (Y/N) ..... ☐ BMH20D

20e) A tooth infection? (Y/N) ..... ☐ BMH20E

20f) A flare up of gout? (Y/N) ..... ☐ BMH20F

20g) A flare up of arthritis? (Y/N) ..... ☐ BMH20G

20h) Other? (Y/N) ..... ☐ BMH20H

20i) Please explain: BMH20I _____

21) Are you allergic to any medications, latex, food, or substances? (Y/N) ..... ☐ BMH21

If **YES**:

List substance:	Reaction
a) BMH21A	BMH21A1
b) BMH21B	BMH21B1
c) BMH21C	BMH21C1
d) BMH21D	BMH21D1
e) BMH21E	BMH21E1

22) In the past 12 months, how often have you consumed any alcohol containing beverage (beer, wine, wine coolers, liquor, or mixed drinks such as margaritas, martinis, or daiquiris)? *(check only one)* BMH22

- Every Day ..... ☐
- 4 to 6 days per week ..... ☐
- 2 to 3 days per week ..... ☐
- Once per week ..... ☐
- 1 to 3 times per month ..... ☐
- Less than once per month ..... ☐
- No alcohol in the past 12 months ..... ☐ →**Go to 29**

23) When you drink alcohol containing beverages, how many do you usually drink at one sitting? *(check only one)* BMH23

- 1 or 2 ..... ☐
- 3 or 4 ..... ☐
- 5 or 6 ..... ☐
- More than 6 ..... ☐

24) What kind of alcoholic beverages do you usually drink? *(check all that apply)*

- Beer ..... ☐ BMH24_1
- Wine ..... ☐ BMH24_2
- Drinks containing liquor ..... ☐ BMH24_3

25) How often do you have eight or more drinks on one occasion? BMH25

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

26) How often during the last year have you been unable to remember what happened the night before because you had been drinking? BMH26

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

27) How often during the last year have you failed to do what was normally expected of you because of your drinking? BMH27

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

28) Has a relative or friend, a doctor or other health worker been concerned about your drinking or suggested you cut down? BMH28

- No ..... ☐
- Yes, but not in the last year ..... ☐
- Yes in the last year ..... ☐

If participant is MALE, skip to 44
If participant is FEMALE, continue

29) At what age did you begin monthly menstruation *(monthly period)*? ..... ☐☐ yrs old BMH29

30) Have you reach menopause? ..... ☐ BMH30

- Yes ..... Y
- No ..... N → **Go to 31**
- I don't know ..... U → **Go to 31**

31) If you have reached menopause, at what age did that occur? ..... ☐☐ yrs old BMH31

32) Did you ever use oral contraceptive medications? ..... ☐ BMH32

- Yes ..... Y
- No ..... N → **Go to 33**

33) If you did use oral contraceptives, for how many years? ..... ☐☐ years BMH33

34) Did you ever use hormone replacement therapy? ..... ☐ BMH34

- Yes ..... Y
- No ..... N → **Go to 35**

35) If you did use hormone replacement therapy, for how many years? ..... ☐☐ years BMH35

36) Have you ever been pregnant *(include miscarriage, abortions)*? ..... [ ] BMH36

Yes ..... Y

No ..... N → **Go to 40**

37) If you have been pregnant, how old were you at the time of your first pregnancy? ..... [ ][ ] yrs old BMH37

38) How many times have you been pregnant? ..... [ ][ ] BMH38

39) Did you ever breastfeed? ..... [ ] BMH39

Yes ..... Y

No ..... N → **Go to 41**

40) If you did breastfeed, for approximately how many total months did you breastfeed *(total for all pregnancies)*? ..... [ ][ ] months BMH40

41) Have you ever had an ovary removed? ..... [ ] BMH41

Yes ..... Y

No ..... N → **Go to END**

42) If you had an ovary removed, was one removed or both? ..... [ ] BMH42

One ..... O

Both ..... B

43) At what age was your ovary or ovaries removed? ..... [ ][ ] yrs old BMH43

BASELINE MEDICAL HISTORY FORM

ID NUMBER:	BLINDID				

FORM CODE: BMH
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ # ☐☐☐

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ 0b) Initials..... ☐☐☐

Instructions: *Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

This questionnaire includes a number of questions about your medical history. This will help us better understand how various medical conditions relate to COPD.

1) Have you had any hospitalizations with in the past 12 months? (Y/N) ..... ☐ BMH01

If **YES**:

1a) Describe: BMH01A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01A1

1b) Describe: BMH01B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01B1

1c) Describe: BMH01C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01C1

1d) Describe: BMH01D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01D1

1e) Describe: BMH01E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01E1

1f) Describe: BMH01F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01F1

1g) Describe: BMH01G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01G1

1h) Describe: BMH01H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH01H1

2) Have you visited an emergency department or urgent care center in the past 12 months? (Y/N) ..... ☐ BMH02

If **YES**:

2a) Describe: BMH02A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02A1

2b) Describe: BMH02B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02B1

2c) Describe: BMH02C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02C1

2d) Describe: BMH02D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02D1

2e) Describe: BMH02E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02E1

2f) Describe: BMH02F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02F1

2g) Describe: BMH02G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02G1

2h) Describe: BMH02H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02H1

2i) Describe: BMH02I _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02I1

2j) Describe: BMH02J _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH02J1

3) Have you ever had any surgeries (lung, heart, other)? (Y/N) ..... ☐ BMH03

If **YES**:

3a) Describe: BMH03A _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03A1

3b) Describe: BMH03B _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03B1

3c) Describe: BMH03C _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03C1

3d) Describe: BMH03D _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03D1

3e) Describe: BMH03E _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03E1

3f) Describe: BMH03F _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03F1

3g) Describe: BMH03G _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03G1

3h) Describe: BMH03H _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03H1

3i) Describe: BMH03I _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03I1

3j) Describe: BMH03J _____

Approximate date: ☐☐/☐☐/☐☐☐☐ BMH03J1

4) Do you get an influenza vaccination (flu shot) every year? BMH04

☐ Yes

☐ I get a flu shot some years

☐ I've never had a flu shot →**Go to 5**

4a) When was you most recent influenza vaccination? (month/year) ..... ☐☐/☐☐☐☐ BMH04A

5) When was your most recent pneumonia vaccination? (Pneumovax) BMH05
- ☐ Never had
- ☐ Within past 5 years
- ☐ More than 5 years ago

6) Have you been diagnosed with alpha-1 anti-trypsin deficiency? BMH06
- ☐ Yes
- ☐ No
- ☐ Don't know

Have you ever seen a physician or other medical provider for any of the following kinds of problems?

	Yes	No	Explain
7) Eyes, ears, nose, throat			
a) Vision problems BMH07A	☐	☐	BMH07A1
b) Hearing problems BMH07B	☐	☐	BMH07B1
c) Dizziness BMH07C	☐	☐	BMH07C1
d) Ears ringing BMH07D	☐	☐	BMH07D1
e) Sinusitis/rhinitis BMH07E	☐	☐	BMH07E1
f) Other BMH07F	☐	☐	BMH07F1

8) Cardiovascular	Yes	No	Explain
a) High blood pressure BMH08A		☐	BMH08A1
b) Coronary artery disease BMH08B		☐	BMH08B1
c) Angina (chest pain) BMH08C	☐	☐	BMH08C1
d) Heart attack BMH08D	☐	☐	BMH08D1
e) Murmur BMH08E	☐	☐	BMH08E1
f) Palpitations, irregular heartbeat BMH08F		☐	BMH08F1
g) Valve disease BMH08G	☐	☐	BMH08G1
h) Congestive heart failure BMH08H		☐	BMH08H1
i) Blood clots BMH08I	☐	☐	BMH08I1
j) Poor circulation (claudication) BMH08J	☐	☐	BMH08J1
k) Other BMH08K	☐	☐	BMH08K1

9) Gastrointestinal	Yes	No	Explain
a) Esophageal condition or disease BMH09A	☐	☐	BMH09A1
b) Ulcers BMH09B	☐	☐	BMH09B1
c) Hepatitis or jaundice BMH09C	☐	☐	BMH09C1
d) Crohn's disease or colitis BMH09D	☐	☐	BMH09D1
e) Gallstones BMH09E	☐	☐	BMH09E1
f) Cirrhosis BMH09F	☐	☐	BMH09F1
g) GERD (heart burn) BMH09G	☐	☐	BMH09G1
h) Hiatal hernia BMH09H	☐	☐	BMH09H1
i) Other BMH09I	☐	☐	BMH09I1

10) Pulmonary/vascular	Yes	No	Explain
a) Intubation or respirator BMH10A	☐	☐	BMH10A1
b) Pneumothorax (collapsed lung) BMH10B	☐	☐	BMH10B1
c) Tuberculosis BMH10C	☐	☐	BMH10C1
d) Pulmonary fibrosis BMH10D	☐	☐	BMH10D1
e) Lung nodules BMH10E	☐	☐	BMH10E1
f) Pulmonary embolism BMH10F	☐	☐	BMH10F1
g) Other BMH10G	☐	☐	BMH10G1

11) Oncology/hematology	Yes	No	Explain
a) Cancer (except basal cell skin cancer) BMH11A	☐	☐	BMH11A1
b) Anemia BMH11B	☐	☐	BMH11BEXP
c) Other BMH11C	☐	☐	BMH11C1

12) Genitourinary and reproductive	Yes	No	Explain
a) Menstrual symptoms (women) BMH12A	☐	☐	BMH12A1
b) Enlarged prostate or BPH (men) BMH12B	☐	☐	BMH12B1
c) Bladder or kidney problems/ kidney stones BMH12C	☐	☐	BMH12C1
d) Other BMH12D	☐	☐	BMH12DEXP

13) Endocrine	Yes	No	Explain
a) Diabetes BMH13A	☐	☐	BMH13A1
b) Thyroid BMH13B	☐	☐	BMH13B1
c) Other BMH13C	☐	☐	BMH13CEXP

14) Neurology	Yes	No	Explain
a) Stroke BMH14A	☐	☐	BMH14A1
b) Headaches BMH14B	☐	☐	BMH14B1
c) Seizure BMH14C	☐	☐	BMH14C1
d) Other BMH14D	☐	☐	BMH14D1

15) Muscular/skeletal	Yes	No	Explain
a) Rheumatoid arthritis BMH15A		☐	BMH15A1
b) Gout BMH15B	☐	☐	BMH15B1
	Yes	No	Explain .....
c) Osteoporosis BMH15C	☐	☐	BMH15C1
d) Fractures BMH15D	☐	☐	BMH15D1
e) Joint pain BMH15E	☐	☐	BMH15E1
f) Osteoarthritis BMH15F	☐	☐	BMH15F1
g) Other BMH15G	☐	☐	BMH15G1

16) Dermatology	Yes	No	Explain
a) Rashes/hives/eczema BMH16A		☐	BMH16A1
b) Psoriasis BMH16B	☐	☐	BMH16BEXP
c) Shingles BMH16C	☐	☐	BMH16C1
d) Other BMH16D	☐	☐	BMH16D1

17) Infectious disease	Yes	No	Explain
a) Atypical mycobacteria (MAC, MAI) BMH17A		☐	BMH17A1
b) Fungal disease BMH17B	☐	☐	BMH17B1
c) Other BMH17C	☐	☐	BMH17C1

18) Psychiatric	Yes	No	Explain
a) Anxiety BMH18A	☐	☐	BMH18A1
b) Depression BMH18B	☐	☐	BMH18B1
c) Other BMH18C	☐	☐	BMH18C1

19) Other significant problems not reported in questions 2-18 BMH19	Yes	No
		☐

a) BMH19A
b) BMH19B
c) BMH19C
d) BMH19D
e) BMH19E

These next questions refer to recent illnesses or problems you may have had.

20) In the last two weeks have you had any of the following:

20a) A fever, cold, flu, or sore throat? (Y/N) ..... ☐ BMH20A

20b) A urinary tract infection? (Y/N) ..... ☐ BMH20B

20c) Seasonal allergies? (Y/N) ..... ☐ BMH20C

20d) A sinus infection or sinusitis? (Y/N) ..... ☐ BMH20D

20e) A tooth infection? (Y/N) ..... ☐ BMH20E

20f) A flare up of gout? (Y/N) ..... ☐ BMH20F

20g) A flare up of arthritis? (Y/N) ..... ☐ BMH20G

20h) Other? (Y/N) ..... ☐ BMH20H

20i) Please explain: BMH20I _____

21) Are you allergic to any medications, latex, food, or substances? (Y/N) ..... ☐ BMH21

If **YES**:

List substance:	Reaction
a) BMH21A	BMH21A1
b) BMH21B	BMH21B1
c) BMH21C	BMH21C1
d) BMH21D	BMH21D1
e) BMH21E	BMH21E1

22) In the past 12 months, how often have you consumed any alcohol containing beverage (beer, wine, wine coolers, liquor, or mixed drinks such as margaritas, martinis, or daiquiris)? *(check only one)* BMH22

- Every Day ..... ☐
- 4 to 6 days per week ..... ☐
- 2 to 3 days per week ..... ☐
- Once per week ..... ☐
- 1 to 3 times per month ..... ☐
- Less than once per month ..... ☐
- No alcohol in the past 12 months ..... ☐ →**Go to 29**

23) When you drink alcohol containing beverages, how many do you usually drink at one sitting? *(check only one)* BMH23

- 1 or 2 ..... ☐
- 3 or 4 ..... ☐
- 5 or 6 ..... ☐
- More than 6 ..... ☐

24) What kind of alcoholic beverages do you usually drink? *(check all that apply)*

- Beer ..... ☐ BMH24_1
- Wine ..... ☐ BMH24_2
- Drinks containing liquor ..... ☐ BMH24_3

25) How often do you have eight or more drinks on one occasion? BMH25

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

26) How often during the last year have you been unable to remember what happened the night before because you had been drinking? BMH26

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

27) How often during the last year have you failed to do what was normally expected of you because of your drinking? BMH27

Never ..... ☐
Less than monthly ..... ☐
Monthly ..... ☐
Weekly ..... ☐
Daily or almost daily ..... ☐

28) Has a relative or friend, a doctor or other health worker been concerned about your drinking or suggested you cut down? BMH28

No ..... ☐
Yes, but not in the last year ..... ☐
Yes in the last year ..... ☐

If participant is MALE, skip to 44
If participant is FEMALE, continue

29) At what age did you begin monthly menstruation *(monthly period)*? ..... ☐☐ yrs old BMH29

30) Have you reach menopause? ..... ☐ BMH30

Yes ..... Y
No ..... N → **Go to 31**
I don't know ..... U → **Go to 31**

31) If you have reached menopause, at what age did that occur? ..... ☐☐ yrs old BMH31

32) Did you ever use oral contraceptive medications? ..... ☐ BMH32

Yes ..... Y
No ..... N → **Go to 33**

33) If you did use oral contraceptives, for how many years? ..... ☐☐ years BMH33

34) Did you ever use hormone replacement therapy? ..... ☐ BMH34

Yes ..... Y
No ..... N → **Go to 35**

35) If you did use hormone replacement therapy, for how many years? ..... ☐☐ years BMH35

36) Have you ever been pregnant *(include miscarriage, abortions)*? ..... [ ] BMH36

Yes ..... Y

No ..... N → **Go to 40**

37) If you have been pregnant, how old were you at the time of your first pregnancy? ..... [ ][ ] yrs old BMH37

38) How many times have you been pregnant? ..... [ ][ ] BMH38

39) Did you ever breastfeed? ..... [ ] BMH39

Yes ..... Y

No ..... N → **Go to 40**

40) If you did breastfeed, for approximately how many total months did you breastfeed *(total for all pregnancies)*? ..... [ ][ ] months BMH40

41) Have you ever had an ovary removed? ..... [ ] BMH41

Yes ..... Y

No ..... N → **Go to 43**

42) If you had an ovary removed, was one removed or both? ..... [ ] BMH42

One ..... O

Both ..... B

43) At what age was your ovary or ovaries removed? ..... [ ][ ] yrs old BMH43

BLOOD PRESSURE FORM

ID NUMBER:	BLINDID	FORM CODE: BPF VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date: ..... ☐☐/☐☐/☐☐☐☐ BPF0A 0b) Initials..... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

1) Was blood pressure taken from right arm? ..... ☐ BPF01

Yes ..... Y → **Go to Item 2**

No ..... N

a) If no, please explain: BPF01A _____

2) Arm circumference (cm) ..... ☐☐ BPF02

3) Cuff size: (arm circumference in brackets) ..... ☐ BPF03

Small 1

Adult 2

Large 3

X Large 4

4) Respiration Rate ..... ☐☐ BPF04 per minute

5) Time first blood pressure taken: ..... BPF05 ☐☐:☐☐ AM / PM *(circle one)* BPF05_AMPM

a) Systolic ..... ☐☐☐ mm Hg BPF05A

b) Diastolic ..... ☐☐☐ mm Hg BPF05B

c) Heart Rate ..... ☐☐☐ beats/min BPF05C

6) Time second blood pressure taken: ..... BPF06 ☐☐:☐☐ AM / PM *(circle one)* BPF06_AMPM

a) Systolic ..... ☐☐☐ mm Hg BPF06A

b) Diastolic ..... ☐☐☐ mm Hg BPF06B

c) Heart Rate ..... ☐☐☐ beats/min BPF06C

7) Time third blood pressure taken: ..... BPF07 : AM / PM *(circle one)* BPF07_AMPM

a) Systolic ..... mm Hg BPF07A

b) Diastolic ..... mm Hg BPF07B

c) Heart Rate ..... beats/min BPF07C

BRONCHOSCOPY SPECIMEN PROCESSING WORKSHEET

ID NUMBER: BLINDID

FORM CODE: **BPW**
VERSION: **3.0** 06/10/14

Visit Number VISIT

SEQ #

0a. Form Date..... __ __/__ __/__ __ __ __ BPW0A 0b. Initials..... __ __ __ BPW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

BLOOD

1. Heparin Tube for Immunophenotyping

a. Time Processed: BPW1A __ __ : __ __ (h h : m m) AM / PM (Circle One) BPW1A1

b. Problems Processing? ☐[1]Yes ☐[0]No BPW1B

- ☐ Broken Tube BPW1B1
- ☐ Sample re-centrifuged BPW1B2
- ☐ Clotted BPW1B3
- ☐ Hemolyzed BPW1B4
- ☐ Lipemic BPW1B5
- ☐ Other BPW1B6

Specify:_____ BPW1B7

c. Number of pre-made blood assay antibody tubes used: __ __ BPW1C

d. Time aliquots placed in refrigerator BPW1D __ __ : __ __ AM / PM (Circle One) BPW1D1

ORAL SPECIMEN

2. Time Processed: BPW2 __ __ : __ __ AM / PM (Circle One) BPW2A

3. Number of 15mL conical tubes: __ BPW3

4. Time 15mL conical tubes placed in refrigerator: BPW4 __ __ : __ __ AM / PM (Circle One) BPW4A

5. Date 15mL conical tubes moved to freezer: __ __/__ __/__ __ __ __ BPW5

6. Time 15mL conical tubes placed in freezer: BPW6 __ __ : __ __ AM / PM (Circle One) BPW6A

ID NUMBER:									FORM CODE: BPW VERSION: **3.0** 06/10/14	Visit Number			SEQ #			

SALINE SPECIMENS

7. Time Sterile Saline placed in freezer: BPW7_V3 ☐☐:☐☐ AM / PM (Circle One) BPW7A_V3

8. Time Scope Saline placed in freezer: BPW8_V3 ☐☐:☐☐ AM / PM (Circle One) BPW8A_V3

PROTECTED BRUSH SPECIMEN

9. Time Processed: BPW7 ☐☐:☐☐ AM / PM (Circle One) BPW7A

10. Problems Processing? ☐Yes ☐No BPW8

☐Blood in the sample BPW8A
☐Other BPW8B
Specify:_____ BPW8C

11. Time placed in refrigerator: BPW9 ☐☐:☐☐ AM / PM (Circle One) BPW9A

12. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW10

13. Time placed in freezer: BPW11 ☐☐ AM / PM (Circle One) BPW11A

INITIAL AIRWAY WASH

14. Was more than 8mL returned from the first 20 cc airway wash? (Y/N) ☐ BPW12
If No, skip to question 19 (Cell Count)

Microbiome sample in RNALater:

15. Time Processed: BPW13 ☐☐ AM / PM (Circle One) BPW13A

16. Time placed in refrigerator: BPW14 ☐☐ AM / PM (Circle One) BPW14A

17. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW15

18. Time placed in freezer: BPW16 ☐☐ AM / PM (Circle One) BPW16A

Cell count:

19. Time Processed: BPW17 ☐☐ AM / PM (Circle One) BPW17A

ID NUMBER:									FORM CODE: BPW VERSION: **3.0** 06/10/14	Visit Number			SEQ #			

20. Total volume returned: ☐☐☐.☐ mL BPW18

21. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4 = ☐☐☐☐☐☐☐☐☐☐ cells/mL BPW19

22. Total cell count= # cells/mL x Wash returned = ☐☐☐☐☐☐☐☐☐☐ cells BPW20

23. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x volume of wash in 10mL tube=
☐☐☐☐☐☐☐☐☐☐ cells in 10 mL tube BPW21

24. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6 = ☐☐☐☐.☐ mL BPW22

25. Number of cytospin slides created: ☐ BPW23

Supernatant Aliquots

26. Time Processed: ☐☐.☐☐ AM / PM **(**Circle One) BPW24A

27. Number of 500ul aliquots created: ☐☐ BPW25

28. Time placed in freezer.....☐☐.☐☐ AM / PM (Circle One) BPW26A

QIAzol RNA prep of cell pellet

29. Time Processed: ☐☐.☐☐ AM / PM (Circle One) BPW27A

30. Time placed in freezer.....☐☐.☐☐ AM / PM (Circle One) BPW28A

BAL:

31. Time Processed: ☐☐.☐☐ AM / PM (Circle One) BPW29A

32. Total volume returned: ☐☐☐☐.☐ mL BPW30

33. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐☐☐ cells/mL BPW31

34. Total cell count= # cells/mL x BAL returned: ☐☐☐☐☐☐☐☐☐☐ cells BPW32

35. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x 10 mL: ☐☐☐☐☐☐☐☐☐☐ BPW33
cells in 10 mL tube

36. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6: ☐☐☐☐.☐ mL BPW34

ID NUMBER:									FORM CODE: BPW VERSION: **3.0** 06/10/14	Visit Number			SEQ #			

Microbiome sample with RNA Later:

37a. Time Processed: BPW35 ☐☐ AM / PM (Circle One) BPW35A

37b. Time placed in refrigerator .... BPW36 ☐☐ AM / PM (Circle One) BPW36A

38a. Date moved to freezer:..... ☐☐/☐☐/☐☐☐☐ BPW37

38b. Time placed in freezer..... BPW38 ☐☐ AM / PM (Circle One) BPW38A

Microbiome sample with no reagent:

39. Time transferred to 15mL conical: BPW39_V3 ☐☐.☐☐ AM / PM (Circle One) BPW39A_V3

40. Time placed in freezer: BPW40_V3 ☐☐.☐☐ AM / PM (Circle One) BPW40A_V3

Supernatant sample:

41. Time Processed: BPW39 ☐☐.☐☐ AM / PM (Circle One) BPW39A

42. Number of 500ul aliquots made: ☐☐ BPW40

42a. Number of 15mL aliquots made: ☐☐ BPW40A

43. Time placed in freezer..... BPW41 ☐☐ AM / PM (Circle One) BPW41A

Cytospin slide sample:

44. Time Processed: BPW42 ☐☐ AM / PM (Circle One) BPW42A

45. Number of cytospin slides: ☐ BPW43

46. Time stained: BPW44 ☐☐ AM / PM (Circle One) BPW44A

Alveolar Macrophage Isolation

47. Time Processed: BPW45 ☐☐ BPW45A AM / PM (Circle One) **(must be exactly 2 hours after collection)**

47b. Volume of BAL remaining: ☐☐☐☐.☐ mL BPW45B
(This is the volume after microbiome (if done), cell count, and cytospin samples are completed)

The total cell concentration remaining (volume of BAL remaining * Question 34 above)/10mL:

48a. Is the time processed less than 2 hours after collection? (Y/N) ☐ BPW46 BPW46A

b. Minutes since collection: ☐☐☐ BPW46B

c. Reason processed before 2 hours:_____ BPW46C

49a. Is the time processed more than 2 hours after collection? (Y/N) ☐ BPW47A

b. Minutes since collection: ☐☐☐ BPW47B

c. Reason processed after 2 hours:_____ BPW47C

50. Time Processing Complete: BPW48 ☐☐ AM / PM (Circle One) BPW48A

51. Time Placed in freezer: BPW49 ☐☐ AM / PM (Circle One) BPW49A

Immunophenotyping BAL:

52. Time Processed: BPW50 ☐☐ AM / PM (Circle One) BPW50A

53. Number of pre-made BAL assay antibody tubes used: ☐☐ BPW51

54. Time placed in refrigerator: BPW52 ☐☐ AM / PM (Circle One) BPW52A

EPITHELIAL BRUSHES:

55. Problems Processing? ☐[1]Yes ☐[0]No BPW53

☐Blood in the sample BPW53A
☐Other BPW53B
Specify:_____ BPW53C

Cytospin Slides:

56. Time Processed: BPW54 ☐☐ AM / PM (Circle One) BPW54A

57. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐☐☐ cells/mL BPW55

58. Number of cytospin slides: ☐ BPW56

Epithelial RNA Extraction:

59. Time Processed: BPW57 ☐☐ AM / PM (Circle One) BPW57A

60. Time placed in freezer: BPW58 ___:___ AM / PM (Circle One) BPW58A

SMALL AIRWAYS EPITHELIAL BRUSHES (OPTIONAL):

61. Were small airways epithelial brushings collected? ☐Yes ☐No BPW61_V3

62. Problems Processing? ☐Yes ☐No BPW62_V3

☐Blood in the sample BPW62A_V3
☐Other BPW62B_V3
Specify:_____ BPW62C_V3

Cytospin Slides:

63. Time Processed: BPW63 ___:___ AM / PM (Circle One) BPW63A

64. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐☐☐ BPW64 cells/mL

65. Number of cytospin slides: ☐ BPW65

Epithelial RNA Extraction:

66. Time Processed: BPW66 ___:___ AM / PM (Circle One) BPW66A

67. Time placed in freezer: BPW67 ___:___ AM / PM (Circle One) BPW67A

BIOPSIES:

Snap Frozen Biopsies:

68. Time placed in freezer: BPW59 ___:___ AM / PM (Circle One) BPW59A

Formalin Fixed Biopsies:

69. Time placed in cold 10% formalin: BPW60 ___:___ AM / PM (Circle One) BPW60A

70. Time moved to fresh cold 10% formalin: BPW61 ___:___ AM / PM (Circle One) BPW61A

71. Time placed in 70% alcohol at 4 degrees (after formalin fixation): BPW62 ___:___ AM / PM (Circle One) BPW62A

72. Date biopsies placed in 70% alcohol (after formalin fixation): ☐☐/☐☐/☐☐☐☐ BPW72

73. Number of biopsies moved to 70% alcohol: ☐ BPW73

74. If biopsies were lost between collection and the final step of sample fixation, please describe how and why they were lost: BPW74 _____

75. Was subsequent biopsy processing and paraffin embedding completed by a core lab (Y/N)? ☐ BPW75

76. Date biopsies sent to pathology lab: ☐☐/☐☐/☐☐☐☐ BPW76

77. Date paraffin block(s) returned from pathology lab: ☐☐/☐☐/☐☐☐☐ BPW77

78. Number of paraffin block(s): ☐ BPW78

BRONCHOSCOPY SPECIMEN PROCESSING WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: **BPW** VERSION: 2.**0** 3/01/12	Visit Number	VISIT	SEQ #	

0a. Form Completion Date..... __ __ / __ __ / __ __ __ __ BPW0A 0b. Initials..... __ __ __ BPW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

BLOOD

1. Heparin Tube for Immunophenotyping

a. Time Processed: BPW1A __ __ : __ __ AM / PM (Circle One) BPW1A1
h h : m m

b. Problems Processing? ☐ 1 Yes ☐ 0 No BPW1B

☐ Broken Tube BPW1B1
☐ Clotted BPW1B3
☐ Hemolyzed BPW1B4
☐ Lipemic BPW1B5
☐ Other BPW1B6
Specify: BPW1B7 _____

c. Number of pre-made blood assay antibody tubes used: ☐ BPW1C

d. Time aliquots placed in refrigerator BPW1D __ __ : __ __ AM / PM (Circle One) BPW1D1

ORAL SPECIMEN

2. Time Processed: BPW2 __ __ : __ __ AM / PM (Circle One) BPW2A

3. Number of 15mL conical tubes: ☐ BPW3

4. Time 15mL conical tubes placed in refrigerator: BPW4 __ __ : __ __ AM / PM (Circle One) BPW4A

5. Date 15mL conical tubes moved to freezer: __ __ / __ __ / __ __ __ __ BPW5

6. Time 15mL conical tubes placed in freezer: BPW6 __ __ : __ __ AM / PM (Circle One)

PROTECTED BRUSH SPECIMEN

7. Time Processed: BPW7 ☐☐:☐☐ AM / PM (Circle One) BPW7A

8. Problems Processing? ☐[1]Yes ☐[0]No BPW8

☐Blood in the sample BPW8A
☐Other BPW8B
Specify:_____ BPW8C

9. Time placed in refrigerator: BPW9 ☐☐ ☐☐ AM / PM (Circle One) BPW9A

10. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW10

11. Time placed in freezer: BPW11 ☐☐ ☐☐ AM / PM (Circle One) BPW11A

INITIAL AIRWAY WASH

12. Was more than 8mL returned from the first 20 cc airway wash? (Y/N) ☐ BPW12
If No, skip to question 17 (Cell Count)

Microbiome sample:

13. Time Processed: BPW13 ☐☐ ☐☐ AM / PM (Circle One) BPW13A

14. Time placed in refrigerator: BPW14 ☐☐ ☐☐ AM / PM (Circle One) BPW14A

15. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW15

16. Time placed in freezer: BPW16 ☐☐ ☐☐ AM / PM (Circle One) BPW16A

Cell count:

17. Time Processed: BPW17 ☐☐ ☐☐ AM / PM (Circle One) BPW17A

18. Total volume returned: ☐☐☐.☐mL BPW18

19. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4 = ☐☐☐☐☐☐☐☐☐☐ BPW19 cells/mL

20. Total cell count= # cells/mL x Wash returned = ☐☐☐☐☐☐☐☐☐☐ cells BPW20

21. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x volume of wash in 10mL tube=
☐☐☐☐☐☐☐☐☐☐ cells in 10 mL tube BPW21

22. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6 = ☐☐☐☐.☐ mL BPW22

23. Number of cytospin slides created: ☐ BPW23

Supernatant Aliquots

24. Time Processed: BPW24 ☐☐:☐☐ AM / PM **(**Circle One) BPW24A

25. Number of 500ul aliquots created: ☐☐ BPW25

26. Time placed in freezer..... BPW26 ☐☐:☐☐ AM / PM (Circle One) BPW26A

QIAzol RNA prep of cell pellet

27. Time Processed: BPW27 ☐☐:☐☐ AM / PM (Circle One) BPW27A

28. Time placed in freezer..... BPW28 ☐☐:☐☐ AM / PM (Circle One) BPW28A

BAL:

29. Time Processed: BPW29 ☐☐:☐☐ AM / PM (Circle One) BPW29A

30. Total volume returned: ☐☐☐☐.☐ mL BPW30

31. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐☐☐ cells/mL BPW31

32. Total cell count= # cells/mL x BAL returned: ☐☐☐☐☐☐☐☐☐☐ cells BPW32

33. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x 10 mL: ☐☐☐☐☐☐☐☐☐☐ BPW33
cells in 10 mL tube

34. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6: ☐☐☐☐.☐mL BPW34

Microbiome sample:

35. Time Processed: BPW35 AM / PM (Circle One) BPW35A

36. Time placed in refrigerator ..... BPW36 AM / PM (Circle One) BPW36A

37. Date moved to freezer:..... / / BPW37

38. Time placed in freezer..... BPW38 AM / PM (Circle One) BPW38A

Supernatant sample:

39. Time Processed: BPW39 AM / PM (Circle One) BPW39A

40. Number of 500ul aliquots made: BPW40

40a. Number of 15mL aliquots made: BPW40A

41. Time placed in freezer..... BPW41 AM / PM (Circle One) BPW41A

Cytospin slide sample:

42. Time Processed: BPW42 AM / PM (Circle One) BPW42A

43. Number of cytospin slides: BPW43

44. Time stained: BPW44 AM / PM (Circle One) BPW44A

Alveolar Macrophage Isolation

45. Time Processed: BPW45 BPW45A AM / PM (Circle One) **(must be exactly 2 hours after collection)**

45b. Volume of BAL remaining: mL BPW45B
(This is the volume after microbiome (if done), cell count, and cytospin samples are completed)

Total cell concentration remaining (volume of BAL remaining * Question 32 above)/10mL:

46a. Is the time processed less than 2 hours after collection? (Y/N) BPW46A

b. Minutes since collection: BPW46B

c. Reason processed before 2 hours:_____ BPW46C

47a. Is the time processed more than 2 hours after collection? (Y/N) ☐ BPW47A

b. Minutes since collection: ☐☐☐ BPW47B

c. Reason processed after 2 hours:_____ BPW47C

48. Time Processing Complete: BPW48 ☐☐.☐☐ AM / PM (Circle One) BPW48A

49. Time Placed in freezer: BPW49 ☐☐.☐☐ AM / PM (Circle One) BPW49A

Immunophenotyping BAL:

50. Time Processed: BPW50 ☐☐.☐☐ AM / PM (Circle One) BPW50A

51. Number of pre-made BAL assay antibody tubes used: ☐ BPW51

52. Time placed in refrigerator: BPW52 ☐☐.☐☐ AM / PM (Circle One) BPW52A

EPITHELIAL BRUSHES:

53. Problems Processing? ☐[1]Yes ☐[0]No BPW53

☐Blood in the sample BPW53A
☐Other BPW53B
Specify:_____ BPW53C

Cytospin Slides:

54. Time Processed: BPW54 ☐☐.☐☐ AM / PM (Circle One) BPW54A

55. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐☐☐cells/mL BPW55

56. Number of cytospin slides: ☐ BPW56

Epithelial RNA Extraction:

57. Time Processed: BPW57 ☐☐.☐☐ AM / PM (Circle One) BPW57A

58. Time placed in freezer: BPW58 ☐☐.☐☐ AM / PM (Circle One) BPW58A

BIOPSIES:

Snap Frozen Biopsies:

59. Time placed in freezer: BPW59 __ __ : __ __ AM / PM (Circle One) BPW59A

Formalin Fixed Biopsies:

60. Time placed in cold 10% formalin: BPW60 __ __ : __ __ AM / PM (Circle One) BPW60A

61. Time moved to fresh cold 10% formalin: BPW61 __ __ : __ __ AM / PM (Circle One) BPW61A

62. Time placed in 70% alcohol at 4 degrees: BPW62 __ __ : __ __ AM / PM (Circle One) BPW62A

BRONCHOSCOPY SPECIMEN PROCESSING WORKSHEET

ID NUMBER: BLINDID

FORM CODE: **BPW**
VERSION: **1.0** 10/27/11

Visit Number VISIT

SEQ #

0a. Form Completion Date..... __ __ / __ __ / __ __ __ __ BPW0A 0b. Initials..... __ __ __ BPW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

BLOOD

1. Heparin Tube for Immunophenotyping

a. Time Processed: BPW1A __ __ : __ __ AM / PM (Circle One) BPW1A1
h h : m m

b. Problems Processing? ☐ 1 Yes ☐ 0 No BPW1B

☐ Broken Tube BPW1B1
☐ Clotted BPW1B3
☐ Hemolyzed BPW1B4
☐ Lipemic BPW1B5
☐ Other BPW1B6
Specify: BPW1B7 _____

c. Number of pre-made blood assay antibody tubes used: ☐ BPW1C

d. Time aliquots placed in refrigerator BPW1D __ __ : __ __ AM / PM (Circle One) BPW1D1

ORAL SPECIMEN

2. Time Processed: BPW2 __ __ : __ __ AM / PM (Circle One) BPW2A

3. Number of 15mL conical tubes: ☐ BPW3

4. Time 15mL conical tubes placed in refrigerator: BPW4 __ __ : __ __ AM / PM (Circle One) BPW4A

5. Date 15mL conical tubes moved to freezer: __ __ / __ __ / __ __ __ __ BPW5

6. Time 15mL conical tubes placed in freezer: BPW6 __ __ : __ __ AM / PM (Circle One)

PROTECTED BRUSH SPECIMEN

7. Time Processed: BPW7 ☐☐ ☐☐ AM / PM (Circle One) BPW7A

8. Problems Processing? ☐[1]Yes ☐[0]No BPW8

☐Blood in the sample BPW8A
☐Other BPW8B
Specify:_____ BPW8C

9. Time placed in refrigerator: BPW9 ☐☐:☐☐ AM / PM (Circle One) BPW9A

10. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW10

11. Time placed in freezer: BPW11 ☐☐ ☐☐ AM / PM (Circle One) BPW11A

INITIAL AIRWAY WASH

12. Was more than 8mL returned from the first 20 cc airway wash? (Y/N) ☐ BPW12

Microbiome sample:

13. Time Processed: BPW13 ☐☐ ☐☐ AM / PM (Circle One) BPW13A

14. Time placed in refrigerator: BPW14 ☐☐ ☐☐ AM / PM (Circle One) BPW14A

15. Date moved to freezer: ☐☐/☐☐/☐☐☐☐ BPW15

16. Time placed in freezer: BPW16 ☐☐ ☐☐ AM / PM (Circle One) BPW16A

Cell count:

17. Time Processed: BPW17 ☐☐ ☐☐ AM / PM (Circle One) BPW17A

18. Total volume returned: ☐☐☐mL BPW18

19. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4 = ☐☐☐☐☐☐☐☐☐☐ BPW19 cells/mL

20. Total cell count= # cells/mL x BAL returned = ☐☐☐☐☐☐☐☐☐☐ BPW20 cells

21. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x 10 mL = ☐☐☐☐☐☐☐☐☐☐ BPW21 cells in 10 mL tube

22. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6 = ☐☐☐ mL BPW22

23. Number of cytospin slides created: ☐ BPW23

Supernatant Aliquots

24. Time Processed: BPW24 ☐☐:☐☐ AM / PM **(**Circle One) BPW24A

25. Number of aliquots created: ☐☐ BPW25

26. Time placed in freezer..... BPW26 ☐☐:☐☐ AM / PM (Circle One) BPW26A

QIAzol RNA prep of cell pellet

27. Time Processed: BPW27 ☐☐:☐☐ AM / PM (Circle One) BPW27A

28. Time placed in freezer..... BPW28 ☐☐:☐☐ AM / PM (Circle One) BPW28A

BAL:

29. Time Processed: BPW29 ☐☐:☐☐ AM / PM (Circle One) BPW29A

30. Total volume returned: ☐☐☐☐ mL BPW30

31. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ☐☐☐☐☐☐☐☐ cells/mL BPW31

32. Total cell count= # cells/mL x BAL returned: ☐☐☐☐☐☐☐☐ cells BPW32

33. Cytospin suspension= Total cells in 10 mL tube= # cells/mL x 10 mL: ☐☐☐☐☐☐☐☐ BPW33 cells in 10 mL tube

34. Volume to resuspend pellet in with PBS= # cells in tube/0.7 x 10^6: ☐☐☐☐mL BPW34

Microbiome sample:

35. Time Processed: BPW35 AM / PM (Circle One) BPW35A

36. Time placed in refrigerator ..... BPW36 AM / PM (Circle One) BPW36A

37. Date moved to freezer:..... / / BPW37

38. Time placed in freezer..... BPW38 AM / PM (Circle One) BPW38A

Supernatant sample:

39. Time Processed: BPW39 AM / PM (Circle One) BPW39A

40. Number of aliquots made: BPW40

41. Time placed in freezer..... BPW41 AM / PM (Circle One) BPW41A

Cytospin slide sample:

42. Time Processed: BPW42 AM / PM (Circle One) BPW42A

43. Number of cytospin slides: BPW43

44. Time stained: BPW44 AM / PM (Circle One) BPW44A

Alveolar Macrophage Isolation

45. Time Processed: BPW45 BPW45A AM / PM (Circle One) **(must be exactly 2 hours after collection)**

46a. Is the time processed less than 2 hours after collection? (Y/N) BPW46A

b. Minutes since collection: BPW46B

c. Reason processed before 2 hours:_____ BPW46C

47a. Is the time processed more than 2 hours after collection? (Y/N) BPW47A

b. Minutes since collection: BPW47B

c. Reason processed after 2 hours:_____ BPW47C

48. Time Processing Complete: BPW48 AM / PM (Circle One) BPW48A

49. Time Placed in freezer: BPW49 ___ ___ . ___ ___ AM / PM (Circle One) BPW49A

Immunophenotyping BAL:

50. Time Processed: BPW50 ___ ___ . ___ ___ AM / PM (Circle One) BPW50A

51. Number of pre-made BAL assay antibody tubes used: ___ BPW51

52. Time placed in refrigerator: BPW52 ___ ___ . ___ ___ AM / PM (Circle One) BPW52A

EPITHELIAL BRUSHES:

53. Problems Processing? ☐ 1 Yes ☐ 0 No BPW53

☐ Blood in the sample BPW53A
☐ Other BPW53B
Specify:_____ BPW53C

Cytospin Slides:

54. Time Processed: BPW54 ___ ___ . ___ ___ AM / PM (Circle One) BPW54A

55. Cell count= # cells/mL= (# cells in 4 squares/4) x 2 x 10^4: ___ ___ ___ ___ ___ ___ ___ ___ cells/mL BPW55

56. Number of cytospin slides: ___ BPW56

Epithelial RNA Extraction:

57. Time Processed: BPW57 ___ ___ . ___ ___ AM / PM (Circle One) BPW57A

58. Time placed in refrigerator: BPW58 ___ ___ . ___ ___ AM / PM (Circle One) BPW58A

BIOPSIES:

Snap Frozen Biopsies:

59. Time placed in freezer: BPW59 ___ ___ . ___ ___ AM / PM (Circle One) BPW59A

Formalin Fixed Biopsies:

60. Time placed in cold 10% formalin: BPW60 ☐☐:☐☐ AM / PM (Circle One) BPW60A

61. Time moved to fresh cold 10% formalin: BPW61 ☐☐:☐☐ AM / PM (Circle One) BPW61A

62. Time placed in 70% alcohol at 4 degrees: BPW62 ☐☐:☐☐ AM / PM (Circle One) BPW62A

BERLIN SLEEP QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: BSQ VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ BSQ0A 0b) Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please read questions exactly as written, and read all responses to the participant before recording an answer.*

This questionnaire assess breathing trouble while sleeping. I will read you all the response choices. Please select the best response for you for each question.

Category 1

1) Do you snore? ..... __ BSQ01

Yes ..... Y
No ..... N → **Go to 5**
Don't know ..... U → **Go to 5**

If you snore:

2) Your snoring is: ..... __ BSQ02

Slightly louder than breathing ..... A
As loud as talking ..... B
Louder than talking C
Very loud—can be heard in adjacent rooms ..... D

3) How often do you snore? ..... __ BSQ03

Nearly every day ..... A
3-4 times a week ..... B
1-2 times a week C
1-2 times a month ..... D
Never or nearly never ..... E

4) Has your snoring ever bothered other people? ..... __ BSQ04

Yes ..... Y
No ..... N
Don't know ..... U

The Berlin Questionnaire: Netzer NC. "Using the Berlin questionnaire to identify patients at risk for the sleep apnea syndrome. Ann. Int. Med; 131(7): 488 © American College of Physicians. October 5, 1999.

5) Has anyone noticed that you quit breathing during your sleep? ..... [ ] BSQ05

Nearly every day .....A
3-4 times a week.....B
1-2 times a week.....C
1-2 times a month .....D
Never or nearly never.....E

Category 2

6) How often do you feel tired or fatigued after your sleep? ..... [ ] BSQ06

Nearly every day .....A
3-4 times a week.....B
1-2 times a week.....C
1-2 times a month .....D
Never or nearly never.....E

7) During your waking time, do you feel tired, fatigued or not up to par?..... [ ] BSQ07

Nearly every day .....A
3-4 times a week.....B
1-2 times a week.....C
1-2 times a month .....D
Never or nearly never.....E

8) Have you ever nodded off or fallen asleep while driving a vehicle? ..... [ ] BSQ08

Yes.....Y
No .....N → **Go to 10**

If yes:

9) How often does this occur? ..... [ ] BSQ09

Nearly every day .....A
3-4 times a week.....B
1-2 times a week.....C
1-2 times a month .....D
Never or nearly never.....E

Category 3

10) Do you have high blood pressure? ..... [ ] BSQ10

Yes.....Y
No .....N
Don't know.....U

The Berlin Questionnaire: Netzer NC. "Using the Berlin questionnaire to identify patients at risk for the sleep apnea syndrome. Ann. Int. Med; 131(7): 488 © American College of Physicians. October 5, 1999.

BRONCHOSCOPY SPUTUM PROCESSING WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: **BSW** VERSION: 2.**0** 03/06/12	Visit Number	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ BSW0A 0b) Initials..... __ __ __ BSW0B

Instructions: *Complete this form while processing the sputum sample. Carefully record all data in the space provided. When entering times mark them as hours, minutes, and circle AM or PM.*

1. Time processing began: ..... BSW1 __ __ : __ __ AM / PM BSW1A
   h h : m m **(Circle One)**

2. Color and Description of Sample:

   a. Salivary Contamination:
      - ☐ Minimal BSW3A1
      - ☐ Mild BSW3A2
      - ☐ Moderate BSW3A3
      - ☐ Excessive BSW3A4

   b. Consistency:
      - ☐ Watery BSW3B1
      - ☐ Mucoid BSW3B2
      - ☐ Purulent (puss) BSW3B3

   c. Mucus "plugs":
      - ☐ Numerous BSW3C1
      - ☐ Moderate number BSW3C2
      - ☐ Sparse BSW3C3
      - ☐ Large BSW3C4
      - ☐ Small BSW3C5
      - ☐ Dense/flocculent BSW3C6
      - ☐ Diffuse opacity BSW3C7

   d. Color of plugs:
      - ☐ Clear BSW3D1
      - ☐ White BSW3D2
      - ☐ Yellow/Tan BSW3D3
      - ☐ Brown BSW3D4
      - ☐ Green BSW3D5

3. General Notes/Comments: BSW4

_____

_____

_____

4. Time immunophenotyping processing began: ..... BSW5 : BSW5A AM/PM (circle 1)

5. Weight of the 50mL Centrifuge tube: ..... . grams BSW6

Remember to zero the balance.

6. Weight of the sputum: ..... . grams BSW7

Make up 1x Sputolysin: combine 1 ml of sputolysin with 9 mls of distilled water and swirl gently to dissolve crystals

7. Volume of Sputolysin to add (weight of sputum x2): ..... . mL BSW8

8. Time placed in 37°C water bath:..... BSW10 : BSW10A AM/PM (circle 1)

Leave in bath approximately 20 minutes or until the sputum appears viscous with vortexing every 5 minutes.

9. Number of times vortexed: BSW11

10. Time removed from water bath:..... BSW12 : BSW12A AM/PM (circle 1)

11. Volume of PBS added: ..... . mL BSW13

Centrifuge at 300 x g for 5 mins, then decant supernatant. Resuspend cells in 1.0 ml Stain Buffer. Briefly centrifuge immunophenotyping sputum assay antibody tubes (supplied by immunophenotyping core) at 300 x g for 2 mins and uncap tubes

12. Time pre-made sputum assay antibody tubes placed in centrifuge:..... BSW14 : BSW14A AM/PM (circle 1)

Add 100 µl of sputum sample to each tube. Wrap rack with tinfoil to protect from light.

13. Number of pre-made sputum assay antibody tubes used: BSW15

Incubate tubes for 25 minutes at room temperature, with shaking or rocking.

14. Time incubation begin: ..... BSW16 : BSW16A AM/PM (circle 1)

15. Time incubation end: ..... BSW17 : BSW17A AM/PM (circle 1)

Add 2 mls of Stain Buffer to each tube. Centrifuge at 300 x g for 5 mins. Decant supernatant. Prepare 2% formaldehyde solution: Combine 0.2 mls 20% formaldehyde with 1.8 mls Stain Buffer. Add 200 µl of 2% formaldehyde to each tube. Replace caps on tubes; they should snap firmly into place. Wrap rack in a new sheet of tinfoil. Store at 4°C until ready to be shipped

16. Time placed in 4°C storage: ..... BSW18 : BSW18A AM/PM (circle 1)

17. Problems processing: BSW19

_____

_____

_____

_____

_____

BRONCHOSCOPY SPUTUM PROCESSING WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: **BSW** VERSION: **1.0** 10/27/11	Visit Number	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ BSW0A 0b) Initials ..... __ __ __ BSW0B

Instructions: *Complete this form while processing the sputum sample. Carefully record all data in the space provided. When entering times mark them as hours, minutes, and circle AM or PM.*

1. Time processing began: ..... BSW1 __ __ : __ __ AM / PM BSW1A
   h h : m m **(Circle One)**

2. Weight of Entire Sample ..... BSW2 __ __ __ . __ __ grams

3. Color and Description of Sample:

   a. Salivary Contamination:
      - ☐ Minimal BSW3A1
      - ☐ Mild BSW3A2
      - ☐ Moderate BSW3A3
      - ☐ Excessive BSW3A4

   b. Consistency:
      - ☐ Watery BSW3B1
      - ☐ Mucoid BSW3B2
      - ☐ Purulent (puss) BSW3B3

   c. Mucus "plugs":
      - ☐ Numerous BSW3C1
      - ☐ Moderate number BSW3C2
      - ☐ Sparse BSW3C3
      - ☐ Large BSW3C4
      - ☐ Small BSW3C5
      - ☐ Dense/flocculent BSW3C6
      - ☐ Diffuse opacity BSW3C7

   d. Color of plugs:
      - ☐ Clear BSW3D1
      - ☐ White BSW3D2
      - ☐ Yellow/Tan BSW3D3
      - ☐ Brown BSW3D4
      - ☐ Green BSW3D5

4. General Notes/Comments: BSW4

_____

_____

_____

5. Time processing began: ..... BSW5 | | : | | BSW5A AM/PM (circle 1)

6. Weight of the 50mL Centrifuge tube: ..... | | | . | | grams BSW6

Remember to zero the balance.

7. Weight of the sputum: ..... | | | . | | grams BSW7

Make up 1x Sputolysin: combine 1 ml of sputolysin with 9 mls of distilled water and swirl gently to dissolve crystals

8. Volume of Sputolysin to add (weight of sputum x2): ..... | | | . | | mL BSW8

9. Total volume of sputum plus sputolysin: ..... | | | . | | mL BSW9

10. Time placed in 37°C water bath:..... BSW10 | | : | | BSW10A AM/PM (circle 1)

Leave in bath approximately 20 minutes or until the sputum appears viscous with vortexing every 5 minutes.

11. Number of times vortexed: ..... | | BSW11

12. Time removed from water bath:..... BSW12 | | : | | BSW12A AM/PM (circle 1)

13. Volume of PBS added: ..... | | | . | | mL BSW13

Centrifuge at 300 x g for 5 mins, then decant supernatant. Resuspend cells in 1.0 ml Stain Buffer. Briefly centrifuge immunophenotyping sputum assay antibody tubes (supplied by immunophenotyping core) at 300 x g for 2 mins and uncap tubes

14. Time pre-made sputum assay antibody tubes placed in centrifuge:.... BSW14 | | : | | BSW14A AM/PM (circle 1)

Add 100 µl of sputum sample to each tube. Wrap rack with tinfoil to protect from light.

15. Number of pre-made sputum assay antibody tubes used: ..... | | BSW15

Incubate tubes for 25 minutes at room temperature, with shaking or rocking.

16. Time incubation begin: ..... BSW16 : BSW16A AM/PM (circle 1)

17. Time incubation end: ..... BSW17 : BSW17A AM/PM (circle 1)

Add 2 mls of Stain Buffer to each tube. Centrifuge at 300 x g for 5 mins. Decant supernatant. Prepare 2% formaldehyde solution: Combine 0.2 mls 20% formaldehyde with 1.8 mls Stain Buffer. Add 200 µl of 2% formaldehyde to each tube. Replace caps on tubes; they should snap firmly into place. Wrap rack in a new sheet of tinfoil. Store at 4°C until ready to be shipped

18. Time placed in 4°C storage: ..... BSW18 : BSW18A AM/PM (circle 1)

19. Problems processing: BSW19

_____

_____

_____

_____

_____

SPIROMICS CANCER ABSTRACTION FORM (CAF)

ID NUMBER:	SUBJID	FORM CODE: CAF VERSION A 2/16/2015	Visit Number	VISIT	SEQ #	

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month/Day/Year) CAF0A 0b. Staff ID: ☐☐☐ CAF0B

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ CAF0C 0d.Event Date: ☐☐/☐☐/☐☐☐☐ CAF0D

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received or classified as unobtainable as indicated on the Medical Record Shipping Form.

A. GENERAL INFORMATION

1. Was the event ***(choose one)***: ☐ CAF1

   1= In hospital only 2= Emergency Dept. visit only (ED) 3= Both ED and in hospital

2. Date of admission: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ CAF2

3. Date of discharge:(mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ CAF3

4. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐ CAF4

5. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐ CAF5

B. CANCER OUTCOMES

6. Has the patient been diagnosed with a primary cancer? Yes ☐ No ☐ CAF6

7. Date of diagnosis: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ CAF7

8. Type of cancer ***(Mark only one)*** CAF8

Accessory sinuses	☐	Cervix	☐	Larynx	☐	Ovary	☐
Adrenal glands	☐	Colon	☐	Leukemia (ALL, CLL)	☐	Pancreas	☐
Anus	☐	Connective tissue (including sarcoma)	☐	Liver	☐	Parotid gland	☐
Appendix	☐	Endocrine glands	☐	Lung	☐	Rectum	☐
Biliary tract	☐	Endometrium	☐	Lymph nodes	☐	Salivary glands	☐
Bladder, ureter	☐	Esophagus	☐	Lymphoma, Hodgkins	☐	Small intestine	☐
Bones, joints, cartilage	☐	Eye and adnexa	☐	Lymphoma, Non-Hodgkins	☐	Stomach	☐
Brain	☐	Gallbladder	☐	Melanoma of the skin	☐	Thyroid	☐
Breast	☐	Genital organs	☐	Multiple myeloma	☐	Tongue	☐
Central Nervous System	☐	Kidney, renal pelvis	☐	Oral or Palate	☐	Uterus	☐

Other, specify:_____ CAF8A

9. Tumor behavior: ***(Mark only one)*** CAF9
   a. ☐ Invasive; malignant; infiltrating; micro-invasive
   b. ☐ In situ; intraepithelial; non-infiltrating; non-invasive; intraductal
   c. ☐ Borderline malignancy; low malignant potential; uncertain if benign or malignant
   d. ☐ Unknown

10. Diagnostic confirmation status: ***(Mark only one. If more than one applies, mark the <u>first</u> applicable category)*** CAF10
   a. ☐ Positive histology (pathology)
   b. ☐ Positive cytology, no positive histology
   c. ☐ Positive histology (pathology), regional or distant metastatic site only
   d. ☐ Positive microscopic confirmation, method not specified
   e. ☐ Clinical diagnosis only
   f. ☐ Unknown

11. Laterality: ***(Mark only one)*** CAF11
   a. ☐ Not a paired site
   b. ☐ Right origin of primary
   c. ☐ Left origin of primary
   d. ☐ One side involved, right or left origin unspecified
   e. ☐ Bilateral involvement, lateral origin unknown; stated to be a single primary
   f. ☐ Paired site but no information on laterality; midline tumor

12. Summary stage: ***(Mark only one)*** CAF12
   a. ☐ In situ
   b. ☐ Localized
   c. ☐ Regional
   d. ☐ Distant
   e. ☐ Unknown

C. LUNG CANCER *(Complete 13-16 for Lung cancer only)*

13. Is lung cancer the primary diagnosed cancer: Yes ☐ No ☐ ***(If No, skip to Q17)*** CAF13

14. Site of the lung cancer ***(Mark one only)*** CAF14

Trachea	☐	Main bronchus	☐	Upper lobe bronchus	☐	Middle lobe bronchus	☐
Lower lobe bronchus	☐	Other parts of bronchus	☐	Overlapping lesion of bronchus or lung	☐	Bronchus or lung unspecified	☐
Parietal pleura	☐	Visceral pleura	☐	Other site, pleura	☐	Pleura, unspecified	☐

15. Type of lung cancer ***(Mark only one)*** CAF15

    a. ☐ Non-small cell lung cancer

        1. ☐ Adenocarcinoma
        2. ☐ Squamous / epitheloid carcinoma
        3. ☐ Large cell carcinoma
        4. ☐ Unspecified

    b. ☐ Small cell lung cancer

    c. ☐ Type unknown

    d. Other, specify _____ CAF15A

16. Treatments ***(Mark all that apply)***

    a. ☐ Surgery CAF16A

    b. ☐ Chemotherapy CAF16B

        1. ☐ Neoadjuvant CAF16B1
        2. ☐ Adjuvant CAF16B2

    c. ☐ Radiation CAF16C

    d. ☐ Targeted drug treatment CAF16D

        1. ☐ Bevacizumab (Avastin) CAF16D1
        2. ☐ Crizotinib (Xalkori) CAF16D2
        3. ☐ Erlotinib (Tarceva) CAF16D3

17. Smoking status ***(Mark only one)***

    a. Former smoker CAF17A1

        1. Pack years: 10 or less ☐ 10 to 20 ☐ 20 or more ☐ Unknown ☐

    b. Current smoker: Yes ☐ No ☐ Unknown ☐ CAF17B

18. Did patient receive a lung transplant? Yes ☐ No ☐ Unknown ☐ CAF18

    a. ☐ Single Right CAF18A

    b. ☐ Single Left

    c. ☐ Bilateral

COPD ASSESSMENT TEST

ID NUMBER:	BLINDID	FORM CODE: CAT VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... __ __ / __ __ / __ __ __ __ CAT0A 0b) Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. For each item below, have the participant select the number that best describes their experience.*

This questionnaire will help us measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. For each item below, tell me the number that best describes you currently. Be sure to only select one response for each question

									SCORE
1)	I never cough	0	1	2	3	4	5	I cough all the time	CAT01
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)	CAT02
3)	My chest does not feel tight at all	0	1	2	3	4	5	My chest feels very tight	CAT03
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	CAT04
5)	I am not limited doing any activities at home	0	1	2	3	4	5	I am very limited doing activities at home	CAT05
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	CAT06
7)	I sleep soundly	0	1	2	3	4	5	I don't sleep soundly because of my lung condition	CAT07
8)	I have lots of energy	0	1	2	3	4	5	I have no energy at all	CAT08

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CBC RESULTS FORM

ID NUMBER: BLINDID

FORM CODE: CBC
VERSION: 1.1 2/16/11

Visit Number VISIT

SEQ #

0a. Form Completion Date: __/__/____ CBC0A 0b. Initials: ___

Instructions: *Input the results of your local lab into this form.*

1. Date Blood Submitted to Lab: __/__/____ CBC01

2. Date Results Received: __/__/____ CBC02

RED BLOOD CELLS

3. Total Red Blood Cells ..... __.__ x10^{12} L CBC03

4. Hemoglobin ..... __.__ g/dL CBC04

5. Hemacrit ..... __.__ % CBC05

6. Mean corpuscular volume ..... ___.__ fL CBC06

7. Red blood cell distribution width ..... __.__ % CBC07

WHITE BLOOD CELLS (ABSOLUTE VALUES)

8. Total white blood cells ..... __.__ x10^9/L CBC08

9. Neutrophil granulocyte ..... __.__ x10^9/L CBC09

9a. Neutrophil granulocyte % ..... __.__ % CBC09A

10. Lymphocytes ..... __.__ x10^9/L CBC10

10a. Lymphocyte % ..... __.__ % CBC10A

11. Monocytes ..... __.__ x10^9/L CBC11

11a. Monocyte % ..... __.__ % CBC11A

12. Eosinophil granulocytes ..... ☐☐.☐ x10^9/L CBC12

12a. Eosinophil granulocyte %..... ☐☐.☐ % CBC12A

13. Basophil granulocytes..... ☐☐.☐ x10^9/L CBC13

13a. Basophil granulocyte % ..... ☐☐.☐ % CBC13A

PLATELETS

14. Platelet Count ..... ☐☐☐ x10^9/L CBC14

15. Mean Platelet Volume..... ☐☐.☐ fL CBC15

16. Comments: CBC16 _____

_____

_____

CBC RESULTS FORM

ID NUMBER:	BLINDID	FORM CODE: CBC VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a. Form Completion Date: __ __/__ __/__ __ __ __ CBC0A 0b. Initials: __ __ __

Instructions: *Input the results of your local lab into this form.*

1. Date Blood Submitted to Lab: __ __/__ __/__ __ __ __ CBC01

2. Date Results Received: __ __/__ __/__ __ __ __ CBC02

RED BLOOD CELLS

3. Total Red Blood Cells ..... __.__ x10^{12} L CBC03

4. Hemoglobin ..... __ __.__ g/dL CBC04

5. Hemacrit ..... __ __.__ % CBC05

6. Mean corpuscular volume ..... __ __ __.__ fL CBC06

7. Red blood cell distribution width ..... __ __.__ % CBC07

WHITE BLOOD CELLS (ABSOLUTE VALUES)

8. Total white blood cells ..... __ __.__ x10^9/L CBC08

9. Neutrophil granulocyte ..... __ __.__ x10^9/L CBC09

10. Lymphocytes ..... __ __.__ x10^9/L CBC10

11. Monocytes ..... __ __.__ x10^9/L CBC11

12. Eosinophil granulocytes ..... __ __.__ x10^9/L CBC12

13. Basophil granulocytes ..... __ __.__ x10^9/L CBC13

PLATELETS

14. Platelet Count ..... ☐☐☐ x10^9/L CBC14

15. Mean Platelet Volume..... ☐☐.☐ fL CBC15

16. Comments: CBC16 _____

_____

_____

COORDINATOR EXACERBATION ASSESSMENT FORM (Wave 1)

ID NUMBER:	BLINDID	FORM CODE: **CEA** VERSION: **1.0** 05/27/14	Visit Number		SEQ #	

0a) Form Completion Date.... ☐☐/☐☐/☐☐☐☐ CEA0a 0b) Staff Code ..... ☐☐☐ CEA0b

Instructions: *This form should be completed any time the participant calls the clinical center with a possible exacerbation event.*

Administrative

Date of contact: ☐☐/☐☐/☐☐☐☐ CEA0c

1. Why did you contact the SPIROMICS center today? (Do not read responses. Check all that apply)

1a. Participant felt they were having an exacerbation (Y/N) ..... ☐ CEA1a

1b. Participant felt he or she met the criteria on the information card (Y/N) ☐ CEA1b

1c. Participant reported the EXACT-Pro Message said to call (Y/N) ..... ☐ CEA1c

1.c.1. Date of first EXACT-Pro Message: ☐☐/☐☐/☐☐☐☐ CEA1c1

Review of Symptoms

2. Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a. Increase or Worsening in Shortness of Breath (Dyspnea)	☐	☐	CEA2a
b. Change in sputum color (purulence).....	☐	☐	CEA2b
c. Increase in sputum volume.....	☐	☐	CEA2c

3) Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a. Runny Nose/Nasal discharge	☐	☐	CEA3a
b. Increase or worsening of wheeze	☐	☐	CEA3b
c. Sore throat	☐	☐	CEA3c
d. Increase or worsening of cough	☐	☐	CEA3d
e. Fever	☐	☐	CEA3e

HCU Event Determination

4. Have you contacted your primary physician or gone to the emergency room, urgent care, or hospital regarding this change in your symptoms? ☐ CEA4

Yes 1

No ..... 0 → Skip to 4d

4a. Date of contact with physician or emergency room/urgent care visit: ☐☐/☐☐/☐☐☐☐ CEA4a

4b. Why did you contact your primary physician or go to the emergency room, urgent care, or hospital for this change in symptoms?

	Yes	No	
1. Sputum color change: the doctor told me to call if my sputum changes color	☐	☐	CEA4b1
2. Thought I might need extra treatment	☐	☐	CEA4b2
3. Knew I needed treatment	☐	☐	CEA4b3
4. Scared or nervous	☐	☐	CEA4b4
5. Wanted to catch it early	☐	☐	CEA4b5
6. Someone (spouse/child) told me to call	☐	☐	CEA4b6
7. Other	☐	☐	CEA4b7

7a. Specify: CEA4b7a _____

4c. Did the participant report going to the emergency room or hospital? .... ☐ CEA4c

Yes 1

No 0

4d. Why didn't you contact your primary physician or go to the emergency room, urgent care, or hospital regarding this change in symptoms?

	Yes	No	
1. Inconvenient	☐	☐	CEA4d1
a. Too far	☐	☐	CEA4d1a
b. Office not open	☐	☐	CEA4d1b
c. Could not make an appointment	☐	☐	CEA4d1c
d. Other e) Specify_____ CEA4d1e	☐	☐	CEA4d1d
2. Cost (co-pay, medications, deductible)	☐	☐	
3. I have treatment at home to take when I feel worse	☐	☐	
4. I didn't feel sick enough to call.	☐	☐	
5. I thought it would go away soon.	☐	☐	
6. I knew it wasn't a problem (past experience)	☐	☐	
7. I don't like to bother my doctor	☐	☐	
8. I don't like or prefer not to take extra medications	☐	☐	
9. Other	☐	☐	

CEA items 2-9 not used

9a. Specify:_____

5. (If yes to Q4) As a result of contacting your physician or going to the emergency room, urgent care, or hospital was there a change in your medical treatment (e.g., changed your medications)? ☐ CEA5

Yes 1

No ..... 0 → Skip to 7

5a. Date of change in medical treatment: ☐☐/☐☐/☐☐☐☐ CEA5a

6. (If no to Q4) Have you changed your medical treatment as directed by your physician because of the change in your symptoms (e.g., filled a prescription of antibiotics)? ..... ☐ CEA6

Yes 1

No 0

6a. Date of change in medical treatment: ☐☐/☐☐/☐☐☐☐ CEA6a

Previous Event/Visit Determination (Do not read to participant)

7. Has the participant had a previous HCU-triggered exacerbation AND completed a study visit for that exacerbation? ..... ☐ CEA7

Yes 1

No ..... 0 → Skip to 9

8. Has the participant had at least three previous events AND completed study visits for these events? ☐ CEA8
   Yes ..... 1 →END (Participant ineligible for another visit)
   No 0

Visit Eligibility Determination (Do not read to participant)

9. Is this participant eligible for an exacerbation clinic visit? ..... ☐ CEA9
   Yes 1
   No ..... 0 → End

Eligibility Criteria:

1) No history of previous HCU exacerbation visit (Q7 = N) and Q4 or Q6 = Y (HCU Exacerbation Visit)

10. Was the participant scheduled for a study visit? ..... ☐ CEA10
    Yes ..... 1 → End
    No 0

11. Reason participant was not scheduled for an exacerbation visit:

	Yes	No	
a. Too far	☐	☐	CEA11a
b. Participant didn't have time to come in	☐	☐	CEA11b
c. Too sick to come in	☐	☐	CEA11c
d. Lack of transportation	☐	☐	CEA11d
e. Unable to schedule visit within 72 hours (participant)	☐	☐	CEA11e
f. Unable to accommodate visit within 72 hours (clinic)	☐	☐	CEA11f
g. Other	☐	☐	CEA11g

g1. Specify CEA11g1

Call Conclusion Prompt:

If the participant has not contacted their physician or gone to the emergency room/urgent care and WILL NOT be coming in for a visit:

"Thank you for contacting us. We recommend that you contact your primary care physician to discuss the worsening symptoms that you are having now and see if he or she recommends treatment."

If the participant has not contacted their physician or gone to the emergency room/urgent care and WILL be coming in for a visit:

"Thank you for contacting us. We recommend that you contact your primary care physician to discuss the worsening symptoms that you are having now and see if he or she recommends treatment. The SPIROMICS visit we're scheduling now does not take the place of a visit with your physician and is for research evaluation only."

If the participant has already contacted their physician or gone to the emergency room/urgent care and WILL be coming in for a visit:

"Thank you for contacting us. As a reminder, the SPIROMICS visit we're scheduling now does not take the place of a visit with your physician and is for research evaluation only."

COORDINATOR EXACERBATION ASSESSMENT FORM (Wave 2)

ID NUMBER:	BLINDID	FORM CODE: **CEF** VERSION: **1.0** 08/13/15	Visit Number	visit	SEQ #	

0a) Form Completion Date.... ☐☐/☐☐/☐☐☐☐ CEF0a 0b) Staff Code ..... ☐☐☐ CEF0b

Instructions: *This form should be completed any time the participant calls the clinical center with a possible exacerbation event.*

Administrative

Date of contact: ☐☐/☐☐/☐☐☐☐ CEF0c

1. Why did you contact the SPIROMICS center today? (Do not read responses. Check all that apply)

1a. Participant felt they were having an exacerbation (Y/N) ..... ☐ CEF1a

1b. Participant felt he or she met the criteria on the information card (Y/N) ☐ CEF1b

1c. Participant reported the EXACT-Pro Message said to call (Y/N) ..... ☐ CEF1c

1.c.1. Date of first EXACT-Pro Message: ☐☐/☐☐/☐☐☐☐ CEF1c1

Review of Symptoms

2. Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a. Increase or Worsening in Shortness of Breath (Dyspnea).....	☐	☐	CEF2a
b. Change in sputum color (purulence)	☐	☐	CEF2b
c. Increase in sputum volume	☐	☐	CEF2c

3) Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a. Runny Nose/Nasal discharge	☐	☐	CEF3a
b. Increase or worsening of wheeze	☐	☐	CEF3b
c. Sore throat	☐	☐	CEF3c
d. Increase or worsening of cough	☐	☐	CEF3d
e. Fever	☐	☐	CEF3e

HCU Event Determination

4. Have you contacted your primary physician or gone to the emergency room, urgent care, or hospital regarding this change in your symptoms? ☐ CEF4

Yes 1

No ..... 0 → Skip to 4d

4a. Date of contact with physician or emergency room/urgent care visit: ☐☐/☐☐/☐☐☐☐ CEF4a

4b. Why did you contact your primary physician or go to the emergency room, urgent care, or hospital for this change in symptoms?

	Yes	No	
1. Sputum color change: the doctor told me to call if my sputum changes color	☐	☐	CEF4b1
2. Thought I might need extra treatment	☐	☐	CEF4b2
3. Knew I needed treatment	☐	☐	CEF4b3
4. Scared or nervous	☐	☐	CEF4b4
5. Wanted to catch it early	☐	☐	CEF4b5
6. Someone (spouse/child) told me to call	☐	☐	CEF4b6
7. Other	☐	☐	CEF4b7

7a. Specify: CEF4b7a _____

4c. Did the participant report going to the emergency room or hospital? .... ☐ CEF4c

Yes 1

No 0

4d. Why didn't you contact your primary physician or go to the emergency room, urgent care, or hospital regarding this change in symptoms?

	Yes	No	
1. Inconvenient	☐	☐	CEF4d1
a. Too far	☐	☐	CEF4d1a
b. Office not open	☐	☐	CEF4d1b
c. Could not make an appointment	☐	☐	CEF4d1c
d. Other e) Specify_____ CEF4d1e	☐	☐	CEF4d1d
2. Cost (co-pay, medications, deductible)	☐	☐	
3. I have treatment at home to take when I feel worse	☐	☐	
4. I didn't feel sick enough to call.	☐	☐	
5. I thought it would go away soon.	☐	☐	
6. I knew it wasn't a problem (past experience)	☐	☐	
7. I don't like to bother my doctor	☐	☐	
8. I don't like or prefer not to take extra medications	☐	☐	
9. Other	☐	☐	

CEF items 2-9 not used

9a. Specify:_____

5. (If yes to Q4) As a result of contacting your physician or going to the emergency room, urgent care, or hospital was there a change in your medical treatment (e.g., changed your medications)? ☐ CEF5

Yes 1

No ..... 0 → Skip to 7

5a. Date of change in medical treatment: ☐☐/☐☐/☐☐☐☐ CEF5a

6. (If no to Q4) Have you changed your medical treatment as directed by your physician because of the change in your symptoms (e.g., filled a prescription of antibiotics)? ..... ☐ CEF6

Yes 1

No 0

6a. Date of change in medical treatment: ☐☐/☐☐/☐☐☐☐ CEF6a

Previous Event/Visit Determination (Do not read to participant)

7. Has the participant had at least three previous events AND completed study visits for these events? ☐ CEF7

Yes ..... 1 →END (Participant ineligible for another visit)

No 0

Visit Eligibility Determination (Do not read to participant)

8. Is this participant eligible for an exacerbation clinic visit? ..... ☐ CEF8
   Yes 1
   No ..... 0 → End

Eligibility Criteria:

1) Fewer than three previous visits (Q7) and

2) Participant reports a change in medical treatment (Q4 or Q6 = Y) OR an EXACT trigger (Q1c=Y)

3) Participant has contacted the site within 72 hours of the EXACT triggering (CEF1c1), contacting his or her physician (CEF4a), or changing medications (CEF6a), whichever occurred first.

9. Was the participant scheduled for a study visit? ..... ☐ CEF9
   Yes ..... 1 → End
   No 0

10. Reason participant was not scheduled for an exacerbation visit:

	Yes	No	
a. Too far	☐	☐	CEF10a
b. Participant didn't have time to come in	☐	☐	CEF10b
c. Too sick to come in	☐	☐	CEF10c
d. Lack of transportation	☐	☐	CEF10d
e. Unable to schedule visit within 72 hours (participant)	☐	☐	CEF10e
f. Unable to accommodate visit within 72 hours (clinic)	☐	☐	CEF10f
g. Other	☐	☐	CEF10g

g1. Specify CEF10g1

Call Conclusion Prompt:

If the participant has not contacted their physician or gone to the emergency room/urgent care and WILL NOT be coming in for a visit:

"Thank you for contacting us. We recommend that you contact your primary care physician to discuss the worsening symptoms that you are having now and see if he or she recommends treatment."

If the participant has not contacted their physician or gone to the emergency room/urgent care and WILL be coming in for a visit:

"Thank you for contacting us. We recommend that you contact your primary care physician to discuss the worsening symptoms that you are having now and see if he or she recommends treatment. The SPIROMICS visit we're scheduling now does not take the place of a visit with your physician and is for research evaluation only."

If the participant has already contacted their physician or gone to the emergency room/urgent care and WILL be coming in for a visit:

"Thank you for contacting us. As a reminder, the SPIROMICS visit we're scheduling now does not take the place of a visit with your physician and is for research evaluation only."

DEATH CERTIFICATE FORM

ID NUMBER:	SUBJID	FORM CODE: DCF VERSION: 1.0 12/15/14	Visit Number	VISIT	SEQ #	

0a. Form Completion Date.... __ __/__ __/__ __ __ __ DCF0A

0b. Code..... __ __ __ DCF0B

0c. Subject ID: __ __ __ __ __ __ __ __ DCF0C

0d. Event Date: __ __/__ __/__ __ __ __ DCF0D

Instructions: *The Death Certificate Form is completed for each death reported from the Quarterly Follow-up Form. A Death Certificate must be requested and obtained prior to completing this form.*

1. Was a death certificate obtained?..... ☐ DCF1
   - Yes .....Y
   - No.....N→**Go to end of form**

2. Date of death: ..... __ __/__ __/__ __ __ __ DCF2

3. Time of death:..... DCF3A __ __ : __ __ DCF3B AM / PM **(Circle One)**

4. Did the decedent die in a hospital?..... ☐ DCF4
   - Yes .....Y
   - No.....N→**Go to Item 6**
   - Unknown .....U→**Go to Item 6**

5. Was the death classified as: *(select one)* ..... ☐ DCF5
   - Dead on Arrival (DOA) 1
   - Emergency Dept. (ED) 2
   - Outpatient.....3
   - Inpatient 4
   - None of the above.....5
   - Not recorded 6

6. Was this a coroner's or medical examiner's case?..... ☐ DCF6
   - Yes .....Y
   - No.....N→**Go to Item 10**

7. Was the name and address of the Coroner or Medical Examiner recorded? ..... ☐ DCF7
   - Yes .....Y
   - No.....N→**Go to Item 10**

8. Name: Removed from Blinded Dataset

9. Address: a. Street Removed from Blinded Dataset

b. City Removed from Blinded Dataset c. State Removed from Blinded Dataset d. Zip code

e. Country Removed from Blinded Dataset

10. Was an autopsy performed? ☐ DCF10

Yes ..... Y

No ..... N

11. Was the underlying cause of death recorded using ICD9 or ICD10 codes? ☐ DCF11

ICD9 ..... 1→**Go to Item 11a**

ICD10 ..... 2→**Go to Item 11b**

No Codes Available..... 3→**Go to Item 13**

11a. **ICD-9 Code** for **UNDERLYING** cause of death: ☐☐☐.☐ DCF11A

11b. **ICD-10 Code** for **UNDERLYING** cause of death: ☐☐☐.☐ DCF11B

12. Were the additional ICD codes recorded using ICD9 or ICD10? ☐ DCF12

ICD9 ..... 1 →**Go to Item 12a**

ICD10 ..... 2→**Go to Item 12b**

No Codes Available..... 3→**Go to Item 13**

12a. All listed **ICD-9 Codes** for death: DCF12A

1. DCF12A1 ☐☐☐.☐	5. DCF12A5 ☐☐☐.☐	9. DCF12A9 ☐☐☐.☐	
2. DCF12A2 ☐☐☐.☐	6. DCF12A6 ☐☐☐.☐	10. ☐☐☐.☐	item not collected
3. DCF12A3 ☐☐☐.☐	7. DCF12A7 ☐☐☐.☐	11. ☐☐☐.☐	item not collected
4. DCF12A4 ☐☐☐.☐	8. DCF12A8 ☐☐☐.☐	12. ☐☐☐.☐	item not collected

12b. All listed **ICD-10 Codes** for death: DCF12B

1. DCF12B1 ___.___
2. DCF12B2 ___.___
3. DCF12B3 ___.___
4. DCF12B4 ___.___
5. DCF12B5 ___.___
6. DCF12B6 ___.___
7. DCF12B7 ___.___
8. DCF12B8 ___.___
9. DCF12B9 ___.___
10. ___.___
11. ___.___
12. ___.___

13. Are there causes of death recorded on the death certificate? ..... ☐ DCF13A

Yes .....Y

No.....N→**Go to Item 14**

13a. Immediate cause: DCF13B _____

_____

13b. Due to or as a consequence of (1) DCF13C _____

_____

13c. Due to or as a consequence of (2) DCF13D _____

_____

13d. Due to or as a consequence of (3) DCF13E _____

_____

14. Are there other significant conditions recorded on the death certificate? ..... ☐ DCF14

Yes .....Y

No.....N→**Go to Item 16**

15. Conditions: DCF15 _____

_____

16. Interval between onset and death for immediate cause of death: ..... ☐ DCF16

Five minutes or less 1
One hour or less.....2
One day or less 3
One week or less 4
One month or less.....5
More than one month 6
Unknown or Not recorded 7

DEMOGRAPHIC INFORMATION FORM

ID NUMBER:	BLINDID	FORM CODE: **DEM** VERSION: 3.**0** 07/08/11	Visit Number	VISIT	SEQ #

0a) Form Date: ..... __ __/__ __/__ __ __ __ DEM0A 0b) Staff Code..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please read all questions exactly as written.*

This questionnaire gathers demographic information. Please select the answer that is most accurate for you.

1) What is your birth year?... __ __ __ __ DEM01 1a) What is your age? ..... __ __ DEM01A

2) What is the highest grade you completed in school? ..... __ __ DEM02
   - Eighth grade or below.....1
   - Trade school or business school instead of high school 2
   - Some high school 3
   - High school graduate.....4
   - Trade school or business school after graduating high school 5
   - Some college.....6
   - Received bachelor's degree 7
   - Graduate or professional education beyond the bachelor's degree.8
   - Graduate or professional degree 9
     - Specify:_DEM02A_____
   - Declines to answer 10

3) What is your current marital status? ..... __ DEM03
   - Never Married.....1
   - Married/Living as Married/Living with Partner 2
   - Widowed.....3
   - Separated.....4
   - Divorced 5
   - Declines to answer 6

4) What is your total yearly household income?..... ☐ DEM04

Under $15,000..... 1
$15,000 - $34,999..... 2
$35,000 - $49,999..... 3
$50,000 - $74,999..... 4
$75,000 or more 5
Declines to answer 6

5a) Are you of Hispanic or Latino heritage?..... ☐ DEM05

Hispanic or Latino (of Spanish culture or origin regardless of race) 1
Not Hispanic or Latino .....2→**Skip 5b**

5b) Which of the following best describes your Hispanic/Latino heritage? *(select only one)* DEM05A

Central American or Central American descent ☐
Cuban or Cuban descent ☐
Mexican or Mexican descent ☐
Puerto - Rican or Puerto Rican descent ☐
South American or South American descent ☐
Dominican or Dominican descent ☐
More than one heritage ☐
Other ☐
If other, please specify: DEM05A1 _____

6) Which of the following categories would you use to describe yourself? You may select more than one. *(check all that apply)*:

Caucasian/White ..... ☐ DEM06A
A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Black or African American ..... ☐ DEM06B
A person having origins in any of the black racial groups of Africa.

Asian ..... ☐ DEM06C
A person having origins in any of the original peoples of the Far East, Southeast Asia including the Philippine Islands, or the Indian subcontinent.

American Indian or Alaska Native..... ☐ DEM06D
A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Native Hawaiian or Other Pacific Islander..... ☐ DEM06E
A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

Participant refused to answer ..... ☐ DEM06F

DEMOGRAPHIC INFORMATION FORM

ID NUMBER:	BLINDID	FORM CODE: DEM VERSION: 2.0 11/09/10	Visit Number	VISIT	SEQ #

0a) Form Date:..... __ __/__ __/__ __ __ __ DEM0A 0b) Initials..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please read all questions exactly as written.*

This questionnaire gathers demographic information. Please select the answer that is most accurate for you.

1) What is your birth year?... __ __ __ __ DEM01 1a) What is your age? ..... __ __ DEM01A

2) What is the highest grade you completed in school? ..... __ __ DEM02
   - Eighth grade or below..... 1
   - Trade school or business school instead of high school 2
   - Some high school 3
   - High school graduate..... 4
   - Trade school or business school after graduating high school..... 5
   - Some college 6
   - Received bachelor's degree 7
   - Graduate or professional education beyond the bachelor's degree 8
   - Graduate or professional degree 9
     - Specify: DEM02A _____
   - Declines to answer 10

3) What is your current marital status? ..... __ DEM03
   - Never Married 1
   - Married 2
   - Widowed 3
   - Separated 4
   - Divorced 5
   - Declines to answer 6

4) What is your total yearly household income? ..... ☐ DEM04

Under $15,000 1
$15,000 - $34,999 2
$35,000 - $49,999 3
$50,000 - $74,999 4
$75,000 or more 5
Declines to answer 6

5a) Are you of Hispanic or Latino heritage? ..... ☐ DEM05

Hispanic or Latino (of Spanish culture or origin regardless of race) 1
Not Hispanic or Latino ..... 2→**Skip 5b**

5b) Which of the following best describes your Hispanic/Latino heritage? *(select only one)* DEM05A

Central American or Central American descent ☐
Cuban or Cuban descent ☐
Mexican or Mexican descent ☐
Puerto - Rican or Puerto Rican descent ☐
South American or South American descent ☐
Dominican or Dominican descent ☐
More than one heritage ☐
Other ☐
If other, please specify: DEM05A1 _____

6) Which of the following categories would you use to describe yourself? You may select more than one. *(check all that apply)*:

Caucasian/White ..... ☐ DEM06A
A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Black or African American ..... ☐ DEM06B
A person having origins in any of the black racial groups of Africa.

Asian..... ☐ DEM06C
A person having origins in any of the original peoples of the Far East, Southeast Asia including the Philippine Islands, or the Indian subcontinent.

American Indian or Alaska Native ..... ☐ DEM06D
A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Native Hawaiian or Other Pacific Islander ..... ☐ DEM06E
A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

Participant refused to answer ..... ☐ DEM06F

DEMOGRAPHIC INFORMATION FORM

ID NUMBER: BLINDID

FORM CODE: DEM
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a) Form Date: ..... __ __ / __ __ / __ __ __ __ DEM0A 0b) Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please read all questions exactly as written.*

This questionnaire gathers demographic information. Please select the answer that is most accurate for you.

1) What is your birth year?... __ __ __ __ DEM01 1a) What is your age? ..... __ __ DEM01A

2) What is the highest grade you completed in school? ..... __ __ DEM02
   - Eighth grade or below 1
   - Trade school or business school instead of high school 2
   - Some high school 3
   - High school graduate 4
   - Trade school or business school after graduating high school 5
   - Some college 6
   - Received bachelor's degree 7
   - Graduate or professional education beyond the bachelor's degree. 8
   - Graduate or professional degree 9
     - Specify: DEM02A _____
   - Declines to answer 10

3) What is your current marital status? ..... __ DEM03
   - Never Married 1
   - Married 2
   - Widowed 3
   - Separated 4
   - Divorced 5
   - Declines to answer 6

4) What is your total yearly household income? ..... __ DEM04
   - Under $15,000 1
   - $15,000 - $34,999 2
   - $35,000 - $49,999 3
   - $50,000 - $74,999 4
   - $75,000 or more 5
   - Declines to answer 6

5) Are you of Hispanic or Latino heritage?..... ☐ DEM05

Hispanic or Latino (of Spanish culture or origin regardless of race) 1

Not Hispanic or Latino 2

6) Which of the following categories would you use to describe yourself? You may select more than one. *(check all that apply)*:

Caucasian/White ..... ☐ DEM06A

A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Black or African American ..... ☐ DEM06B

A person having origins in any of the black racial groups of Africa.

Asian ..... ☐ DEM06C

A person having origins in any of the original peoples of the Far East, Southeast Asia including the Philippine Islands, or the Indian subcontinent.

American Indian or Alaska Native..... ☐ DEM06D

A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Native Hawaiian or Other Pacific Islander..... ☐ DEM06E

A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

SPIROMICS DIABETES ABSTRACTION FORM (DMF)

ID NUMBER:	SUBJID	FORM CODE: DMF VERSION:A 2/19/2015	Visit Number	VISIT	SEQ #

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month/Day/Year) DMF0A 0b. Staff ID: ☐☐☐ DMF0B

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ DMF0C 0d. Event Date: ☐☐/☐☐/☐☐☐☐ DMF0D

Instructions: *Answers are derived from the medical records received. Do not complete this form until all records are received or classified as unobtainable as indicated on the Medical Record Shipping Form.*

A. GENERAL INFORMATION

1. Was the event ***(choose one)***: ☐ DMF1

   1= In hospital only 2= Emergency Dept. visit only (ED) 3= Both ED and in hospital

2. Date of admission: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ DMF2

3. Date of discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ DMF3

4. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐ DMF4

5. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐ DMF5

B. DIAGNOSIS AND VALUES

6. Type of Diabetes Mellitus diagnosed: ***(Mark only one)*** DMF6
   a. ☐ Type 1
   b. ☐ Type 2

7. First measured weight available: ☐☐☐.☐☐ DMF7 1= Lbs 2= Kgs: ☐ DMF7A

8. Height: ☐☐☐.☐☐ DMF8 1= Inches 2= Centimeters: ☐ DMF8A

9. BMI: ☐☐.☐ DMF9

10. Most recent A1c test result: ***(Mark only one; may use pre-hospitalization value recorded by a physician)*** DMF10

    a. ☐ < 5.7%
    b. ☐ 5.7 – 6.4%
    c. ☐ > 6.4%

11. Most recent fasting glucose test result: ***(Mark only one; may use pre-hospitalization value recorded by a physician)*** DMF11

a. ☐ ≤ 100 mg/dl
b. ☐ > 101 mg/dl

C. CONTRIBUTING HISTORY

12. Patient's contributing health history: ***(Mark any that apply)***

a. ☐ Pancreatitis DMF12A
b. ☐ Pancreatic carcinoma DMF12B
c. ☐ Pancreatectomy DMF12C
d. ☐ Endocrinopathy (Cushing's disease, pheochromocytoma) DMF12D
e. ☐ None/Not Recorded DMF12E
f. ☐ Other, specify_____ DMF12F _____

D. SEQUELAE OF DIABETES

13. Health impacts *from Diabetes*: ***(Mark all that apply)***

a. ☐ Diabetic nephropathy DMF13A
   1. ☐ Diagnosis of renal failure of any severity DMF13A1
   2. ☐ Patient is on dialysis DMF13A2
b. ☐ Peripheral Neuropathy DMF13B
   1. ☐ Non-healing ulcers DMF13B1
   2. ☐ Lower extremity amputation (toe, forefoot, heel, below the knee) DMF13B2
   3. ☐ Charcot joint DMF13B3
c. ☐ Eye complications DMF13C
   1. ☐ Retinopathy DMF13C1
   2. ☐ Glaucoma DMF13C2
   3. ☐ Cataracts DMF13C3
   4. ☐ Macular edema DMF13C4
d. ☐ Gastrointestinal complications DMF13D
   1. ☐ Gastroparesis DMF13D1
   2. ☐ Diabetic diarrhea DMF13D2
   3. ☐ Candidiasis DMF13D3
e. ☐ Cardiovascular / Atherosclerotic complications DMF13E
   1. ☐ Cardiovascular disease DMF13E1
   2. ☐ Peripheral vascular disease DMF13E2
   3. ☐ Cerebrovascular disease DMF13E3

E. TREATMENT

14. Medications: ***(Mark all that apply)***

	Admission	Discharge
a. ☐ Oral Sufonylureas (Glipizide, Glyburide,Glimepiride)	☐ DMF14A1	☐ DMF14A2
b. ☐ Oral Glinides (GlucoNorm, Starlix)	☐ DMF14B1	☐ DMF14B2
c. ☐ Oral DDP-4 inhibitors (Januvia, Onglyza)	☐ DMF14C1	☐ DMF14C2
d. ☐ Oral GPL analogs (Victoza, Byetta)	☐ DMF14D1	☐ DMF14D2
e. ☐ Oral Metformin	☐ DMF14E1	☐ DMF14E2
f. ☐ Injectable Insulin	☐ DMF14F1	☐ DMF14F2

EXACERBATION ASSESSMENT FORM

ID NUMBER:	BLINDID	FORM CODE: **EAF** VERSION: **1.0** 05/27/14	Visit Number	visit	SEQ #	

0a) Form Completion Date.... ☐☐/☐☐/☐☐☐☐ EAF0a 0b) Staff Code ..... ☐☐☐ EAF0b

Instructions: *This form should be completed when a participant comes to the clinical center for an exacerbation study visit. This form should be completed before proceeding with the rest of the study visit.*

Administrative Information

1) Date of clinic visit: ☐☐/☐☐/☐☐☐☐ EAF1

2) What type of Event is this? ..... ☐ EAF2

Participant/HCU-triggered 1

Symptom/EXACT-Triggered 2

Examination (completed by Coordinator):

3) Temperature ☐☐☐.☐ °C EAF3

4) Weight ☐☐☐.☐ kg EAF4

5) Pulse ☐☐☐ min^{-1} EAF5

6) Sp02 ☐☐☐ % EAF6

7) Notes: EAF7

Participant Interview (completed by Coordinator):

8) Have you had any changes to your **respiratory** medications related to this event (this includes new prescriptions or self-medication)? ..... ☐ EAF8

Yes 1

No..... 0→**Go to 12**

Please specify type of medication for this event by checking the appropriate box:

9) MEDICATION	Date Prescribed	Duration (Days)
a1) Antibiotic 1: EAF9a1 _____	☐☐/☐☐/☐ EAF9a1a	☐☐☐ EAF9a1b
a2) Antibiotic 2: EAF9a2 _____	☐☐/☐☐/☐ EAF9a2a	☐☐☐ EAF9a2b
b1) Inhaled corticosteroids: EAF9b1 _____	☐☐/☐☐/☐ EAF9b1a	☐☐☐ EAF9b1b
c1) Inhaled corticosteroids w/long-acting $ß_2$-agonists: EAF9c1 _____	☐☐/☐☐/☐ EAF9c1a	☐☐☐ EAF9c1b
d1) Aminophyllines: EAF9d1 _____	☐☐/☐☐/☐ EAF9d1a	☐☐☐ EAF9d1b
e1) $ß_2$-agonists Short-Acting: EAF9e1 _____	☐☐/☐☐/☐ EAF9e1a	☐☐☐ EAF9e1b
f1) $ß_2$-agonists Long-Acting: EAF9f1 _____	☐☐/☐☐/☐ EAF9f1a	☐☐☐ EAF9f1b
g1) Short-acting anticholinergic EAF9g1 _____	☐☐/☐☐/☐ EAF9g1a	☐☐☐ EAF9g1b
h1) Long-acting anticholinergic EAF9h1 _____	☐☐/☐☐/☐ EAF9h1a	☐☐☐ EAF9h1b
i1)Short-acting $ß_2$-agonists/anticholinergic: EAF9i1 _____	☐☐/☐☐/☐ EAF9i1a	☐☐☐ EAF9i1b
j1) Long-acting $ß_2$-agonists/anticholinergic: EAF9j1 _____	☐☐/☐☐/☐ EAF9j1a	☐☐☐ EAF9j1b
k1) Roflumilast (Daxas, Daliresp) (Y/N): ☐ EAF9k1	☐☐/☐☐/☐ EAF9k1a	☐☐☐ EAF9k1b
l1) Leukotriene antagonists: EAF9l1 _____	☐☐/☐☐/☐ EAF9l1a	☐☐☐ EAF9l1b
m1) Other Medications: (Y/N): ☐ EAF9m1		
Specify: EAF9m1a _____	☐☐/☐☐/☐ EAF9m1b	☐☐☐ EAF9m1c

10) TREATMENTS	Date Prescribed	Duration (Days)
a) Pulmonary Rehabilitation (Y/N): ☐ EAF10a	☐☐/☐☐/☐ EAF10a1	☐☐☐ EAF10a2
b) Supplemental Oxygen (Y/N): ☐ EAF10b	☐☐/☐☐/☐ EAF10b1	☐☐☐ EAF10b2
c) Other Clinical Treatments (Y/N): ☐ EAF10c		
Specify: EAF10c1 _____	☐☐/☐☐/☐ EAF10c2	☐☐☐ EAF10c3

11) Have you had a new or changed prescription for oral steroids as a result of the change in your respiratory symptoms? ☐ EAF11

Yes 1

No..... 0→**Go to 12**

11a) What type of oral steroids were prescribed? EAF11a _____

11a1) Specify: EAF11a1 _____

11b) What date were the oral steroids prescribed? ☐☐/☐☐/☐☐☐☐ EAF11b

11c) What is the duration of this prescription? ☐☐☐ days EAF11c

11d) What was the total dosage of oral steroids prescribed? ☐☐☐ mg EAF11d

12) Have you taken any pain medications such as aspirin, Advil, Aleve, or Tylenol? ☐ EAF12

Yes 1

No..... 0→**Go to 13**

12a) Pain medicine 1: EAF12a _____

12a1) Specify: EAF12a1 _____

Date Started	Dose Taken (mg)	Times per day (1-6 or >6)	Duration (Days)
☐☐/☐☐/☐ EAF12a2	EAF12a3	EAF12a4	☐☐☐ EAF12a5

12b) Pain medicine 2: EAF12b _____

12b1) Specify: EAF12b1 _____

Date Started	Dose Taken (mg)	Times per day (1-6 or >6)	Duration (Days)
☐☐/☐☐/☐ EAF12b2	EAF12b3	EAF12b4	☐☐☐ EAF12b5

12c) Pain medicine 3: EAF12c _____

12c1) Specify: EAF12c1 _____

Date Started	Dose Taken (mg)	Times per day (1-6 or >6)	Duration (Days)
☐☐/☐☐/☐ EAF12c2	EAF12c3	EAF12c4	☐☐☐ EAF12c5

12d) Pain medicine 4: EAF12d _____

12d1) Specify: EAF12d1 _____

Date Started	Dose Taken (mg)	Times per day (1-6 or >6)	Duration (Days)
☐☐/☐☐/☐ EAF12d2	EAF12d3	EAF12d4	☐☐☐ EAF12d5

Review of Symptoms (Completed by Coordinator)

13) How serious is this flare-up/exacerbation compared to previous flare ups/exacerbations? ☐ EAF13

More serious 1

As serious 2

Less serious 3

Never had an exacerbation before 4

14) Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a) Increase or Worsening in Shortness of Breath (Dyspnea)	☐	☐	EAF14a
b) Change in sputum color (purulence).....	☐	☐	EAF14b
c) Increase in sputum volume.....	☐	☐	EAF14c

15) Since the start or worsening of your symptoms, have you experienced any of the following for at least 2 or more consecutive days?

	Yes	No	
a) Runny Nose/Nasal discharge	☐	☐	EAF15a
b) Increase or worsening of Wheeze	☐	☐	EAF15b
c) Sore throat.....	☐	☐	EAF15c
d) Increase or worsening of Cough.....	☐	☐	EAF15d
e) Fever	☐	☐	EAF15e

16) Have you had any OTHER **new** Symptoms related to this event? ☐ EAF16

Yes 1

No ..... 0→**Go to 17**

a) Symptom 1: EAF16a _____

b) Symptom 2: EAF16b _____

c) Symptom 3: EAF16c _____

d) Symptom 4: EAF16d _____

e) Symptom 5: EAF16e _____

f) Symptom 6: EAF16f _____

g) Symptom 7: EAF16g _____

h) Symptom 8: EAF16h _____

i) Symptom 9: EAF16i _____

j) Symptom 10: EAF16j _____

Physician Assessment

17) Wheezes: EAF17
- ☐ Yes
- ☐ No

18) Crackles: EAF18
- ☐ Yes
- ☐ No

19) Gallop: EAF19
- ☐ Yes
- ☐ No

20) Edema: EAF20
- ☐ Yes
- ☐ No

21) Were other conditions present at the time of this event? (Y/N) ☐ → If no skip to 23 EAF21

22) If yes, please specify the conditions present:

a) Pneumonia: EAF22a
- ☐ Yes
- ☐ No→Go to 22c

b) Pneumonia confirmed by:
- ☐ Chest film EAF22b
- ☐ Clinical examination
- ☐ Both

c) Congestive Heart Failure: EAF22c
- ☐ Yes
- ☐ No

d) Other: EAF22d
- ☐ Yes
- ☐ No

Specify:_____ EAF22d1

e) Other: EAF22e
- ☐ Yes
- ☐ No
- ☐ Specify:_____ EAF22e1

f) Other: EAF22f
- ☐ Yes
- ☐ No

Specify:_____ EAF22f1

23) Diagnosis of a COPD exacerbation: EAF23
- ☐ Yes
- ☐ No → **Skip to Q29**

24) Exacerbation severity: EAF24
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Very Severe

25) Duration to date: EAF25
- ☐ Less than 1 Day
- ☐ 1-2 Days
- ☐ 3-5 Days
- ☐ 1 Week
- ☐ More than 1 Week
- ☐ Unknown

26) Potential Etiology EAF26
- ☐ Infectious **(answer Q27)**
- ☐ Weather
- ☐ Treatment Non-Compliance
- ☐ Air pollution
- ☐ Unknown

27) Potential Infectious Etiology: EAF27
- ☐ Viral
- ☐ Bacterial
- ☐ Unknown
- ☐ Other (specify): EAF27a_____

28) Participant to proceed with exacerbation visit? EAF28
- ☐ Yes → **END**
- ☐ No
  - ☐ Not COPD exacerbation
  - ☐ Outside of visit window (> 72 hrs)
  - ☐ Other

Specify:_____ EAF28a

→ **END (Do not proceed to Q29 or 30)**

29) If not a COPD exacerbation, what: EAF29
- ☐ Lack of symptomatic criteria
- ☐ Upper respiratory tract infection
- ☐ Change in comorbid condition →**Go to Q28**
- ☐ Other

Specify:_____ EAF29a

30) Change(s) in what comorbid condition (s)? EAF30
- ☐ Cardiovascular (Angina, CHF, etc)
- ☐ Neurological
- ☐ Other

Specify:_____ EAF30a

eCigarette Use Assessment

ID NUMBER:	BLINDID	FORM CODE: **ECA** VERSION: **1.0** 06/11/14	Visit Number	VISIT	SEQ #

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) ECA0A 0b. Staff Code: ☐☐☐ ECA0B

Instructions: *Please complete this questionnaire during one of the study annual visits. This version of the questionnaire should be completed the first time the questionnaire is administered.*

1. Have you ever used an electronic cigarette or eCigarette?..... ☐ ECA1

Yes.....1
No .....0 → **Go to END**

2. When you did start smoking eCigarettes? ☐☐/☐☐/☐☐☐☐ ECA2

3a. Usually, were the eCigarettes you smoke/smoked with flavorings?..... ☐ ECA3A

Yes.....1
No 0
Don't Know.....2

3b. If yes, what flavor was it? ECA3B

Menthol 1
Candy.....2
Fruit.....3
Other 4

4. Do you still smoke eCigarettes?..... ☐ ECA4

Yes.....1
No .....0 → **Go to Q14**

5a. Do you still smoke regular tobacco cigarettes?..... ☐ ECA5A

Yes.....1
No .....0 → **Go to Q6**

5b. If Yes, how many regular cigarettes do you smoke a day: ☐☐☐ ECA5B

5c. Has your use of eCigarettes decreased the number of regular cigarettes you smoke each day?..... ☐ ECA5C

Yes.....1
No .....0 → **Go to Q6**

5c1. If **Yes**, about how many *fewer* cigarettes a day do you now smoke? ☐☐☐ ECA5C1

6. How often do you smoke eCigarettes?..... ☐ ECA6

Every day 1
Most days (4+ days a week) 2
Some days (1-3 days a week) .. 3
Less than once a week 4
Less than once a month 5

7. When did you last smoke an eCigarette?..... ☐ ECA7

Within the last hour..... 1
Sometime today 2
Yesterday..... 3
Within the last week 4
Within the last month..... 5
More than a month ago 6

8. In the last 24 hours, how many times have you smoked an eCigarette? ..... ☐☐ ECA8 times

9. What brand of eCigarette do you now smoke?..... ☐ ECA9A

blu 1
Henley.....2
Joye 3
NJOY 4
V2 5
Other 6
Specify: ECA9B _____

10. What cartridge size do you use most often with your eCigarettes?..... ECA10A

0 mg.....1
6-8 mg.....2
9-12 mg.....3
13-16 mg.....4
Do not know.....5
Other.....6
Specify: ☐☐ mg ECA10B

11. In one week, how many eCigarette cartridges do you use? ☐☐ cartridges ECA11

12. Did you start smoking eCigarettes because you wanted to cut down or stop smoking regular cigarette?..... ECA12

Yes.....1
No.....0

13. Did you start smoking eCigarettes because you wanted to improve your health?..... ECA13

Yes.....1
No.....0

Answer the following questions only if you no longer smoke eCigarettes (i.e., Question 4= N)

14. If **No**, for how long did you smoke eCigarettes?

ECA14A ☐☐ days ECA14B ☐☐ months ECA14C ☐☐ years

15. How long has it been since you smoked an eCigarette?

ECA15A ☐☐ days ECA15B ☐☐ months ECA15C ☐☐ years

16. When you did smoke eCigarettes, how often did you smoke eCigarettes?..... ECA16

Every day..... 1
Most days..... 2
4+ days a week..... 3
1-3 days a week..... 4

Less than once a week..... 5
Less than once a month 6

17. What brand of eCigarette did you usually smoke?..... ECA17

blu 1
Henley..... 2
Joye 3
NJOY 4
V2 5
Other..... 6
Specify: ECA17A_____

18. What cartridge size did you use most often with your eCigarettes?..... ECA18A

0 mg..... 1
6-8 mg..... 2
9-12 mg..... 3
13-16 mg..... 4
Do not know 5
Other..... 6
Specify: ☐☐ mg ECA18B

19. On average, in one week, how many eCigarette cartridges did you use? ☐☐ cartridges ECA19

eCigarette Use Assessment for Follow-up

ID NUMBER:	BLINDID	FORM CODE: **ECF** VERSION: **1.0** 06/11/14	Visit Number	VISIT	SEQ #

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ ECF0A (Month / Day / Year) 0b. Code: ☐☐☐ ECF0B

Instructions: *Please complete this questionnaire during annual study visits after the study visit where the ECA is administered.*

0c. Has this participant previously completed the ECA – eCigarrette Use Assessment form? ..... ☐ ECF0C

Yes..... 1
No ..... 0 → **Go to END; Complete ECA**

1. Have you used electronic cigarettes or eCigarettes since your last visit? ..... ☐ ECF1

Yes..... 1
No ..... 0 → **Go to END**

2. When did you start smoking eCigarettes? ☐☐/☐☐/☐☐☐☐ ECF2

3a. Usually were the eCigarettes you smoke/smoked with flavorings? ..... ☐ ECF3A

Yes..... 1
No 0
Don't Know..... 2

3b. If yes, what flavor was it? ECF3B

Menthol 1
Candy..... 2
Fruit..... 3
Other 4

4. Do you still smoke eCigarettes? ..... ☐ ECF4

Yes 1
No ..... 0 → **Go to Q14**

5. Do you still smoke regular tobacco cigarettes? ..... ☐ ECF5A

Yes 1
No ..... 0 → **Go to Q6**

5b. If Yes, how many regular cigarettes do you smoke a day: ☐☐☐ ECF5B

5c. Has your use of eCigarettes decreased the number of regular cigarettes you smoke each day? ..... ☐ ECF5C

Yes 1
No ..... 0 → **Go to Q6**

5c1. If **Yes**, about how many *fewer* cigarettes a day do you now smoke? ☐☐☐ ECF5C1

6. How often do you smoke eCigarettes? ..... ☐ ECF6

Every day 1
Most days 2
4+ days a week 3
1-3 days a week 4
Less than once a week 5
Less than once a month 6

7. When did you last smoke an eCigarette? ..... ☐ ECF7

Within the last hour 1
Sometime today 2
Yesterday 3
Within the last week 4
Within the last month 5
More than a month ago 6

8. In the last 24 hours, how many times have you smoked an

eCigarette? ..... ☐☐ times ECF8

9. What brand of eCigarette do you now smoke?..... ☐ ECF9A

blu 1
Henley 2
Joye 3
NJOY 4
V2 5
Other 6
Specify: ECF9B _____

10. What cartridge size do you use most often with your eCigarettes?..... ☐ ECF10A

0 mg 1
6-8 mg 2
9-12 mg 3
13-16 mg 4
Do not know 5
Other 6
Specify: ☐☐ mg ECF10B

11. In one week, how many eCigarette cartridges do you use? ☐☐ cartridges ECF11

12. Did you start smoking eCigarettes because you wanted to cut down or stop smoking regular cigarettes?..... ☐ ECF12

Yes 1
No 0

13. Did you start smoking eCigarettes because you wanted to improve your health?..... ☐ ECF13

Yes 1
No 0

Answer the following questions only if you no longer smoke eCigarettes (i.e., Question 4= N)

14. If **No**, for how long did you smoke eCigarettes?

ECF14A ☐☐ days ECF14B ☐☐ months ECF14C ☐☐ years

15. How long has it been since you smoked an eCigarette?

ECF15A ☐☐ days ECF15B ☐☐ months ECF15C ☐☐ years

16. When you did smoke eCigarettes, how often did you smoke eCigarettes?..... ☐ ECF16

Every day 1
Most days..... 2
4+ days a week 3
1-3 days a week 4
Less than once a week..... 5
Less than once a month 6

17. What brand of eCigarette did you usually smoke?..... ☐ ECF17

blu 1
Henley..... 2
Joye 3
NJOY 4
V2 5
Other 6
Specify: ECF17A _____

18. What cartridge size did you use most often with your eCigarettes?..... ☐ ECF18A

0 mg 1
6-8 mg..... 2
9-12 mg..... 3
13-16 mg..... 4
Do not know 5
Other 6
Specify: ☐☐ mg ECF18B

19. On average, in one week, how many eCigarette cartridges did you use? ☐☐ cartridges ECF19

EXACERBATION RESOLUTION FORM

ID NUMBER:	BLINDID				

FORM CODE: **ERF**
VERSION: **1.0** 08/9/13

Visit Number visit

SEQ # ☐☐☐

0a) Form Date: ..... ☐☐/☐☐/☐☐☐☐ EEF0a

0b) Initials ..... ☐☐☐ EEF0b

Instructions: *Twenty-eight days after the HCU exacerbation visit in Wave 1, contact the participant to determine whether exacerbation symptoms have resolved. If the symptoms have not resolved, contact the participant again in seven days. Repeat contacts every seven days until symptoms resolve OR more than 56 days have elapsed since the HCU exacerbation visit. When the participant reports his/her symptoms have resolved or more than 56 days have elapsed since the visit, the PDA must be updated to allow symptom-driven event triggering.*

A. Date of contact	B. Result Code	C. **Prompt:** Have you recovered from your exacerbation/flare-up?	D. If no: Date of next scheduled call
1) EEF1a	EEF1b	Yes ☐ No ☐ EEF1c	☐☐/☐☐/☐☐☐☐ EEF1d
2) EEF2a	EEF2b	Yes ☐ No ☐ EEF2c	☐☐/☐☐/☐☐☐☐ EEF2d
3) EEF3a	EEF3b	Yes ☐ No ☐ EEF3c	☐☐/☐☐/☐☐☐☐ EEF3d
4) EEF4a	EEF4b	Yes ☐ No ☐ EEF4c	☐☐/☐☐/☐☐☐☐ EEF4d
5) EEF5a	EEF5b	Yes ☐ No ☐ EEF5c	☐☐/☐☐/☐☐☐☐ EEF5d
6) EEF6a	EEF6b	Yes ☐ No ☐ EEF6c	☐☐/☐☐/☐☐☐☐ EEF6d
7) EEF7a	EEF7b	Yes ☐ No ☐ EEF7c	☐☐/☐☐/☐☐☐☐ EEF7d
8) EEF8a	EEF8b	Yes ☐ No ☐ EEF8c	☐☐/☐☐/☐☐☐☐ EEF8d

Result codes:

Contacted, call complete ..... A → **Go to 9**
Contacted, asked to call back ..... B
Reported alive, not available..... C
Reported alive, too sick to complete call ..... D
Reported alive, in hospital ..... E
Reported alive, proxy answered questions .. F
No answer ..... G

EMPLOYMENT HISTORY FORM – ANNUAL VISITS

ID NUMBER:	BLINDID	FORM CODE: **EHA** VERSION: **1.0** 9/21/2011	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ EHA0A 0b) Staff Code .... ☐

> ***Instructions:*** *This form should be interviewer administered, and completed during the participant's visit. Carefully answer each question regarding employment in the last 12 months. For check box questions please select "Yes" or "No" on all items. Please answer all questions.*

The following questions concern employment.

1) Has your employment status changed in the last 12 months?..... ☐ EHA1

Yes.....Y
No .....N →**Go to Item 18**
No Answer .....U →**Go to Item 18**

2) How has your employment situation changed in the last 12 months? ..... ☐ EHA2

Have you (*Please read all options before recording an answer*):

Started a new job .....1 →**Go to Item 3**
On leave but still employed .....2 →**Go to Item 18**
Temporarily laid off.....3 →**Go to Item 18**
Unemployed and looking for work .....4 →**Go to Item 9**
Unable to work .....5 →**Go to Item 9**
Going to school .....6 →**Go to Item 9**
Keeping house .....7 →**Go to Item 9**
Retired .....8 →**Go to Item 9**
Other.....9 →**Go to Item 9**
No answer.....0 →**Go to Item 18**

3) In your new job, what kind of work do you do? That is, what is your occupation?

Occupation : EHA3 _____

4) In this job, what are your usual activities or duties?

Job Duties: EHA4 _____

5) What is your business or industry? (If necessary: what do they make or do in this business?)

Business: EHA5 _____

6) Approximately what date did you begin working in this job? ..... ☐☐/☐☐☐☐ (MM/YYYY) EHA6

7) On average, how many hours per week do you work? ..... ☐☐ EHA7

8) Does your current job expose you to vapors, gas, dust, or fumes? ..... ☐ EHA8

Yes ..... Y
No ..... N
Don't know ..... U

I'm now going to ask you a few questions about the last job you had.

9) Did you leave your last job because of breathing or lung problems? ..... ☐ EHA9

Yes ..... Y
No ..... N
No Answer/Don't know ..... U

10) Did your last job expose you to vapors, gas, dust or fumes? ..... ☐ EHA10

Yes ..... Y
No ..... N
Don't know ..... U

11) Are you no longer working at your last job at least in part to avoid the things that caused you difficulty breathing, such as air quality, temperature, or physical exertion? ..... ☐ EHA11

Yes ..... Y
No ..... N
Don't know ..... U

12) Thinking back to where you were last employed, did you stop working there, at least in part, because of missed time due to illness ? ..... ☐ EHA12

Yes ..... Y
No ..... N
Don't know ..... U

ID NUMBER:									FORM CODE: **EHA** VERSION: **1.0** 9/21/11	Visit Number			SEQ #			

I'm now going to ask you a series of questions that might describe your current job. [Questions 13-15 should only be answered by participants who answered Started a new job in the past 12 months in Question 2]

13) Do you now work:		Yes	No	How many months?	
a) in a cotton, flax or hemp mill?	EHA13A	☐	☐	☐☐.☐	EHA13A1
b) in a foundry?	EHA13B	☐	☐	☐☐.☐	EHA13B1
c) in a glass works?	EHA13C	☐	☐	☐☐.☐	EHA13C1
d) in a mine?	EHA13D	☐	☐	☐☐.☐	EHA13D1
e) in a pottery?	EHA13E	☐	☐	☐☐.☐	EHA13E1
f) in a power plant?	EHA13F	☐	☐	☐☐.☐	EHA13F1
g) in a quarry?	EHA13G	☐	☐	☐☐.☐	EHA13G1
h) in a refinery?	EHA13H	☐	☐	☐☐.☐	EHA13H1
i) or with asbestos?	EHA13I	☐	☐	☐☐.☐	EHA13I1
j) in synthetic fibers or fabric manufacturing?	EHA13J	☐	☐	☐☐.☐	EHA13J1
k) in a paper mill?	EHA13K	☐	☐	☐☐.☐	EHA13K1
l) in building or highway construction?	EHA13L	☐	☐	☐☐.☐	EHA13L1
m) in an aluminum factory?	EHA13M	☐	☐	☐☐.☐	EHA13M1
n) in a rubber tire plant?	EHA13N	☐	☐	☐☐.☐	EHA13N1
o) in HVAC?	EHA13O	☐	☐	☐☐.☐	EHA13O1
p) in demolition?	EHA13P	☐	☐	☐☐.☐	EHA13P1
q) in remodeling?	EHA13Q	☐	☐	☐☐.☐	EHA13Q1
r) in professional cleaning?	EHA13R	☐	☐	☐☐.☐	EHA13R1
s) in beauty care?	EHA13S	☐	☐	☐☐.☐	EHA13S1
t) in agriculture?	EHA13T	☐	☐	☐☐.☐	EHA13T1
u) in the flooring industry?	EHA13U	☐	☐	☐☐.☐	EHA13U1

14) Do you now work as:		Yes	No	How many months?	
a) a boilermaker?	EHA14A	☐	☐	☐☐.☐	EHA14A1
b) a carpenter?	EHA14B	☐	☐	☐☐.☐	EHA14B1
c) a chemical worker?	EHA14C	☐	☐	☐☐.☐	EHA14C1
d) an electrician?	EHA14D	☐	☐	☐☐.☐	EHA14D1
e) an elevator operator?	EHA14E	☐	☐	☐☐.☐	EHA14E1
f) an insulator?	EHA14F	☐	☐	☐☐.☐	EHA14F1
g) a lather?	EHA14G	☐	☐	☐☐.☐	EHA14G1
h) a machinist?	EHA14H	☐	☐	☐☐.☐	EHA14H1
i) a mechanic?	EHA14I	☐	☐	☐☐.☐	EHA14I1
j) a millwright?	EHA14J	☐	☐	☐☐.☐	EHA14J1
k) a pipefitter?	EHA14K	☐	☐	☐☐.☐	EHA14K1
l) a plasterer?	EHA14L	☐	☐	☐☐.☐	EHA14L1
m) a plumber?	EHA14M	☐	☐	☐☐.☐	EHA14M1
n) a sander?	EHA14N	☐	☐	☐☐.☐	EHA14N1

		Yes	No	How many months?	
o) a sheet metal worker?	EHA14O	☐	☐	☐☐.☐	EHA14O1
p) a steelworker?	EHA14P	☐	☐	☐☐.☐	EHA14P1
q) a welder?	EHA14Q	☐	☐	☐☐.☐	EHA14Q1
r) a pig farmer?	EHA14R	☐	☐	☐☐.☐	EHA14R1
s) a rigger?	EHA14S	☐	☐	☐☐.☐	EHA14S1
t) a roofer?	EHA14T	☐	☐	☐☐.☐	EHA14T1
u) a painter?	EHA14U	☐	☐	☐☐.☐	EHA14U1
v) a mason?	EHA14V	☐	☐	☐☐.☐	EHA14V1

15) In your job, do you come into regular contact with any of the following specific examples of vapors, gas, dust or fumes?

		Yes	No	How many months?	
a) Irritant gases, such as chlorine or ammonia	EHA15A	☐	☐	☐☐.☐	EHA15A1
b) Fire, smoke or other combustion products	EHA15B	☐	☐	☐☐.☐	EHA15B1
c) Incinerators, boilers, or oil refineries	EHA15C	☐	☐	☐☐.☐	EHA15C1
d) Coal dust or powder	EHA15D	☐	☐	☐☐.☐	EHA15D1
e) Silica or sand, or concrete, cement, or rock dust	EHA15E	☐	☐	☐☐.☐	EHA15E1
f) Indoor fuel powered motors, compressors, or engines	EHA15F		☐	☐☐.☐	EHA15F1
g) Diesel engine exhaust	EHA15G	☐	☐	☐☐.☐	EHA15G1
h) Wheat flour or other grain dusts	EHA15H	☐	☐	☐☐.☐	EHA15H1
i) Animal feeds or fodder	EHA15I	☐	☐	☐☐.☐	EHA15I1
j) Cotton dust or cotton processing	EHA15J	☐	☐	☐☐.☐	EHA15J1
k) Wood dust or saw dust	EHA15K	☐	☐	☐☐.☐	EHA15K1
l) Cadmium fumes or batteries or silver solder	EHA15L	☐	☐	☐☐.☐	EHA15L1
m) Other metal dusts or metal fumes	EHA15M	☐	☐	☐☐.☐	EHA15M1
n) Welding or flame cutting	EHA15N	☐	☐	☐☐.☐	EHA15N1
o) Fiberglass or other man-made mineral fibers	EHA15O	☐	☐	☐☐.☐	EHA15O1
p) Explosives or blasting fumes	EHA15P	☐	☐	☐☐.☐	EHA15P1

If Question 13d = Y (that is, history of working in a mine) answer questions 16-17)

In question 13 you indicated you work in a mine.

16) Why type of mine is it? ..... ☐ EHA16

Open pit 1
Underground 2
Other 3
Specify: EHA16A _____

17) What is mined? ..... [ ] EHA17

Hard rock (e.g., lead, zinc, silver, gold, etc) 1
Uranium 2
Coal 3
Other 4
Specify: EHA17A _____

18) During your last visit you indicated you worked in the following location(s). We'd like to know for how many years you worked in this(these) location(s). [DO NOT READ: If none are marked skip to question 19]

		Yes	No	How many years?
a) in a cotton, flax or hemp mill?	EHA18A	☐	☐	☐☐.☐ EHA18A1
b) in a foundry?	EHA18B	☐	☐	☐☐.☐ EHA18B1
c) in a glass works?	EHA18C	☐	☐	☐☐.☐ EHA18C1
d) in a mine?	EHA18D	☐	☐	☐☐.☐ EHA18D1
e) in a pottery?	EHA18E	☐	☐	☐☐.☐ EHA18E1
f) in a power plant?	EHA18F	☐	☐	☐☐.☐ EHA18F1
g) in a quarry?	EHA18G	☐	☐	☐☐.☐ EHA18G1
h) in a refinery?	EHA18H	☐	☐	☐☐.☐ EHA18H1
i) or with asbestos?	EHA18I	☐	☐	☐☐.☐ EHA18I1
j) in synthetic fibers or fabric manufacturing?	EHA18J	☐	☐	☐☐.☐ EHA18J1
k) in a paper mill?	EHA18K	☐	☐	☐☐.☐ EHA18K1
l) in building or highway construction?	EHA18L	☐	☐	☐☐.☐ EHA18L1
m) in an aluminum factory?	EHA18M	☐	☐	☐☐.☐ EHA18M1
n) in a rubber tire plant?	EHA18N	☐	☐	☐☐.☐ EHA18N1
o) in HVAC?	EHA18O	☐	☐	☐☐.☐ EHA18O1
p) in demolition?	EHA18P	☐	☐	☐☐.☐ EHA18P1
q) in remodeling?	EHA18Q	☐	☐	☐☐.☐ EHA18Q1
r) in professional cleaning?	EHA18R	☐	☐	☐☐.☐ EHA18R1
s) in beauty care?	EHA18S	☐	☐	☐☐.☐ EHA18S1
t) in agriculture?	EHA18T	☐	☐	☐☐.☐ EHA18T1
u) in the flooring industry?	EHA18U	☐	☐	☐☐.☐ EHA18U1

19) During your last visit you indicated you worked in the following occupation(s). We'd like to know for how many years you worked in this(these) occupation(s). [DO NOT READ: If none are marked skip to question 20]

		Yes	No	How many years?
a) a boilermaker?	EHA19A	☐	☐	☐☐.☐ EHA19A1
b) a carpenter?	EHA19B	☐	☐	☐☐.☐ EHA19B1
c) a chemical worker?	EHA19C	☐	☐	☐☐.☐ EHA19C1
d) an electrician?	EHA19D	☐	☐	☐☐.☐ EHA19D1
e) an elevator operator?	EHA19E	☐	☐	☐☐.☐ EHA19E1
f) an insulator?	EHA19F	☐	☐	☐☐.☐ EHA19F1
g) a lather?	EHA19G	☐	☐	☐☐.☐ EHA19G1
h) a machinist?	EHA19H	☐	☐	☐☐.☐ EHA19H1
i) a mechanic?	EHA19I	☐	☐	☐☐.☐ EHA19I1
j) a millwright?	EHA19J	☐	☐	☐☐.☐ EHA19J1
k) a pipefitter?	EHA19K	☐	☐	☐☐.☐ EHA19K1
l) a plasterer?	EHA19L	☐	☐	☐☐.☐ EHA19L1
m) a plumber?	EHA19M	☐	☐	☐☐.☐ EHA19M1

n)	a sander?	EHA19N	☐	☐	☐☐.☐ EHA19N1
o)	a sheet metal worker?	EHA19O	☐	☐	☐☐.☐ EHA19O1
p)	a steelworker?	EHA19P	☐	☐	☐☐.☐ EHA19P1
q)	a welder?	EHA19Q	☐	☐	☐☐.☐ EHA19Q1
r)	a pig farmer?	EHA19R	☐	☐	☐☐.☐ EHA19R1
s)	a rigger?	EHA19S	☐	☐	☐☐.☐ EHA19S1
t)	a roofer?	EHA19T	☐	☐	☐☐.☐ EHA19T1
u)	a painter?	EHA19U	☐	☐	☐☐.☐ EHA19U1
v)	a mason?	EHA19V	☐	☐	☐☐.☐ EHA19V1

20) During your last visit, you indicated that as part of a job you regularly came into contact with one or more of the following specific examples of vapors, gas, dust or fumes. [DO NOT READ: If none are marked skip to question 21]

			Yes	No	How many years?
a)	Irritant gases, such as chlorine or ammonia	EHA20A	☐	☐	☐☐.☐ EHA20A1
b)	Fire, smoke or other combustion products	EHA20B	☐	☐	☐☐.☐ EHA20B1
c)	Incinerators, boilers, or oil refineries	EHA20C	☐	☐	☐☐.☐ EHA20C1
d)	Coal dust or powder	EHA20D	☐	☐	☐☐.☐ EHA20D1
e)	Silica or sand, or concrete, cement, or rock dust	EHA20E	☐	☐	☐☐.☐ EHA20E1
f)	Indoor fuel powered motors, compressors, or engines	EHA20F	☐	☐	☐☐.☐ EHA20F1
g)	Diesel engine exhaust	EHA20G	☐	☐	☐☐.☐ EHA20G1
h)	Wheat flour or other grain dusts	EHA20H	☐	☐	☐☐.☐ EHA20H1
i)	Animal feeds or fodder	EHA20I	☐	☐	☐☐.☐ EHA20I1
j)	Cotton dust or cotton processing	EHA20J	☐	☐	☐☐.☐ EHA20J1
k)	Wood dust or saw dust	EHA20K	☐	☐	☐☐.☐ EHA20K1
l)	Cadmium fumes or batteries or silver solder	EHA20L	☐	☐	☐☐.☐ EHA20L1
m)	Other metal dusts or metal fumes	EHA20M	☐	☐	☐☐.☐ EHA20M1
n)	Welding or flame cutting	EHA20N	☐	☐	☐☐.☐ EHA20N1
o)	Fiberglass or other man-made mineral fibers	EHA20O	☐	☐	☐☐.☐ EHA20O1
p)	Explosives or blasting fumes	EHA20P	☐	☐	☐☐.☐ EHA20P1

If Question 18d = Y (that is, history of working in a mine) answer questions 21-22)

In question 18 you indicated you have worked in a mine.

21) Why type of mine was it? ..... ☐ EHA21

Open pit 1
Underground 2
Other 3
Specify: EHA21A _____

22) What was mined?..... ☐ EHA22

Hard rock (e.g., lead, zinc, silver, gold, etc).....1
Uranium 2
Coal 3
Other 4
Specify: EHA22A _____

EMPLOYMENT HISTORY FORM

ID NUMBER:	BLINDID					FORM CODE: EHF VERSION: 2.1 5/8/11	Visit Number	VISIT	SEQ #			

0a) Form Date..... ☐☐/☐☐/☐☐☐☐ EHF0A 0b) Staff Code .... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Carefully answer each question regarding current and past employment. For check box questions please select "Yes" or "No" on all items. Please answer all questions.*

The following questions concern employment.

1) Have you ever been employed for a wage or salary, either part-time or full-time?..... ☐ EHF01

Yes..... Y
No ..... N →**Go to Item 18**
No Answer ..... U →**Go to Item 18**

2) Which of the following best describes your current employment situation?..... ☐ EHF02

Are you currently:

Working..... 1 →**Go to Item 13**
On leave but still employed..... 2 →**Go to Item 13**
Temporarily laid off ..... 3 →**Go to Item 13**
Unemployed and looking for work 4
Unable to work..... 5
Going to school..... 6
Keeping house..... 7
Retired 8
Other..... 9
No answer..... 0 →**Go to Item 18**

3) In your last job, what kind of work did you do? That is, what was your occupation?

Occupation : EHF3 _____

4) In this job, what were your usual activities or duties?

Job Duties: EHF04 _____

5) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF05 _____

6) What year did you begin working in this job? ..... ☐☐☐☐ EHF06

7) How many years, altogether, did you work in this job? ..... [ ][ ] EHF07

7a) On average, how many hours per week did you work in this job? ..... [ ][ ] EHF07A

8) Did you leave your last job because of breathing or lung problems? ..... [ ] EHF08

Yes ..... Y
No ..... N
No Answer/Don't know ..... U

9) Are you not working at least in part to avoid the things that caused you difficulty breathing, such as air quality, temperature, or physical exertion? ..... [ ] EHF09

Yes ..... Y
No ..... N
Don't know ..... U

10) Thinking back to when you were last employed, did you stop working, at least in part, because of missed time due to illness ? ..... [ ] EHF10

Yes ..... Y
No ..... N
Don't know ..... U

11) Did this job expose you to vapors, gas, dust or fumes? ..... [ ] EHF11

Yes ..... Y
No ..... N
Don't know ..... U

12) Was this work the longest job that you have ever held? ..... [ ] EHF12

Yes ..... Y → **Go to Item 18**
No ..... N
Don't know ..... U → **Go to Item 18**

a) In your longest held job, what kind of work did you do? That is, what was your occupation?

Occupation: EHF12A _____

b) In this job, what were your usual activities or duties?

Job Duties: EHF12B _____

c) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF12C _____

d) Did this job expose you to vapors, gas, dust or fumes?..... EHF12D

Yes..... Y
No ..... N
Don't know ..... U

e) What year did you begin working in this job?..... EHF12E

f) How many years, altogether, did you work in this job? EHF12F

g) On average, how many hours per week did you work in this job?..... EHF12G

If Question 2 = 1, 2, or 3 (that is, currently employed) answer questions 13-17)

13) At this job, what kind of work do you do? That is, what is your occupation?

Occupation:_EHF13_____

14) In this job, what are your usual activities or duties?

Job Duties:_EHF14_____

15) What is your business or industry? (If necessary: what do they make or do in this business?)

Business:_EHF15_____

16) How many years, altogether, have you worked in this job? EHF16

17) On average, how many hours per week do you work? EHF17

ID NUMBER:									FORM CODE: EHF VERSION: 2.1 5/8/11	Visit Number			SEQ #			

18) Have you ever worked:		Yes	No	How many years?	
a) in a cotton, flax or hemp mill?	EHF18A	☐	☐	☐☐.☐	EHF18A1
b) in a foundry?	EHF18B	☐	☐	☐☐.☐	EHF18B1
c) in a glass works?	EHF18C	☐	☐	☐☐.☐	EHF18C1
d) in a mine?	EHF18D	☐	☐	☐☐.☐	EHF18D1
e) in a pottery?	EHF18E	☐	☐	☐☐.☐	EHF18E1
f) in a power plant?	EHF18F	☐	☐	☐☐.☐	EHF18F1
g) in a quarry?	EHF18G	☐	☐	☐☐.☐	EHF18G1
h) in a refinery?	EHF18H	☐	☐	☐☐.☐	EHF18H1
i) or with asbestos?	EHF18I	☐	☐	☐☐.☐	EHF18I1
j) in synthetic fibers or fabric manufacturing?	EHF18J	☐	☐	☐☐.☐	EHF18J1
k) in a paper mill?	EHF18K	☐	☐	☐☐.☐	EHF18K1
l) in building or highway construction?	EHF18L	☐	☐	☐☐.☐	EHF18L1
m) in an aluminum factory?	EHF18M	☐	☐	☐☐.☐	EHF18M1
n) in a rubber tire plant?	EHF18N	☐	☐	☐☐.☐	EHF18N1
o) in HVAC?	EHF18O	☐	☐	☐☐.☐	EHF18O1
p) in demolition?	EHF18P	☐	☐	☐☐.☐	EHF18P1
q) in remodeling?	EHF18Q	☐	☐	☐☐.☐	EHF18Q1
r) in professional cleaning?	EHF18R	☐	☐	☐☐.☐	EHF18R1
s) in beauty care?	EHF18S	☐	☐	☐☐.☐	EHF18S1
t) in agriculture?	EHF18T	☐	☐	☐☐.☐	EHF18T1
u) in the flooring industry?	EHF18U	☐	☐	☐☐.☐	EHF18U1

19) Have you ever worked as:		Yes	No	How many years?	
a) a boilermaker?	EHF19A	☐	☐	☐☐.☐	EHF19A1
b) a carpenter?	EHF19B	☐	☐	☐☐.☐	EHF19B1
c) a chemical worker?	EHF19C	☐	☐	☐☐.☐	EHF19C1
d) an electrician?	EHF19D	☐	☐	☐☐.☐	EHF19D1
e) an elevator operator?	EHF19E	☐	☐	☐☐.☐	EHF19E1
f) an insulator?	EHF19F	☐	☐	☐☐.☐	EHF19F1
g) a lather?	EHF19G	☐	☐	☐☐.☐	EHF19G1
h) a machinist?	EHF19H	☐	☐	☐☐.☐	EHF19H1
i) a mechanic?	EHF19I	☐	☐	☐☐.☐	EHF19I1
j) a millwright?	EHF19J	☐	☐	☐☐.☐	EHF19J1
k) a pipefitter?	EHF19K	☐	☐	☐☐.☐	EHF19K1
l) a plasterer?	EHF19L	☐	☐	☐☐.☐	EHF19L1
m) a plumber?	EHF19M	☐	☐	☐☐.☐	EHF19M1
n) a sander?	EHF19N	☐	☐	☐☐.☐	EHF19N1

		Yes	No	How many years?	
o) a sheet metal worker?	EHF19O	☐	☐	☐☐.☐	EHF19O1
p) a steelworker?	EHF19P	☐	☐	☐☐.☐	EHF19P1
q) a welder?	EHF19Q	☐	☐	☐☐.☐	EHF19Q1
r) a pig farmer?	EHF19R	☐	☐	☐☐.☐	EHF19R1
s) a rigger?	EHF19S	☐	☐	☐☐.☐	EHF19S1
t) a roofer?	EHF19T	☐	☐	☐☐.☐	EHF19T1
u) a painter?	EHF19U	☐	☐	☐☐.☐	EHF19U1
v) a mason?	EHF19V	☐	☐	☐☐.☐	EHF19V1

20) In your job, do/did you come into regular contact with any of the following specific examples of vapors, gas, dust or fumes?

		Yes	No	How many years?	
a) Irritant gases, such as chlorine or ammonia	EHF20A	☐	☐	☐☐.☐	EHF20A1
b) Fire, smoke or other combustion products	EHF20B	☐	☐	☐☐.☐	EHF20B1
c) Incinerators, boilers, or oil refineries	EHF20C	☐	☐	☐☐.☐	EHF20C1
d) Coal dust or powder	EHF20D	☐	☐	☐☐.☐	EHF20D1
e) Silica or sand, or concrete, cement, or rock dust	EHF20E	☐	☐	☐☐.☐	EHF20E1
f) Indoor fuel powered motors, compressors, or engines	EHF20F		☐	☐☐.☐	EHF20F1
g) Diesel engine exhaust	EHF20G	☐	☐	☐☐.☐	EHF20G1
h) Wheat flour or other grain dusts	EHF20H	☐	☐	☐☐.☐	EHF20H1
i) Animal feeds or fodder	EHF20I	☐	☐	☐☐.☐	EHF20I1
j) Cotton dust or cotton processing	EHF20J	☐	☐	☐☐.☐	EHF20J1
k) Wood dust or saw dust	EHF20K	☐	☐	☐☐.☐	EHF20K1
l) Cadmium fumes or batteries or silver solder	EHF20L	☐	☐	☐☐.☐	EHF20L1
m) Other metal dusts or metal fumes	EHF20M	☐	☐	☐☐.☐	EHF20M1
n) Welding or flame cutting	EHF20N	☐	☐	☐☐.☐	EHF20N1
o) Fiberglass or other man-made mineral fibers	EHF20O	☐	☐	☐☐.☐	EHF20O1
p) Explosives or blasting fumes	EHF20P	☐	☐	☐☐.☐	EHF20P1

If Question 18d = Y (that is, history of working in a mine) answer questions 21-22)

In question 18 you indicated you have worked in a mine.

21) What type of mine was it? ☐ EHF21

Open pit 1
Underground 2
Other 3
Specify: EHF21A _____

22) What was mined?..... EHF22

Hard rock (e.g., lead, zinc, silver, gold, etc)..... 1
Uranium 2
Coal 3
Other 4
Specify: EHF22A _____

If Question 2 = 1, 2, or 3 (that is, currently employed) answer question 23)

The following questions relate either to your current job or your longest held job.

23) Does your current job expose you to vapors, gas, dust or fumes?..... EHF23

Yes..... Y
No ..... N
Don't know ..... U

24) Is your current work the longest job that you have ever held? EHF24

Yes..... Y →**End**
No ..... N
Don't know ..... U →**End**

a) In your longest held job, what kind of work did you do? That is, what was your occupation?

Occupation: EHF24A _____

b) In this job, what were your usual activities or duties?

Job Duties: EHF24B _____

c) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF24C _____

d) Did this job expose you to vapors, gas, dust or fumes?..... EHF24D

Yes..... Y
No ..... N
Don't know ..... U

e) What year did you begin working in this job?..... EHF24E

f) How many years, altogether, did you work in this job? EHF24F

g) On average, how many hours per week did you work in this job?..... EHF24G

EMPLOYMENT HISTORY FORM

ID NUMBER:	BLINDID	FORM CODE: **EHF** VERSION: **2.0** 9/21/11	Visit Number	VISIT	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ EHF0A 0b) Staff Code .... __ __ __

Instructions: *This form should be completed during the participant's visit. Carefully answer each question regarding current and past employment. For check box questions please select "Yes" or "No" on all items. Please answer all questions.*

The following questions concern employment.

1) Have you ever been employed for a wage or salary, either part-time or full-time? ..... ☐ EHF01

Yes ..... Y
No ..... N → **Go to Item 18**
No Answer ..... U → **Go to Item 18**

2) Which of the following best describes your current employment situation? ..... ☐ EHF02

Are you currently:

Working ..... 1 → **Go to Item 13**
On leave but still employed ..... 2 → **Go to Item 13**
Temporarily laid off ..... 3 → **Go to Item 13**
Unemployed and looking for work 4
Unable to work 5
Going to school 6
Keeping house 7
Retired 8
Other 9
No answer ..... 0 → **Go to Item 18**

3) In your last job, what kind of work did you do? That is, what was your occupation?

Occupation : EHF3 _____

4) In this job, what were your usual activities or duties?

Job Duties: EHF04 _____

5) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF05 _____

6) What year did you begin working in this job? ..... ☐☐☐☐ EHF06

7) How many years, altogether, did you work in this job? EHF07

7a) On average, how many hours per week did you work in this job? EHF07A

8) Did you leave your last job because of breathing or lung problems? EHF08

Yes ..... Y
No ..... N
No Answer/Don't know ..... U

9) Are you not working at least in part to avoid the things that caused you difficulty breathing, such as air quality, temperature, or physical exertion? EHF09

Yes ..... Y
No ..... N
Don't know ..... U

10) Thinking back to when you were last employed, did you stop working, at least in part, because of missed time due to illness ? EHF10

Yes ..... Y
No ..... N
Don't know ..... U

11) Did this job expose you to vapors, gas, dust or fumes? EHF11

Yes ..... Y
No ..... N
Don't know ..... U

12) Was this work the longest job that you have ever held? EHF12

Yes ..... Y → **Go to Item 18**
No ..... N
Don't know ..... U → **Go to Item 18**

a) In your longest held job, what kind of work did you do? That is, what was your occupation?

Occupation: EHF12A _____

b) In this job, what were your usual activities or duties?

Job Duties: EHF12B _____

c) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF12C _____

d) Did this job expose you to vapors, gas, dust or fumes?..... EHF12D

Yes.....Y
No.....N
Don't know .....U

e) What year did you begin working in this job?..... EHF12E

f) How many years, altogether, did you work in this job? EHF12F

g) On average, how many hours per week did you work in this job? EHF12G

If Question 2 = 1, 2, or 3 (that is, currently employed) answer questions 13-17)

13) At this job, what kind of work do you do? That is, what is your occupation?

Occupation:_EHF13_____

14) In this job, what are your usual activities or duties?

Job Duties:_EHF14_____

15) What is your business or industry? (If necessary: what do they make or do in this business?)

Business:_EHF15_____

16) How many years, altogether, have you worked in this job?..... EHF16

17) On average, how many hours per week do you work? EHF17

ID NUMBER:									FORM CODE: **EHF** VERSION: **2.0** 9/21/11	Visit Number			SEQ #			

18) Have you ever worked:

		Yes	No	How many years?	
a) in a cotton, flax or hemp mill?	EHF18A	☐	☐	☐☐.☐	EHF18A1
b) in a foundry?	EHF18B	☐	☐	☐☐.☐	EHF18B1
c) in a glass works?	EHF18C	☐	☐	☐☐.☐	EHF18C1
d) in a mine?	EHF18D	☐	☐	☐☐.☐	EHF18D1
e) in a pottery?	EHF18E	☐	☐	☐☐.☐	EHF18E1
f) in a power plant?	EHF18F	☐	☐	☐☐.☐	EHF18F1
g) in a quarry?	EHF18G	☐	☐	☐☐.☐	EHF18G1
h) in a refinery?	EHF18H	☐	☐	☐☐.☐	EHF18H1
i) or with asbestos?	EHF18I	☐	☐	☐☐.☐	EHF18I1
j) in synthetic fibers or fabric manufacturing?	EHF18J	☐	☐	☐☐.☐	EHF18J1
k) in a paper mill?	EHF18K	☐	☐	☐☐.☐	EHF18K1
l) in building or highway construction?	EHF18L	☐	☐	☐☐.☐	EHF18L1
m) in an aluminum factory?	EHF18M	☐	☐	☐☐.☐	EHF18M1
n) in a rubber tire plant?	EHF18N	☐	☐	☐☐.☐	EHF18N1
o) in HVAC?	EHF18O	☐	☐	☐☐.☐	EHF18O1
p) in demolition?	EHF18P	☐	☐	☐☐.☐	EHF18P1
q) in remodeling?	EHF18Q	☐	☐	☐☐.☐	EHF18Q1
r) in professional cleaning?	EHF18R	☐	☐	☐☐.☐	EHF18R1
s) in beauty care?	EHF18S	☐	☐	☐☐.☐	EHF18S1
t) in agriculture?	EHF18T	☐	☐	☐☐.☐	EHF18T1
u) in the flooring industry?	EHF18U	☐	☐	☐☐.☐	EHF18U1

19) Have you ever worked as:

		Yes	No	How many years?	
a) a boilermaker?	EHF19A	☐	☐	☐☐.☐	EHF19A1
b) a carpenter?	EHF19B	☐	☐	☐☐.☐	EHF19B1
c) a chemical worker?	EHF19C	☐	☐	☐☐.☐	EHF19C1
d) an electrician?	EHF19D	☐	☐	☐☐.☐	EHF19D1
e) an elevator operator?	EHF19E	☐	☐	☐☐.☐	EHF19E1
f) an insulator?	EHF19F	☐	☐	☐☐.☐	EHF19F1
g) a lather?	EHF19G	☐	☐	☐☐.☐	EHF19G1
h) a machinist?	EHF19H	☐	☐	☐☐.☐	EHF19H1
i) a mechanic?	EHF19I	☐	☐	☐☐.☐	EHF19I1
j) a millwright?	EHF19J	☐	☐	☐☐.☐	EHF19J1
k) a pipefitter?	EHF19K	☐	☐	☐☐.☐	EHF19K1
l) a plasterer?	EHF19L	☐	☐	☐☐.☐	EHF19L1
m) a plumber?	EHF19M	☐	☐	☐☐.☐	EHF19M1
n) a sander?	EHF19N	☐	☐	☐☐.☐	EHF19N1

		Yes	No	How many years?	
o)	a sheet metal worker?	EHF19O ☐	☐	☐☐.☐	EHF19O1
p)	a steelworker?	EHF19P ☐	☐	☐☐.☐	EHF19P1
q)	a welder?	EHF19Q ☐	☐	☐☐.☐	EHF19Q1
r)	a pig farmer?	EHF19R ☐	☐	☐☐.☐	EHF19R1
s)	a rigger?	EHF19S ☐	☐	☐☐.☐	EHF19S1
t)	a roofer?	EHF19T ☐	☐	☐☐.☐	EHF19T1
u)	a painter?	EHF19U ☐	☐	☐☐.☐	EHF19U1
v)	a mason?	EHF19V ☐	☐	☐☐.☐	EHF19V1

20) In your job, do/did you come into regular contact with any of the following specific examples of vapors, gas, dust or fumes?

		Yes	No	How many years?	
a)	Irritant gases, such as chlorine or ammonia	EHF20A ☐	☐	☐☐.☐	EHF20A1
b)	Fire, smoke or other combustion products	EHF20B ☐	☐	☐☐.☐	EHF20B1
c)	Incinerators, boilers, or oil refineries	EHF20C ☐	☐	☐☐.☐	EHF20C1
d)	Coal dust or powder	EHF20D ☐	☐	☐☐.☐	EHF20D1
e)	Silica or sand, or concrete, cement, or rock dust	EHF20E ☐	☐	☐☐.☐	EHF20E1
f)	Indoor fuel powered motors, compressors, or engines	EHF20F	☐	☐☐.☐	EHF20F1
g)	Diesel engine exhaust	EHF20G ☐	☐	☐☐.☐	EHF20G1
h)	Wheat flour or other grain dusts	EHF20H ☐	☐	☐☐.☐	EHF20H1
i)	Animal feeds or fodder	EHF20I ☐	☐	☐☐.☐	EHF20I1
j)	Cotton dust or cotton processing	EHF20J ☐	☐	☐☐.☐	EHF20J1
k)	Wood dust or saw dust	EHF20K ☐	☐	☐☐.☐	EHF20K1
l)	Cadmium fumes or batteries or silver solder	EHF20L ☐	☐	☐☐.☐	EHF20L1
m)	Other metal dusts or metal fumes	EHF20M ☐	☐	☐☐.☐	EHF20M1
n)	Welding or flame cutting	EHF20N ☐	☐	☐☐.☐	EHF20N1
o)	Fiberglass or other man-made mineral fibers	EHF20O ☐	☐	☐☐.☐	EHF20O1
p)	Explosives or blasting fumes	EHF20P ☐	☐	☐☐.☐	EHF20P1

If Question 18d = Y (that is, history of working in a mine) answer questions 23-24)

In question 18 you indicated you have worked in a mine.

21) What type of mine was it? ☐ EHF21

Open pit 1
Underground 2
Other 3
Specify: EHF21A _____

22) What was mined?..... EHF22

Hard rock (e.g., lead, zinc, silver, gold, etc) 1
Uranium 2
Coal 3
Other 4
Specify: EHF22A _____

If Question 2 = 1, 2, or 3 (that is, currently employed) answer question 23)

The following questions relate either to your current job or your longest held job.

23) Does your current job expose you to vapors, gas, dust or fumes?..... EHF23

Yes.....Y
No .....N
Don't know .....U

24) Is your current work the longest job that you have ever held? EHF24

Yes.....Y →**End**
No .....N
Don't know .....U →**End**

a) In your longest held job, what kind of work did you do? That is, what was your occupation?

Occupation: EHF24A _____

b) In this job, what were your usual activities or duties?

Job Duties: EHF24B _____

c) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF24C _____

d) Did this job expose you to vapors, gas, dust or fumes?..... EHF24D

Yes.....Y
No .....N
Don't know .....U

e) What year did you begin working in this job?..... EHF24E

f) How many years, altogether, did you work in this job? EHF24F

g) On average, how many hours per week did you work in this job? EHF24G

EMPLOYMENT HISTORY FORM

ID NUMBER:	BLINDID	FORM CODE: EHF VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ EHF0A 0b) Initials ..... __

Instructions: *This form should be completed during the participant's visit. Carefully answer each question regarding current and past employment. For check box questions please select "Yes" or "No" on all items. Please answer all questions.*

The following questions concern employment.

1) Have you ever been employed for a wage or salary, either part-time or full-time? ..... __ EHF01

Yes ..... Y
No ..... N → **Go to Item 18**
No Answer ..... U → **Go to Item 18**

2) Which of the following best describes your current employment situation? ..... __ EHF02

Are you currently:

Working ..... 1 → **Go to Item 13**
On leave but still employed ..... 2 → **Go to Item 13**
Temporarily laid off ..... 3 → **Go to Item 13**
Unemployed and looking for work 4
Unable to work 5
Going to school 6
Keeping house 7
Retired 8
Other 9
No answer ..... 0 → **Go to Item 18**

3) In your last job, what kind of work did you do? That is, what was your occupation?

Occupation : EHF3 _____

4) In this job, what were your usual activities or duties?

Job Duties: EHF04 _____

5) What was your business or industry? (If necessary: what did they make or do in this business?)

Business: EHF05 _____

6) What year did you begin working in this job? ..... __ __ __ __ EHF06

7) How many years, altogether, did you work in this job? ..... [ ][ ] EHF07

8) Did you leave your last job because of breathing or lung problems? ..... [ ] EHF08

Yes.....Y
No.....N
No Answer/Don't know.....U

9) Are you not working at least in part to avoid the things that caused you difficulty breathing, such as air quality, temperature, or physical exertion? ..... [ ] EHF09

Yes.....Y
No.....N
Don't know.....U

10) Thinking back to when you were last employed, did you stop working, at least in part, because of missed time due to illness ? ..... [ ] EHF10

Yes.....Y
No.....N
Don't know.....U

11) Did this job expose you to vapors, gas, dust or fumes?..... [ ] EHF11

Yes.....Y
No.....N
Don't know.....U

12) Was this work the longest job that you have ever held? ..... [ ] EHF12

Yes.....Y →**Go to Item 18**
No.....N
Don't know.....U →**Go to Item 18**

a) In your longest held job, what kind of work did you do? That is, what was your occupation?

Occupation:_EHF12A_____

b) In this job, what were your usual activities or duties?

Job Duties:_EHF12B_____

c) What was your business or industry? (If necessary: what did they make or do in this business?)

Business:_EHF12C_____

d) Did this job expose you to vapors, gas, dust or fumes?..... ☐ EHF12D

Yes.....Y
No.....N
Don't know.....U

If Question 2 = 1, 2, or 3 (that is, currently employed) answer questions 13-17)

13) At this job, what kind of work do you do? That is, what is your occupation?
Occupation: EHF13 _____

14) In this job, what are your usual activities or duties?
Job Duties: EHF14 _____

15) What is your business or industry? (If necessary: what do they make or do in this business?)
Business: EHF15 _____

16) How many years, altogether, have you worked in this job?..... ☐☐ EHF16

17) On average, how many hours per week do you work? ..... ☐☐ EHF17

18) Have you ever worked:

	Yes	No	
a) in a cotton, flax or hemp mill?	☐	☐	EHF18A
b) in a foundry?	☐	☐	EHF18B
c) in a glass works?	☐	☐	EHF18C
d) in a mine?	☐	☐	EHF18D
e) in a pottery?	☐	☐	EHF18E
f) in a power plant?	☐	☐	EHF18F
g) in a quarry?	☐	☐	EHF18G
h) in a refinery?	☐	☐	EHF18H
i) or with asbestos?	☐	☐	EHF18I
j) in synthetic fibers or fabric manufacturing?	☐	☐	EHF18J
k) in a paper mill?	☐	☐	EHF18K
l) in building or highway construction?	☐	☐	EHF18L
m) in an aluminum factory?	☐	☐	EHF18M
n) in a rubber tire plant?	☐	☐	EHF18N
o) in HVAC?	☐	☐	EHF18O

	Yes	No	
p) in demolition?	☐	☐	EHF18P
q) in remodeling?	☐	☐	EHF18Q
r) in professional cleaning?	☐	☐	EHF18R
s) in beauty care?	☐	☐	EHF18S
t) in agriculture?	☐	☐	EHF18T
u) in the flooring industry?	☐	☐	EHF18U

19) Have you ever worked as:

	Yes	No	
a) a boilermaker?	☐	☐	EHF19A
b) a carpenter?	☐	☐	EHF19B
c) a chemical worker?	☐	☐	EHF19C
d) an electrician?	☐	☐	EHF19D
e) an elevator operator?	☐	☐	EHF19E
f) an insulator?	☐	☐	EHF19F
g) a lather?	☐	☐	EHF19G
h) a machinist?	☐	☐	EHF19H
i) a mechanic?	☐	☐	EHF19I
j) a millwright?	☐	☐	EHF19J
k) a pipefitter?	☐	☐	EHF19K
l) a plasterer?	☐	☐	EHF19L
m) a plumber?	☐	☐	EHF19M
n) a sander?	☐	☐	EHF19N
o) a sheet metal worker?	☐	☐	EHF19O
p) a steelworker?	☐	☐	EHF19P
q) a welder?	☐	☐	EHF19Q
r) a pig farmer?	☐	☐	EHF19R
s) a rigger?	☐	☐	EHF19S
t) a roofer?	☐	☐	EHF19T
u) a painter?	☐	☐	EHF19U
v) a mason?	☐	☐	EHF19V

20) In your job, do/did you come into regular contact with any of the following specific examples of vapors, gas, dust or fumes?

	Yes	No	
a) Irritant gases, such as chlorine or ammonia	☐	☐	EHF20A
b) Fire, smoke or other combustion products	☐	☐	EHF20B
c) Incinerators, boilers, or oil refineries	☐	☐	EHF20C
d) Coal dust or powder	☐	☐	EHF20D
e) Silica or sand, or concrete or cement dust	☐	☐	EHF20E
f) Indoor fuel powered motors, compressors, or engines	☐	☐	EHF20F

	Yes	No	
g) Diesel engine exhaust	☐	☐	EHF20G
h) Wheat flour or other grain dusts	☐	☐	EHF20H
i) Animal feeds or fodder	☐	☐	EHF20I
j) Cotton dust or cotton processing	☐	☐	EHF20J
k) Wood dust or saw dust	☐	☐	EHF20K
l) Cadmium fumes or batteries or sliver solder	☐	☐	EHF20L
m) Other metal dusts or metal fumes	☐	☐	EHF20M
n) Welding or flame cutting	☐	☐	EHF20N
o) Fiberglass or other man-made mineral fibers	☐	☐	EHF20O
p) Explosives or blasting fumes	☐	☐	EHF20P

EVENT REVIEW FORM

ID NUMBER:									FORM CODE: **ERF** VERSION: **1.0** 01/19/16	Visit Number	VISIT	SEQ #	

0a. Form Completion Date.... ☐☐/☐☐/☐☐☐☐ ERF0A 0b. Reviewer Code ☐☐☐ ERF0B

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ EVENTID 0d. Event Date: ☐☐/☐☐/☐☐☐☐ ERF0D

PART A: Administration Information

1. Type of Review ..... ☐ ERF1

   Original 1
   Adjudication 2
   Special review 3

PART B: Review of Symptoms

2. Participant experienced an increase in the following "major" symptoms for at least 2 or more consecutive days:

	No/NR	Yes	
a. Dyspnea	☐	☐	ERF2A
b. Sputum purulence	☐	☐	ERF2B
c. Sputum volume	☐	☐	ERF2C

3. Participant experienced an increase in the following "minor" symptoms for at least 2 or more consecutive days:

	No/NR	Yes	
a. Nasal discharge	☐	☐	ERF3A
b. Wheeze	☐	☐	ERF3B
c. Sore throat	☐	☐	ERF3C
d. Cough	☐	☐	ERF3D
e. Fever	☐	☐	ERF3E

4. Was the participant prescribed new antibiotics for this respiratory event? ..... ☐ ERF4
   Yes 1
   No/NR..... 0
5. Was the participant prescribed new steroids for this respiratory event?..... ☐ ERF5
   Yes 1
   No/NR..... 0
6. Did the subject have radiographic evidence suggestive of pneumonia? ..... ☐ ERF6
   Yes 1
   No/NR..... 0
7. Did the participant have acute respiratory failure with no known cause? ..... ☐ ERF7
   Yes 1
   No/NR..... 0

PART C: Classification of Event

8. Did the participant have a COPD exacerbation? ……. [display chain message] ERF8

   (Click to run exacerbation eligibility)

9. Do you agree with the symptomatic classification? ..... ☐ ERF9
   Yes 1
   No 0

10. If no, provide reason and cite any relevant case law
ERF10
_____
_____
_____

11. Was this event a death? ..... ☐ ERF11
   Yes 1
   No ..... 0 → **Skip to Q19**

12. What was the primary cause of death? (enter one cause here, then proceed to the question indicated)... ☐ ERF12

a. Respiratory ..... 1 → **Skip to Q13**
b. Cardiovascular ..... 2 → **Skip to Q14**
c. Cancer ..... 3 → **Skip to Q15**
d. Other, Known ..... 4 → **Skip to Q16**
e. Unknown……5 → **Skip to Q17**

13. Respiratory (select only one) ..... ☐ ERF13

COPD Exacerbation with pneumonia…… 1
COPD Exacerbation without pneumonia….. 2
COPD without exacerbation…… 3
Other respiratory…….. 4

13a. Specify: ERF13A _____

14. Cardiovascular (select only one) ..... ☐ ERF14

Myocardial infarction…….. 1
Heart failure……...2
Stroke/aneurysm……3
DVT/PE……4
Other heart problem ..... …….5

14a. Specify: ERF14A _____

14b. Type of Cardiovascular death (select only one)..... ☐ ERF14B

14b1. "Sudden Death," defined as death that occurs within 24 hours of being observed alive and without evidence of a deteriorating medical condition)…..... 1

14b2. "Sudden Cardiac Death," defined as death that occurs within 1 hour of being observed alive and without evidence of a deteriorating medical condition…….. 2

14b3. Neither of the above…… 3

15. Cancer (select only one)..... ☐ ERF15

Lung……1
Other cancer……..……2

15a. Specify: ERF15A _____

16. Other, Known

Specify: ERF16 _____

17. Reason for Unknown cause of death (select only one) ..... ☐ ERF17

Information is inadequate……1
Indeterminate (information available but cause unclear)….. 2

Please answer for any type of death:

18. Do you believe that a diagnosis of COPD contributed to the death of this individual?..... ☐ ERF18

Yes ……...…..1
No ……..……...2

19. Should this case be reviewed by the Committee? …….. ☐ ERF19

Yes ……...…..1
No ……..……...2

Note: Question 19 must be answered for the form to be considered complete

Comments:

ERF19A _____

_____

_____

_____ **End form**

Event Tracking Form

EVENT ID NUMBER:	SUBJID	FORM CODE: ETF VERSION: 1.0 12/15/14	Visit Number	VISIT	SEQ #

0a. Form Date ..... __ __/__ __/__ __ __ __ ETF0A 0b. Code ETF0B

0c. Participant ID: ETF0C 0d. Event Date: __ __/__ __/__ __ __ __ ETF0D

Instructions: *This form is completed to document the stages in the records acquisition process.*

***RESULT CODES for Records Processing**

0 Pending records request
1 Release of Information requested from Participant
2 Release of Information obtained from Participant
3 Participant refused to release information→ **END**
4 Discharge Summary, Admission and Physical History, and/or Visit Summary Requested
5 Discharge Summary, Admission and Physical History, and/or Visit Summary Received → **Go to Question 25a**
6 Full Event Record requested (Attempt 1)
7 Full Event Record requested (Attempt 2)
8 Full Event Record requested (Attempt 3)
9 Event Record requested (Continuing attempts)
10 Confirmed, no events to investigate→ **END**
11 Confirmed, duplicate event, no further investigation under this ID→ **END**
12 Confirmed, Records Not Available → **END**
13 Medical records received for event (for Full Event Requests) → **Go to Question 25a**
14 Supplemental records requested
15 Requested Death Certificate
16 Received Death Certificate
17 Unable to obtain Death Certificate
18 Transfer records to Coordinating Center [cover sheet for shipping produced] → **Go to Question 28**

	Date (MM/DD/YYYY)	Result Code*	Staff Code	Notes
1	ETF1A / /	ETF1C	ETF1D	ETF1B
2	ETF2A / /	ETF2C	ETF2D	ETF2B
3	ETF3A / /	ETF3C	ETF3D	ETF3B
4	ETF4A / /	ETF4C	ETF4D	ETF4B
5	ETF5A / /	ETF5C	ETF5D	ETF5B
6	ETF6A / /	ETF6C	ETF6D	ETF6B

7	ETF7A / /	ETF7C	ETF7D	ETF7B
8	ETF8A / /	ETF8C	ETF8D	ETF8B
9	ETF9A / /	ETF9C	ETF9D	ETF9B
10	ETF10A / /	ETF10C	ETF10D	ETF10B
11	ETF11A / /	ETF11C	ETF11D	ETF11B
12	ETF12A / /	ETF12C	ETF12D	ETF12B
13	ETF13A / /	ETF13C	ETF13D	ETF13B
14	ETF14A / /	ETF14C	ETF14D	ETF14B
15	ETF15A / /	ETF15C	ETF15D	ETF15B
16	ETF16A / /	ETF16C	ETF16D	ETF16B
17	ETF17A / /	ETF17C	ETF17D	ETF17B
18	ETF18A / /	ETF18C	ETF18D	ETF18B
19	ETF19A / /	ETF19C	ETF19D	ETF19B
20	ETF20A / /	ETF20C	ETF20D	ETF20B
21	ETF21A / /	ETF21C	ETF21D	ETF21B
22	ETF22A / /	ETF22C	ETF22D	ETF22B
23	ETF23A / /	ETF23C	ETF23D	ETF23B
24	ETF24A / /	ETF24C	ETF24D	ETF24B

Please indicate whether any of the following ICD9 codes are listed on the Discharge Summary, Admission and Physical History, and/or Visit Summary:

25a. Were ICD9 Codes used? (Y/N) ETF25A

Diagnoses	ICD9		Diagnoses	ICD9	
Acute upper respiratory infection	465.X	☐ ETF25B1	Pulmonary congestion and hypostasis (includes pulmonary edema NOS chronic)	514.X	☐ ETF25B2
Acute bronchitis	466.X	☐ ETF25B3	Other diseases of lung	518.X	☐ ETF25B4
Viral Pneumonia	480.X	☐ ETF25B5	Heart Failure	428.X	☐ ETF25B6
Pneumococcal pneumonia	481.X	☐ ETF25B7	Lung cancer	162.X	☐ ETF25B8
Other bacterial pneumonia	482.X	☐ ETF25B9	Lung cancer	163.X	☐ ETF25B10
Pneumonia due to other specified organism	483.X	☐ ETF25B11	Diabetes	249.X	☐ ETF25B12
Bronchopneumonia, organism unspecified	485.X	☐ ETF25B13	Diabetes	250.X	☐ ETF25B14
Pneumonia, organism unspecified	486.X	☐ ETF25B15	Other venous embolism and thrombosis Venous thrombosis (DVT)	453.X	☐ ETF25B16
Influenza	487.X	☐ ETF25B17	Acute pulmonary heart disease	415.X	☐ ETF25B18
Influenza due to certain identified influenza viruses	488.X	☐ ETF25B19	Pulmonary embolus	415.1	☐ ETF25B20
Bronchitis	490.X	☐ ETF25B21	Osteoporosis	733.X	☐ ETF25B22
Chronic bronchitis	491.X	☐ ETF25B23	Hip Fracture	820.X	☐ ETF25B24
Emphysema	492.X	☐ ETF25B25	Hip Fracture	821.X	☐ ETF25B26
Asthma	493.X	☐ ETF25B27	Acute Myocardial Infarction	410.X	☐ ETF25B28
Bronchiectasis	494.X	☐ ETF25B29	Other acute and sub-acute forms of ischemic heart disease Myocardial Infarction	411.X	☐ ETF25B30
COPD	496.X	☐ ETF25B31	Other forms of chronic ischemic heart disease Myocardial Infarction	414.X	☐ ETF25B32
Pneumonitis due to solids and liquids	507.X	☐ ETF25B33	Occlusion and stenosis of pre-cerebral arteries	433.X	☐ ETF25B34
Empyema	510.X	☐ ETF25B35	Occlusion of cerebral arteries Stroke or transient ischemic attack	434.X	☐ ETF25B36
Pleurisy	511.X	☐ ETF25B37	Transient cerebral ischemia	435.X	☐ ETF25B38
Pneumothorax and air leak	512.X	☐ ETF25B39	Abscess of lung and mediastinum	513.X	☐ ETF25B40

ID NUMBER:									FORM CODE: ETF VERSION: 1.0 12/15/14	Visit Number			SEQ #			

Please indicate whether any of the following ICD10 codes are listed on the Discharge Summary, Admission and Physical History, and/or Visit Summary:

26a. Were ICD10 Codes used? (Y/N) ETF26A

Diagnoses	ICD10		Diagnoses	ICD10	
Acute upper respiratory infections of multiple and unspecified sites	J06.X	ETF26B1	Pleural effusion, not elsewhere classified	J90.X	ETF26B2
Influenza due to identified novel influenza A virus	J09.X	ETF26B3	Pleural effusion in conditions classified elsewhere	J91.X	ETF26B4
Influenza due to other identified influenza virus	J10.X	ETF26B5	Pneumothorax and air leak	J93.X	ETF26B6
Influenza, due to unidentified influenza virus	J11.X	ETF26B7	Other pleural conditions	J94.X	ETF26B8
Viral pneumonia, not elsewhere classified	J12.X	ETF26B9	Intraoperative and post-procedural complications and disorders of respiratory system, not elsewhere classified	J95.X	ETF26B10
Pneumonia due to Streptococcus pneumonia	J13.X	ETF26B11	Respiratory failure, not elsewhere classified	J96.X	ETF26B12
Pneumonia due to Haemophilus influenzae	J14.X	ETF26B13	Other respiratory disorders	J98.X	ETF26B14
Bacterial pneumonia, not elsewhere classified	J15.X	ETF26B15	Heart Failure	I50.X	ETF26B16
Pneumonia due to other infectious organisms, not elsewhere classified	J16.X	ETF26B17	Malignant neoplasm of trachea	C33.X	ETF26B18
Pneumonia in diseases classified elsewhere	J17.X	ETF26B19	Malignant neoplasm of bronchus and lung	C34.X	ETF26B20
Pneumonia, unspecified organism	J18.X	ETF26B21	Malignant neoplasm of pleura	C38.4	ETF26B22
Acute bronchitis	J20.X	ETF26B23	Diabetes mellitus, Type 1	E10.X	ETF26B24
Acute bronchiolitis	J21.X	ETF26B25	Diabetes mellitus, Type 2	E11.X	ETF26B26
Unspecified acute lower respiratory infection	J22.X	ETF26B27	Phlebitis and thrombophlebitis	I80.X	ETF26B28
Bronchitis, not specified as acute or chronic	J40.X	ETF26B29	Portal vein thrombosis	I81.X	ETF26B30
Simple and mucopurulent chronic bronchitis	J41.X	ETF26B31	Other venous embolism and thrombosis	I82.X	ETF26B32
Unspecified chronic bronchitis	J42.X	ETF26B33	Pulmonary embolism	I26.X	ETF26B34
Emphysema	J43.X	ETF26B35	Osteoporosis with current pathological fracture	M80.X	ETF26B36
Other chronic obstructive pulmonary disease	J44.X	ETF26B37	Osteoporosis without current pathological fracture	M81.X	ETF26B38
Asthma	J45.X	ETF26B39	Osteoporosis in diseases classified elsewhere	M82.X	ETF26B40
Status asthmaticus (acute severe asthma)	J46.X	ETF26B41	Fracture of femur	S72.X	ETF26B42
Bronchiectasis	J47.X	ETF26B43	Angina pectoris	I20.X	ETF26B44

Diagnoses	ICD10	Diagnoses	ICD10
Respiratory conditions due to inhalation of chemicals, gases, fumes and vapors	J68.X ☐ ETF26B45	ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	I21.X ETF26B46
Pneumonitis due to solids and liquids	J69.X ☐ ETF26B47	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction	I22.X ETF26B48
Respiratory conditions due to other external agents	J70.X ☐ ETF26B49	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)	I23.X ETF26B50
Adult respiratory distress syndrome	J80.X ETF26B51	Other acute ischemic heart diseases	I24.X ETF26B52
Pulmonary edema	J81.X ETF26B53	Cerebral infarction	I63 ETF26B54
Abscess of lung and mediastinum	J85.X ☐ ETF26B55	Stroke, not specified as hemorrhage or infarction	I64 ETF26B56
Pyothorax	J86.X ETF26B57	Transient cerebral ischemic attacks and related syndromes	G45.X ETF26B58
Chronic ischemic heart disease	I25.X ☐ ETF26B59		

27a. Were additional diagnoses or procedures listed on coding summary requiring full medical records request? (Y/N) ETF27A

Mechanical Ventilation not in the setting of a surgical procedure ☐ ETF27B1

Lung Transplantation ☐ ETF27B2

Report of other respiratory problem treated ☐ ETF27B3

28. For each of the items below, please indicate if the record is included in the packet to the GIC:

Medical Record	**Status**	
ICD-9 or -10 Coding Summary	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28A
Admission History and Physical	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28B
Discharge Summary	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28C
Emergency Department Report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28D
General labs	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28E
Microbiology labs	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28F
Procedure or surgical reports	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28G
Spirometry report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28H
Echo report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28I
RVG or MUGA report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28J
Doppler Flow Study report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28K
Pulse oximetry reports	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28L
Arterial blood gas report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28M
Discharge medication report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28N
Chest X-ray reports	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28O
Chest CT scan reports	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28P
Pulmonary angiography report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28Q
V/Q Lung scan	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28R
Autopsy or Medical examiner report	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28S
Death Certificate	□ Included □ Available, not included □ Unavailable □ Not collected	ETF28T

EVT – GIC Event Packet Tracking
V1 20150109

0a. Event ID: EVENTID _____ 0b. Event Date: EVT0B _____

0c. Last Accessed Date: _____ 0d. Staff Code: _____

1. Date Packet Received: EVT1 _____
2. Initials of check-in processor: EVT2 ___
3. Number of pages in the packet: EVT3 ___
4. Diagnosis codes used: ICD9/ICD10

3a.	ICD9 Codes	3b.	ICD10 Codes
	EVT4A1 ☐.☐☐		EVT4B1 ☐.☐☐
	EVT4A2 ☐.☐☐		EVT4B2 ☐.☐☐
	EVT4A3 ☐.☐☐		EVT4B3 ☐.☐☐
	EVT4A4 ☐.☐☐		EVT4B4 ☐.☐☐
	EVT4A5 ☐.☐☐		EVT4B5 ☐.☐☐
	EVT4A6 ☐.☐☐		EVT4B6 ☐.☐☐
	EVT4A7 ☐.☐☐		EVT4B7 ☐.☐☐
	EVT4A8 ☐.☐☐		EVT4B8 ☐.☐☐
	EVT4A9 ☐.☐☐		EVT4B9 ☐.☐☐
	EVT4A10 ☐.☐☐		EVT4B10 ☐.☐☐
	EVT4A11 ☐.☐☐		EVT4B11 ☐.☐☐
	EVT4A12 ☐.☐☐		EVT4B12 ☐.☐☐
	EVT4A13 ☐.☐☐		EVT4B13 ☐.☐☐
	EVT4A14 ☐.☐☐		EVT4B14 ☐.☐☐
	EVT4A15 ☐.☐☐		EVT4B15 ☐.☐☐
	EVT4A16 ☐.☐☐		EVT4B16 ☐.☐☐
	EVT4A17 ☐.☐☐		EVT4B17 ☐.☐☐
	EVT4A18 ☐.☐☐		EVT4B18 ☐.☐☐
	EVT4A19 ☐.☐☐		EVT4B19 ☐.☐☐
	EVT4A20 ☐.☐☐		EVT4B20 ☐.☐☐

5. Initial Packet Event Assessment: EVT5
   Eligible Event……..1
   Ineligible Event……...2

6. Initial Packet Review Status: Packet Complete EVT6
   Complete…….1 (skip 6a)
   Incomplete…….0 *(specify missing items and rest of form skipped)*

6a. Select missing items that apply

	Y/N
ICD Coding Summary	☐ EVT6A1
Admission History and Physical	☐ EVT6A2
Discharge Summary	☐ EVT6A3
Emergency Department Report	☐ EVT6A4
General labs	☐ EVT6A5

Microbiology labs	☐ EVT6A6
Procedure or surgical reports	☐ EVT6A7
Spirometry report	☐ EVT6A8
Echo report	☐ EVT6A9
Pulse oximetry reports	☐ EVT6A10
Arterial blood gas report	☐ EVT6A11
Discharge medication report	☐ EVT6A12
Chest X-ray reports	☐ EVT6A13
Chest CT scan reports	☐ EVT6A14
Pulmonary angiography report	☐ EVT6A15
V/Q Lung scan	☐ EVT6A16
Autopsy or Medical examiner report	☐ EVT6A17
Death certificate	☐ EVT6A18
Improperly blinded	☐ EVT6A19
Improperly labeled	☐ EVT6A20
Other	☐ EVT6A21

6b) Specify other:____EVT6B_____

7. Abstractor Packet Review Status: EVT7
   Complete…….1 (skip 7a)
   Incomplete…….0 *(specify missing items and rest of form skipped)*

7a. Select missing items that apply

	Y/N
ICD Coding Summary	☐ EVT7A1
Admission History and Physical	☐ EVT7A2
Discharge Summary	☐ EVT7A3
Emergency Department Report	☐ EVT7A4
General labs	☐ EVT7A5
Microbiology labs	☐ EVT7A6
Procedure or surgical reports	☐ EVT7A7
Spirometry report	☐ EVT7A8
Echo report	☐ EVT7A9
Pulse oximetry reports	☐ EVT7A10
Arterial blood gas report	☐ EVT7A11
Discharge medication report	☐ EVT7A12
Chest X-ray reports	☐ EVT7A13
Chest CT scan reports	☐ EVT7A14
Pulmonary angiography report	☐ EVT7A15
V/Q Lung scan	☐ EVT7A16
Autopsy or Medical examiner report	☐ EVT7A17
Death certificate	☐ EVT7A18
Improperly blinded	☐ EVT7A19
Improperly labeled	☐ EVT7A20
Other	☐ EVT7A21

7b) Specify other:____EVT7B_____

8. Event eligible for abstraction? EVT8
   Yes…….1
   No……..0

9. Abstraction Status : EVT9

Complete…….1

In-progress….…....0

FACIT-F (Version 4)

ID NUMBER:	BLINDID	FORM CODE: FCT VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... __ __ / __ __ / __ __ __ __ FCT0A 0b) Initials..... __ __ __

Instructions: *Form is to be completed during the study visit. Read all questions exactly as written.*

Below is a list of statements that other people with your illness have said are important. Please indicate your response as it applies to the past 7 days.

	PHYSICAL WELL-BEING	**Not at all**	**A little bit**	**Some -what**	**Quite a bit**	**Very much**	
1	I have a lack of energy	0	1	2	3	4	FCT01
2	I have nausea	0	1	2	3	4	FCT02
3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4	FCT03
4	I have pain	0	1	2	3	4	FCT04
5	I am bothered by side effects of treatment	0	1	2	3	4	FCT05
6	I feel ill	0	1	2	3	4	FCT06
7	I am forced to spend time in bed	0	1	2	3	4	FCT07

English (Universal)
Copyright 1987, 1997

ID NUMBER:								

FORM CODE: FCT
VERSION: 1.0 10/26/10

Visit Number | | |

SEQ # | | | |

SOCIAL/FAMILY WELL-BEING

		Not at all	A little bit	Some -what	Quite a bit	Very much	
8	I feel close to my friends	0	1	2	3	4	FCT08
9	I get emotional support from my family	0	1	2	3	4	FCT09
10	I get support from my friends	0	1	2	3	4	FCT10
11	My family has accepted my illness	0	1	2	3	4	FCT11
12	I am satisfied with family communication about my illness	0	1	2	3	4	FCT12
13	I feel close to my partner (or the person who is my main support)	0	1	2	3	4	FCT13
14	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.* FCT14						
15	I am satisfied with my sex life	0	1	2	3	4	FCT15

English (Universal)
Copyright 1987, 1997

ID NUMBER:									FORM CODE: FCT VERSION: 1.0 10/26/10	Visit Number			SEQ #			

Please indicate your response as it applies to the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some -what	Quite a bit	Very much	
16	I feel sad	0	1	2	3	4	FCT16
17	I am satisfied with how I am coping with my illness	0	1	2	3	4	FCT17
18	I am losing hope in the fight against my illness	0	1	2	3	4	FCT18
19	I feel nervous	0	1	2	3	4	FCT19
20	I worry about dying	0	1	2	3	4	FCT20
21	I worry that my condition will get worse	0	1	2	3	4	FCT21

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some -what	Quite a bit	Very much	
22	I am able to work (include work at home)	0	1	2	3	4	FCT22
23	My work (include work at home) is fulfilling	0	1	2	3	4	FCT23
24	I am able to enjoy life	0	1	2	3	4	FCT24
25	I have accepted my illness	0	1	2	3	4	FCT25
26	I am sleeping well	0	1	2	3	4	FCT26
27	I am enjoying the things I usually do for fun	0	1	2	3	4	FCT27
28	I am content with the quality of my life right now	0	1	2	3	4	FCT28

English (Universal)
Copyright 1987, 1997

ID NUMBER:									FORM CODE: FCT VERSION: 1.0 10/26/10	Visit Number			SEQ #			

Please indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some -what	Quite a bit	Very much	
29	I feel fatigued	0	1	2	3	4	FCT29
30	I feel weak all over	0	1	2	3	4	FCT30
31	I feel listless ("washed out")	0	1	2	3	4	FCT31
32	I feel tired	0	1	2	3	4	FCT32
33	I have trouble starting things because I am tired	0	1	2	3	4	FCT33
34	I have trouble finishing things because I am tired	0	1	2	3	4	FCT34
35	I have energy	0	1	2	3	4	FCT35
36	I am able to do my usual activities	0	1	2	3	4	FCT36
37	I need to sleep during the day	0	1	2	3	4	FCT37
38	I am too tired to eat	0	1	2	3	4	FCT38
39	I need help doing my usual activities	0	1	2	3	4	FCT39
40	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4	FCT40
41	I have to limit my social activity because I am tired	0	1	2	3	4	FCT41

English (Universal)
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FOLLOW-UP QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: **FUQ** VERSION: **1.0** 11/2/10	Visit Number	VISIT	SEQ #	

0a) Form Date..... ☐☐/☐☐/☐☐☐☐ FUQ0A 0b) Initials ..... ☐☐☐ FUQ0B

> ***Instructions:*** *This form should be completed during the follow up phone conversations with study participants. Read the form carefully to familiarize yourself with the script as well as questions and skip patterns.*

INTERVIEWER: Hello, my name is *(interviewer name),* and I am calling to follow up with *(participant name)* about the Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS), a health study in which s/he is currently enrolled. Is s/he available?

No → When would it be convenient to call back? .....Thank you. I will call again.

Yes → Hello, *(participant name),* this is *(interviewer name)* with the SPIROMICS study. I'm calling to see how you have been since your last (*visit to our center* or *telephone contact)*. Do you have a few minutes to speak on the phone?

No → When would it be convenient to call back?.....Thank you. I will call again.

Yes → We'd like to gather information about your general health and about specific medical conditions that you may have had since your last (*visit to our center* or *telephone contact)*. I will ask you some questions about your health since your last (*visit to our center* or *telephone contact)* on *(date of contact).*

INTERVIEWER: I want you to focus on what happened from *(date of contact)* until today.

1) *(Do not ask participant)* Participant status (choose one): FUQ01

Contacted and alive	1 ☐	→ **Go to Item 2**
Contacted and refused interview	2 ☐	→ **End Call**
Not contacted, reported alive	3 ☐	→ **End Call**
Not contacted, reported deceased	4 ☐	→ **Go to Item 1a**
Unknown	5 ☐	→ **End Call**

1a) What was the date of death? ..... ☐☐/☐☐/☐☐☐☐ FUQ01A

1b) What city, state, and country did the death occur? _Removed from Blinded Dataset__

1c) Do you know if (*insert decedent's name*) was hospitalized or visited an emergency room for any reason since (*date of last contact*) and his/her death? FUQ01C

Yes 1 ☐ Record date and name of hospitalization in question 21a.
No 0 ☐ End interview

HOSPITALIZATIONS
(If non-COPD participant, skip to question 20)
(For COPD Participants Only):

2) Since your last (*clinic visit* or *telephone contact*) on (*date*), have you had a flare-up of your chest trouble? (Y/N)..... ☐ FUQ02
(if 'No' go to item 20)

If Yes:

2a) How many episodes of chest trouble flare ups have you had since (*date*)? ..... ☐ FUQ02A

How was/were the episode(s) of breathing problem(s) treated? Please answer for each episode (if more than one) by checking all relevant treatments given for each episode. Starting with the first episode since (*date*):

3) For the first episode of breathing problems you had since *(date)*:

3a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ3A

3b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ FUQ3B

3c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ3C

3d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ FUQ3D

3e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ FUQ3E

During that visit were you given (check all that apply):

3e1) An additional antibiotic ..... ☐ FUQ03E1
3e2) Additional steroids ..... ☐ FUQ03E2
3e3) Don't know ..... ☐ FUQ03E3
3e4) Don't remember..... ☐ FUQ03E4

3f) Were you evaluated in an Emergency Department? ..... ☐ FUQ03F

During that visit were you given (check all that apply):

3f1) An additional antibiotic ..... ☐ FUQ03F1
3f2) Additional steroids ..... ☐ FUQ03F2
3f3) Don't know ..... ☐ FUQ03F3
3f4) Don't remember..... ☐ FUQ03F4

3g) Were you admitted to the hospital? ..... ☐ FUQ03G

If participant was admitted to hospital:

4a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ04A

4b) What is the name of the medical facility? Removed from Blinded Dataset

4c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

4d) For clarification of our records, under what name is this record?

4d1) First Name: Removed from Blinded Dataset

4d2) Second Name: Removed from Blinded Dataset

4d3) Last Name: Removed from Blinded Dataset

4d4) Maternal Last Name: Removed from Blinded Dataset

5) (do not ask) Did the participant have a second episode? (if 'No', go to 20) ..... ☐ FUQ05

6) For the second episode of breathing problems you had since *(date)*:

6a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ06A

6b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ06B

6c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ06C

6d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ06D

6e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ FUQ06E

During that visit were you given (check all that apply):

6e1) An additional antibiotic ..... ☐ FUQ06E1

6e2) Additional steroids ..... ☐ FUQ06E2

6e3) Don't know ..... ☐ FUQ06E3

6e4) Don't remember ..... ☐ FUQ06E4

6f) Were you evaluated in an Emergency Department? ..... ☐ FUQ06F

During that visit were you given (check all that apply):

6f1) An additional antibiotic ..... ☐ FUQ06F1

6f2) Additional steroids ..... ☐ FUQ06F2

6f3) Don't know ..... ☐ FUQ06F3

6f4) Don't remember ..... ☐ FUQ06F4

g) Where you admitted to the hospital FUQ06G

If participant was admitted to hospital:

7a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ07A

7b) What is the name of the medical facility? Removed from Blinded Dataset

7c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

7d) For clarification of our records, under what name is this record?

7d1) First Name: Removed from Blinded Dataset

7d2) Second Name: Removed from Blinded Dataset

7d3) Last Name: Removed from Blinded Dataset

7d4) Maternal Last Name: Removed from Blinded Dataset

8) (do not ask) Did the participant have a third episode? (if 'No', go to 20) ..... ☐ FUQ08

9) For the third episode of breathing problems you had since *(date)*:

9a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ09A

9b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ FUQ09B

9c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ09C

9d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ FUQ09D

9e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ FUQ09E

During that visit were you given (check all that apply):

9e1) An additional antibiotic ..... ☐ FUQ09E1

9e2) Additional steroids ..... ☐ FUQ09E2

9e3) Don't know ..... ☐ FUQ09E3

9e4) Don't remember..... ☐ FUQ09E4

9f) Were you evaluated in an Emergency Department? ..... ☐ FUQ09F

During that visit were you given (check all that apply):

9f1) An additional antibiotic ..... ☐ FUQ09F1

9f2) Additional steroids ..... ☐ FUQ09F2

9f3) Don't know ..... ☐ FUQ09F3

9f4) Don't remember..... ☐ FUQ09F4

9g) Were you admitted to the hospital? ..... ☐ FUQ09G

If participant was admitted to hospital:

10a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ FUQ10A

10b) What is the name of the medical facility? Removed from Blinded Dataset

10c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

10d) For clarification of our records, under what name is this record?

10d1) First Name: Removed from Blinded Dataset

10d2) Second Name: Removed from Blinded Dataset

10d3) Last Name: Removed from Blinded Dataset

10d4) Maternal Last Name: Removed from Blinded Dataset

11) (do not ask) Did the participant have a fourth episode? (if 'No', go to 20) ..... ☐ FUQ11

12) For the fourth episode of breathing problems you had since *(date)*:

12a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ12A

12b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ FUQ12B

12c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ12C

12d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ FUQ12D

12e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ FUQ12E

During that visit were you given (check all that apply):

12e1) An additional antibiotic ..... ☐ FUQ12E1

12e2) Additional steroids ..... ☐ FUQ12E2

12e3) Don't know ..... ☐ FUQ12E3

12e4) Don't remember..... ☐ FUQ12E4

12f) Were you evaluated in an Emergency Department? ..... ☐ FUQ12F

During that visit were you given (check all that apply):

12f1) An additional antibiotic ..... ☐ FUQ12F1

12f2) Additional steroids ..... ☐ FUQ12F2

12f3) Don't know ..... ☐ FUQ12F3

12f4) Don't remember..... ☐ FUQ12F4

12g) Were you admitted to the hospital? ..... ☐ FUQ12G

If participant was admitted to hospital:

13a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ FUQ13A

13b) What is the name of the medical facility? Removed from Blinded Dataset

13c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

13d) For clarification of our records, under what name is this record?

13d1) First Name: Removed from Blinded Dataset

13d2) Second Name: Removed from Blinded Dataset

13d3) Last Name: Removed from Blinded Dataset

13d4) Maternal Last Name: Removed from Blinded Dataset

14) (do not ask) Did the participant have a fifth episode? (if 'No', go to 20)..... ☐ FUQ14

15) For the fifth episode of breathing problems you had since *(date)*:

15a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ15A

15b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ FUQ15B

15c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ15C

15d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ FUQ15D

15e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ FUQ15E

During that visit were you given (check all that apply):

15e1) An additional antibiotic ..... ☐ FUQ15E1

15e2) Additional steroids ..... ☐ FUQ15E2

15e3) Don't know ..... ☐ FUQ15E3

15e4) Don't remember..... ☐ FUQ15E4

15f) Were you evaluated in an Emergency Department? ..... ☐ FUQ15F

During that visit were you given (check all that apply):

15f1) An additional antibiotic ..... ☐ FUQ15F1

15f2) Additional steroids ..... ☐ FUQ15F2

15f3) Don't know ..... ☐ FUQ15F3

15f4) Don't remember..... ☐ FUQ15F4

15g) Were you admitted to the hospital? ..... ☐ FUQ15G

If participant was admitted to hospital:

16a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ FUQ16A

16b) What is the name of the medical facility? Removed from Blinded Dataset

16c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

16d) For clarification of our records, under what name is this record?

16d1) First Name: Removed from Blinded Dataset

16d2) Second Name: Removed from Blinded Dataset

16d3) Last Name: Removed from Blinded Dataset

16d4) Maternal Last Name: Removed from Blinded Dataset

17) (do not ask) Did the participant have a sixth episode? (if 'No', go to 20) ..... ☐ FUQ17

18) For the sixth episode of breathing problems you had since *(date)*:

18a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ FUQ18A

18b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ FUQ18B

18c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ FUQ18C

18d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ FUQ18D

18e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ FUQ18E

During that visit were you given (check all that apply):

18e1) An additional antibiotic ..... ☐ FUQ18E1

18e2) Additional steroids ..... ☐ FUQ18E2

18e3) Don't know ..... ☐ FUQ18E3

18e4) Don't remember..... ☐ FUQ18E4

18f) Were you evaluated in an Emergency Department? ..... ☐ FUQ18F

During that visit were you given (check all that apply):

18f1) An additional antibiotic ..... ☐ FUQ18F1

18f2) Additional steroids ..... ☐ FUQ18F2

18f3) Don't know ..... ☐ FUQ18F3

18f4) Don't remember ..... ☐ FUQ18F4

18g) Were you admitted to the hospital? ..... ☐ FUQ18G

If participant was admitted to hospital:

19a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ FUQ19A

19b) What is the name of the medical facility? Removed from Blinded Dataset

19c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

19d) For clarification of our records, under what name is this record?

19d1) First Name: Removed from Blinded Dataset

19d2) Second Name: Removed from Blinded Dataset

19d3) Last Name: Removed from Blinded Dataset

19d4) Maternal Last Name: Removed from Blinded Dataset

INTERVIEWER: (For non-COPD participants only) "The following questions are about any hospitalizations you may have had since your last *(center visit or telephone contact)* on *(date).*"

20) Since your last (*center visit* or *telephone contact)* on *(date),* have you at any time been admitted to a hospital (For COPD Participants: *for any reason other than a chest flare up*)? FUQ20

No 0 ☐ → **Go to Item 27**
Yes 1 ☐
Unsure 9 ☐ → **Go to Item 27**

20a) How many hospitalizations have you had since *(date)*?..... ☐ FUQ20A

INTERVIEWER: The next few questions are about one event. If there were more than one we would like to talk about each one separately. Let's start with the first event after your *(visit* or *teleconference)* on *(date).*"

21a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ21A

21b) What is the name of the medical facility? Removed from Blinded Dataset

21c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

21d) For clarification of our records, under what name is this record?

21d1)First Name: Removed from Blinded Dataset

21d2) Second Name: Removed from Blinded Dataset

21d3) Last Name: Removed from Blinded Dataset

21d4) Maternal Last Name: Removed from Blinded Dataset

21e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** FUQ21E
Yes 1 ☐

22a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ22A

22b) What is the name of the medical facility? Removed from Blinded Dataset

22c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

22d) For clarification of our records, under what name is this record?

22d1)First Name: Removed from Blinded Dataset

22d2) Second Name: Removed from Blinded Dataset

22d3) Last Name: Removed from Blinded Dataset

22d4) Maternal Last Name: Removed from Blinded Dataset

22e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** FUQ22E
Yes 1 ☐

23a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ23A

23b) What is the name of the medical facility? Removed from Blinded Dataset

23c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

23d) For clarification of our records, under what name is this record?

23d1)First Name: Removed from Blinded Dataset

23d2) Second Name: Removed from Blinded Dataset

23d3) Last Name: Removed from Blinded Dataset

23d4) Maternal Last Name: Removed from Blinded Dataset

23e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** FUQ23E
Yes 1 ☐

24a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ24A

24b) What is the name of the medical facility? Removed from Blinded Dataset

24c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

24d) For clarification of our records, under what name is this record?

24d1)First Name: Removed from Blinded Dataset

24d2) Second Name: Removed from Blinded Dataset

24d3) Last Name: Removed from Blinded Dataset

24d4) Maternal Last Name: Removed from Blinded Dataset

24e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** FUQ24E
Yes 1 ☐

25a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ25A

25b) What is the name of the medical facility? Removed from Blinded Dataset

25c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

25d) For clarification of our records, under what name is this record?

25d1)First Name: Removed from Blinded Dataset

25d2) Second Name: Removed from Blinded Dataset

25d3) Last Name: Removed from Blinded Dataset

25d4) Maternal Last Name: Removed from Blinded Dataset

25e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** FUQ25E
Yes 1 ☐

26a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ FUQ26A

26b) What is the name of the medical facility? Removed from Blinded Dataset

26c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

26d) For clarification of our records, under what name is this record?

26d1)First Name: Removed from Blinded Dataset

26d2) Second Name: Removed from Blinded Dataset

26d3) Last Name: Removed from Blinded Dataset

26d4) Maternal Last Name: Removed from Blinded Dataset

INTERVIEWER: I'd now like to ask you some other questions about your health since your last (*clinic visit* or *telephone contact*) on (*date*).

(Questions 27-28 are for COPD participants only.)

Since your last (*clinic visit* or *telephone contact*) on (*date*)

27) Did your doctor put you on oxygen? (Y/N) ..... ☐ FUQ27

28) Have you been listed for or received a lung transplant? (Y/N) ..... ☐ FUQ28

29) Are you currently smoking cigarettes? (Y/N) ..... ☐ FUQ29

30) Since your last (*clinic visit* or *telephone contact*) on (*date*), have you been diagnosed with other medical problems or been injured? (Y/ N) ..... ☐ FUQ30

If answered 'Yes' to question 30

31) Were you diagnosed with:

31a) Lung cancer (Y/N) ..... ☐ FUQ31A

31b) Other type of cancer (Y/N) ..... ☐ FUQ31B

If so, what type? FUQ31B1 _____

31c) Diabetes (Y/N) ..... ☐ FUQ31C

31d) Blood Clots (Y/N) ..... ☐ FUQ31D

31e) Osteoporosis (Y/N) ..... ☐ FUQ31E

31f) Broken Hip (Y/N) ..... ☐ FUQ31F

31g) Heart attack or myocardial infarction (Y/N) ..... ☐ FUQ31G

31h) Stroke (Y/N) ..... ☐ FUQ31H

31i) Coronary artery disease (atherosclerosis) (Y/N) ..... ☐ FUQ31I

INTERVIEWER: "Thank you very much for your participation in the SPIROMICS study. I'd like to ask you just a few more questions to make sure our contact information for you is up-to-date. All information you provide us is strictly confidential and will not be shared with anyone else."

32) Current home address:

Address line 1: Removed from Blinded Dataset _____

Address line 2: Removed from Blinded Dataset

City: Removed from Blinded Dataset State: Removed from Blinded Dataset

Zip Code: Removed from Blinded Dataset

a) When did you begin living here? ..... __ __ / __ __ / __ __ __ __ FUQ32A1

33) Primary Phone Number: ..... (Removed from Blinded Dataset

34) What is the best time of day to reach you at this number?

Morning ..... ☐ FUQ34A
Afternoon..... ☐ FUQ34B
Evening ..... ☐ FUQ34C

35) Secondary Phone Number: ..... (Removed from Blinded Dataset

36) What is the best time of day to reach you at this number?

Morning ..... ☐ FUQ36A
Afternoon..... ☐ FUQ36B
Evening ..... ☐ FUQ36C

INTERVIEWER: *Thank you for answering these questions.*

(If the next contact is by telephone): We'll be contacting you again around (*date*) for another telephone contact.

(If next contact is a clinic visit): We'll be contacting you around (*date*) to schedule an in-person visit at (*insert institution*) to take place around (*date*).

Thank you again for your time and participation.

(end call)

HOSPITAL ANXIETY AND DEPRESSION SCALE

ID NUMBER:	BLINDID	FORM CODE: HDS VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... __ __/__ __/__ __ __ __ HDS0A 0b) Initials..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please answer all questions.*

For each of the questions, choose the one best response. For each question answer immediately without thinking too long about the answers.

1) I feel tense or 'wound up'..... ☐ HDS01

Most of the time.....3
A lot of the time.....2
From time to time, occasionally.....1
Not at all.....0

2) I still enjoy the things I used to enjoy ..... ☐ HDS02

Definitely as much.....0
Not quite so much.....1
Only a little.....2
Hardly at all.....3

3) I get a sort of frightened feeling as if something awful is about to happen ..... ☐ HDS03

Very definitely and quite badly.....3
Yes, but not too badly 2
A little, but it doesn't worry me.....1
Not at all.....0

4) I can laugh and see the funny side of things..... ☐ HDS04

As much as I always could 0
Not quite so much now.....1
Definitely not so much now 2
Not at all.....3

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5) Worrying thoughts go through my mind HDS05

A great deal of the time 3
A lot of the time 2
Not too often 1
Very little 0

6) I feel cheerful HDS06

Never 3
Not often 2
Sometimes 1
Most of the time.....0

7) I can site at ease and feel relaxed HDS07

Definitely 0
Usually 1
Not Often.....2
Not at all.....3

8) I feel as if I am slowed down..... HDS08

Nearly all the time 3
Very often 2
Sometimes 1
Not at all.....0

9) I get a sort of frightened feeling like 'butterflies' in the stomach HDS09

Not at all.....0
Occasionally 1
Quite Often.....2
Very Often.....3

10) I have lost interest in my appearance HDS10

Definitely 3
I don't take as much care as I should 2
I may not take quite as much care.....1
I take just as much care as ever 0

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11) I feel restless as I have to be on the move..... HDS11

Very much indeed 3
Quite a lot 2
Not very much.....1
Not at all.....0

12) I look forward with enjoyment to things..... HDS12

As much as I ever did.....0
Rather less than I used to 1
Definitely less than I used to 2
Hardly at all 3

13) I get sudden feelings of panic HDS13

Very often indeed 3
Quite often 2
Not very often.....1
Not at all.....0

14) I can enjoy a good book or radio or TV program..... HDS14

Often 0
Sometimes.....1
Not often 2
Very seldom 3

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HOSPITALIZATIONS AND EXACERBATIONS

ID NUMBER:	BLINDID	FORM CODE: **HEF** VERSION: **1.0** 9/21/11	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ HEF0A 0b) Code ..... ☐☐☐

Instructions: *This form should be completed during the follow up phone conversations with study participants. Read the form carefully to familiarize yourself with the script, as well as questions and skip patterns.*

HOSPITALIZATIONS
(If non-COPD participant, skip to question 19)
(For COPD Participants Only):

1) Since your last (*clinic visit* or *telephone contact*) on (*date*), have you had a flare-up of your chest trouble? (Y/N)..... ☐ HEF1
(if 'No' go to item 19)

If Yes:

1a) How many episodes of chest trouble flare ups have you had since (*date*)?..... ☐ HEF1A

How was/were the episode(s) of breathing problem(s) treated? Please answer for each episode (if more than one) by checking all relevant treatments given for each episode. Starting with the first episode since (*date*):

2) For the first episode of breathing problems you had since *(date)*:

2a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF2A

2b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ HEF2B

2c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF2C

2d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N).... ☐ HEF2D

2e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF2E

During that visit were you given (check all that apply):

2e1) An additional antibiotic ..... ☐ HEF2E1

2e2) Additional steroids ..... ☐ HEF2E2

2e3) Don't know ..... ☐ HEF2E3

2e4) Don't remember ..... ☐ HEF2E4

2f) Were you evaluated in an Emergency Department? ..... ☐ HEF2F

During that visit were you given (check all that apply):

2f1) An additional antibiotic ..... ☐ HEF2F1

2f2) Additional steroids ..... ☐ HEF2F2

2f3) Don't know ..... ☐ HEF2F3

2f4) Don't remember ..... ☐ HEF2F4

2g) Were you admitted to the hospital? ..... ☐ HEF2G

If participant was admitted to hospital:

3a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF3A

3b) What is the name of the medical facility? HEF3B _____

3c) What is the address of this medical facility? HEF3C _____
(Leave blank if unknown)

3d) For clarification of our records, under what name is this record?

3d1) First Name: HEF3D1 _____

3d2) Second Name: HEF3D2 _____

3d3) Last Name: HEF3D3 _____

3d4) Maternal Last Name: HEF3D4 _____

4) (do not ask) Did the participant have a second episode? (if 'No', go to 19) ..... ☐ HEF4

5) For the second episode of breathing problems you had since *(date)*:

5a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF5A

5b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF5B

5c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF5C

5d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) .... ☐ HEF5D

5e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF5E

During that visit were you given (check all that apply):

5e1) An additional antibiotic ..... ☐ HEF5E1

5e2) Additional steroids ..... ☐ HEF5E2

5e3) Don't know ..... ☐ HEF5E3

5e4) Don't remember ..... ☐ HEF5E4

5f) Were you evaluated in an Emergency Department? ..... ☐ HEF5F

During that visit were you given (check all that apply):

5f1) An additional antibiotic ..... ☐ HEF5F1

5f2) Additional steroids ..... ☐ HEF5F2

5f3) Don't know ..... ☐ HEF5F3

5f4) Don't remember ..... ☐ HEF5F4

5g) Were you admitted to the hospital? ..... ☐ HEF5G

If participant was admitted to hospital:

6a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF6A

6b) What is the name of the medical facility? HEF6B _____

6c) What is the address of this medical facility? HEF6C _____
(Leave blank if unknown)

6d) For clarification of our records, under what name is this record?

6d1) First Name: HEF6D1 _____

6d2) Second Name: HEF6D2 _____

6d3) Last Name: HEF6D3 _____

6d4) Maternal Last Name: HEF6D4 _____

7) (do not ask) Did the participant have a third episode? (if 'No', go to 19) ..... ☐ HEF7

8) For the third episode of breathing problems you had since *(date)*:

8a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF8A

8b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF8B

8c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF8C

8d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) .... ☐ HEF8D

8e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF8E

During that visit were you given (check all that apply):

8e1) An additional antibiotic ..... ☐ HEF8E1

8e2) Additional steroids ..... ☐ HEF8E2

8e3) Don't know ..... ☐ HEF8E3

8e4) Don't remember ..... ☐ HEF8E4

8f) Were you evaluated in an Emergency Department? ..... ☐ HEF8F

During that visit were you given (check all that apply):

8f1) An additional antibiotic ..... ☐ HEF8F1

8f2) Additional steroids ..... ☐ HEF8F2

8f2) Don't know ..... ☐ HEF8F3

8f4) Don't remember ..... ☐ HEF8F4

8g) Were you admitted to the hospital? ..... ☐ HEF8G

If participant was admitted to hospital:

9a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF9A

9b) What is the name of the medical facility? HEF9B _____

9c) What is the address of this medical facility? HEF9C _____
(Leave blank if unknown)

9d) For clarification of our records, under what name is this record?

9d1) First Name: HEF9D1 _____

9d2) Second Name: HEF9D2 _____

9d3) Last Name: HEF9D3 _____

9d4) Maternal Last Name: HEF9D4 _____

10) (do not ask) Did the participant have a fourth episode? (if 'No', go to 19) ..... ☐ HEF10

11) For the fourth episode of breathing problems you had since *(date)*:

11a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF11A

11b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF11B

11c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF11C

11d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N) .... ☐ HEF11D

11e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF11E

During that visit were you given (check all that apply):

11e1) An additional antibiotic ..... ☐ HEF11E1

11e2) Additional steroids ..... ☐ HEF11E2

11e3) Don't know ..... ☐ HEF11E3

11e4) Don't remember ..... ☐ HEF11E4

11f) Were you evaluated in an Emergency Department? ..... ☐ HEF11F

During that visit were you given (check all that apply):

11f1) An additional antibiotic ..... ☐ HEF11F1

11f2) Additional steroids ..... ☐ HEF11F2

11f3) Don't know ..... ☐ HEF11F3

11f4) Don't remember ..... ☐ HEF11F4

11g) Were you admitted to the hospital? ..... ☐ HEF11G

If participant was admitted to hospital:

12a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ HEF12A

12b) What is the name of the medical facility? HEF12B _____

12c) What is the address of this medical facility? HEF12C _____
(Leave blank if unknown)

12d) For clarification of our records, under what name is this record?

12d1) First Name: HEF12D1 _____

12d2) Second Name: HEF12D2 _____

12d3) Last Name: HEF12D3 _____

12d4) Maternal Last Name: HEF12D4 _____

13) (do not ask) Did the participant have a fifth episode? (if 'No', go to 19) ..... ☐ HEF13

14) For the fifth episode of breathing problems you had since *(date)*:

14a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF14A

14b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ HEF14B

14c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF14C

14d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N).... ☐ HEF14D

14e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF14E

During that visit were you given (check all that apply):

14e1) An additional antibiotic ..... ☐ HEF14E1

14e2) Additional steroids ..... ☐ HEF14E2

14e3) Don't know ..... ☐ HEF14E3

14e4) Don't remember ..... ☐ HEF14E4

14f) Were you evaluated in an Emergency Department? ..... ☐ HEF14F

During that visit were you given (check all that apply):

14f1) An additional antibiotic ..... ☐ HEF14F1

14f2) Additional steroids ..... ☐ HEF14F2

14f3) Don't know ..... ☐ HEF14F3

14f4) Don't remember ..... ☐ HEF14F4

14g) Were you admitted to the hospital? ..... ☐ HEF14G

If participant was admitted to hospital:

15a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ HEF15A

15b) What is the name of the medical facility? HEF15B _____

15c) What is the address of this medical facility? HEF15C _____
(Leave blank if unknown)

15d) For clarification of our records, under what name is this record?

15d1) First Name: HEF15D1 _____

15d2) Second Name: HEF15D2 _____

15d3) Last Name: HEF15D3 _____

15d4) Maternal Last Name: HEF15D4 _____

16) (do not ask) Did the participant have a sixth episode? (if 'No', go to 19)..... ☐ HEF16

17) For the sixth episode of breathing problems you had since *(date)*:

17a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ HEF17A

17b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ HEF17B

17c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ HEF17C

17d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N).... ☐ HEF17D

17e) Were you evaluated in a physician's office or urgent care? (Y/N) ..... ☐ HEF17E

During that visit were you given (check all that apply):

17e1) An additional antibiotic ..... ☐ HEF17E1

17e2) Additional steroids ..... ☐ HEF17E2

17e3) Don't know ..... ☐ HEF17E3

17e4) Don't remember ..... ☐ HEF17E4

17f) Were you evaluated in an Emergency Department? ..... ☐ HEF17F

During that visit were you given (check all that apply):

17f1) An additional antibiotic ..... ☐ HEF17F1

17f2) Additional steroids ..... ☐ HEF17F2

17f3) Don't know ..... ☐ HEF17F3

17f4) Don't remember ..... ☐ HEF17F4

17g) Were you admitted to the hospital? ..... ☐ HEF17G

If participant was admitted to hospital:

18a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ HEF18A

18b) What is the name of the medical facility? HEF18B _____

18c) What is the address of this medical facility? HEF18C _____
(Leave blank if unknown)

18d) For clarification of our records, under what name is this record?

18d1) First Name: HEF18D1 _____

18d2) Second Name: HEF18D2 _____

18d3) Last Name: HEF18D3 _____

18d4) Maternal Last Name: HEF18D4 _____

INTERVIEWER: (Read prompt for non-COPD participants only) "The following questions are about any hospitalizations you may have had since your last *(center visit or telephone contact)* on *(date)."*

19) Since your last (*center visit* or *telephone contact)* on *(date),* have you at any time been admitted to a hospital (For COPD Participants: *for any reason other than a chest flare up*)?

No 0 ☐ → **Go to End** HEF19

Yes 1 ☐

Unsure 9 ☐ → **Go to End**

20) How many hospitalizations have you had since *(date)*? ..... ☐ HEF20

INTERVIEWER: The next few questions are about one event. If there were more than one we would like to talk about each one separately. Let's start with the first event after your *(visit* or *teleconference)* on *(date)."*

21a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF21A

21b) What is the name of the medical facility? HEF21B _____

21c) What is the address of this medical facility? HEF21C _____
(Leave blank if unknown)

21d) For clarification of our records, under what name is this record?

21d1) First Name: HEF21D1 _____

21d2) Second Name: HEF21D2 _____

21d3) Last Name: HEF21D3 _____

21d4) Maternal Last Name: HEF21D4 _____

21e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to End** HEF21E
Yes 1 ☐

22a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF22A

22b) What is the name of the medical facility? HEF22B _____

22c) What is the address of this medical facility? HEF22C _____
(Leave blank if unknown)

22d) For clarification of our records, under what name is this record?

22d1) First Name: HEF22D1 _____

22d2) Second Name: HEF22D2 _____

22d3) Last Name: HEF22D3 _____

22d4) Maternal Last Name: HEF22D4 _____

22e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to End** HEF22E
Yes 1 ☐

23a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF23A

23b) What is the name of the medical facility? HEF23B _____

23c) What is the address of this medical facility? HEF23C _____
(Leave blank if unknown)

23d) For clarification of our records, under what name is this record?

23d1) First Name: HEF23D1 _____

23d2) Second Name: HEF23D2 _____

23d3) Last Name: HEF23D3 _____

23d4) Maternal Last Name: HEF23D4 _____

23e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to End** HEF23E
Yes 1 ☐

24a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF24A

24b) What is the name of the medical facility? HEF24B _____

24c) What is the address of this medical facility? HEF24C _____
(Leave blank if unknown)

24d) For clarification of our records, under what name is this record?

24d1) First Name: HEF24D1 _____

24d2) Second Name: HEF24D2 _____

24d3) Last Name: HEF24D3 _____

24d4) Maternal Last Name: HEF24D4 _____

24e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to End** HEF24E
Yes 1 ☐

25a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ HEF25A

25b) What is the name of the medical facility? HEF25B _____

25c) What is the address of this medical facility? HEF25C _____
(Leave blank if unknown)

25d) For clarification of our records, under what name is this record?

25d1) First Name: HEF25D1 _____

25d2) Second Name: HEF25D2 _____

25d3) Last Name: HEF25D3 _____

25d4) Maternal Last Name: HEF25D4 _____

25e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to End** HEF25E

Yes 1 ☐

26a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ HEF26A

26b) What is the name of the medical facility? HEF26B _____

26c) What is the address of this medical facility? HEF26C _____
(Leave blank if unknown)

26d) For clarification of our records, under what name is this record?

26d1) First Name: HEF26D1 _____

26d2) Second Name: HEF26D2 _____

26d3) Last Name: HEF26D3 _____

26d4) Maternal Last Name: HEF26D4 _____

SPIROMICS HIP FRACTURE ABSTRACTION FORM (HFF)

ID NUMBER:					SUBJID	FORM CODE: HFF VERSION: A 2/12/2015	Visit Number	VISIT	SEQ #	

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ HFF0A 0b. Staff ID: ☐☐☐ HFF0B
Month/Day/Year

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ HFF0C 0d. Event Date: ☐☐/☐☐/☐☐☐☐ HFF0D

Instructions: *Answers are derived from the medical records received. Do not complete this form until all records are received or classified as unobtainable as indicated on the Medical Record Shipping Form.*

A. GENERAL INFORMATION

1. Was the event ***(choose one)***: ☐ HFF1

   1= In hospital only 2= Emergency Dept. visit only (ED) 3= Both ED and in hospital

2. Date of admission: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ HFF2

3. Date of discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ HFF3

4. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐ HFF4

5. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐ HFF5

B. HIP FRACTURE

6. Is a hip fracture confirmed? Yes ☐ No ☐ [***skip to 10***] HFF6

7. What was the fracture site? ***(Mark the one that applies best)*** HFF7

   a. ☐ Neck of femur (transcervical, cervical)
   b. ☐ Greater trochanter
   c. ☐ Intertrochanteric fracture
   d. ☐ Unspecified part of the proximal femur

8. Side of the hip fracture? ***(Mark the one that applies best)*** HFF8

   a. ☐ Right
   b. ☐ Left
   c. ☐ Both
   d. ☐ Unknown

9. Hip fracture based on: ***(Mark the one category that applies best)***

   a. ☐ A written radiology report read by a radiologist which identifies the presence of a new, acute, or healing fracture of the proximal femur (femoral neck, intertrochanteric region, or the greater trochanter region) also documented on the discharge summary. HFF9A

b. ☐ A radiologist's report confirming a proximal femur fracture, but the hospital discharge summary does not confirm the diagnosis or is equivocal or missing. HFF9B

c. ☐ All of the following: HFF9C

1. a hospital discharge summary listing fracture of the proximal femur, femoral neck fracture, intertrochanteric fracture, greater trochanteric fracture, or hip fracture;
2. equivocal written radiology report of the hip (i.e. "possible" or "probably" or "suspected" hip fracture; and
3. a written radiologist's report of either a bone scan, MRI, or CT scan unequivocally stating that a new hip fracture or healing hip fracture is present.

d. ☐ A hip fracture diagnosis is documented in the discharge summary or other written report but no radiology report is available or the radiograph is not read by a radiologist. HFF9D

10. Was the hip fracture pathologic: a fracture resulting from bone tumors or cysts, Paget's disease, bone or joint prostheses, or surgical manipulation? Osteoporotic fracture is not considered a pathologic fracture. ***(Mark the one category that applies best)*** HFF10

Yes	No	Possibly
☐	☐	☐

C. OSTEOPOROSIS

11. Diagnosis of low bone mass/bone loss in this patient? ***(Mark the one that applies best)*** HFF11

a. ☐ Osteopenia b. ☐ Osteoporosis c. ☐ Not Documented

12. Documentation of DEXA scan testing results? ***(Mark the one that applies best)*** HFF12

a. ☐ T-Score of 2.5 or lower b. ☐ T-Score of 1.0 – 2.5 c. ☐ Not Documented

13. Prior to admission or at discharge, was the patient on any of the following medications? ***(Mark all that apply)***

	Admit	Discharge	NR
a. Oral bisphosphonate (Actonel, Fosamax, Boniva, Atelvia)	☐ HFF13A1	☐ HFF13A2	☐ HFF13A3
b. IV bisphosphonate (Reclast, Zometa)	☐ HFF13B1	☐ HFF13B2	☐ HFF13B3
c. Denosumab (Xgeva, Prolia) *for bone loss*	☐ HFF13C1	☐ HFF13C2	☐ HFF13C3
d. Raloxifene (Evista) or Estrogen therapy *for bone loss*	☐ HFF13D1	☐ HFF13D1	☐ HFF13D3
e. Other (Calcitonin, Teriparatide)	☐ HFF13E1	☐ HFF13E2	☐ HFF13E3
f. Calcium supplementation	☐ HFF13F1	☐ HFF13F2	☐ HFF13F3
g. Vitamin D supplementation	☐ HFF13G1	☐ HFF13G2	☐ HFF13G3

14. Did bone loss (osteopenia/osteoporosis) contribute to the confirmed hip fracture? Yes ☐ No ☐ NR ☐ HFF14

HOSPITAL RECORD ABSTRACTION FORM

ID NUMBER:				SUBJID	

FORM CODE: **HRA**
VERSION: A 10/23/2015

Visit Number VISIT SEQ # ☐☐

0a. Form Completion Date.... ☐☐/☐☐/☐☐☐☐ HRA0A 0b. Staff Code..... ☐☐☐ HRA0B

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ HRA0C 0d. Event Date: ☐☐/☐☐/☐☐☐☐ HRA0D

Instructions: *Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Medical Record Shipping Form.*

A. GENERAL INFORMATION

1. Was the event (choose one): ..... ☐ **→if response is '2' skip to Item 3** HRA1
   ED, ED Observation or 23hr Observation 1
   Hospitalization (with or without preceding ED visit) . 2

2. Was the hospital stay less than 24 hours? ..... Yes ☐ No/ NR ☐ HRA2

3. Date of arrival: (mm/dd/yyyy) ..... ☐☐/☐☐/☐☐☐☐ HRA3

   a. Date of admission ..... ☐☐/☐☐/☐☐☐☐ HRA3A

4. Date of discharge:(mm/dd/yyyy) ..... ☐☐/☐☐/☐☐☐☐ HRA4

5. What was the primary admitting diagnosis code?..... ☐☐☐☐.☐☐☐☐ HRA5

6. What was the primary discharge diagnosis code?..... ☐☐☐☐.☐☐☐☐ HRA6

	Yes	No/NR	
7. Did an emergency medical service unit transport patient to this hospital?	☐	☐	HRA7
8. Was the patient transferred to this hospital from another hospital?.....	☐	☐	HRA8
9. Was the patient's code status ever "no-code" or "DNR" (do not resuscitate)?	☐	☐	HRA9
10. Was the patient alive at discharge?.....	☐	☐	HRA10

B. SIGNS AND SYMPTOMS

I. Signs and Symptoms

Did the patient have any of the following signs or symptoms at the time of the event and what was the duration of each before seeking acute care:

	Yes	No	NR	
11. New onset or increase in dyspnea?	☐	☐	☐	HRA11
a. Duration of new or increased dyspnea	☐ days	HRA11A		
12. New onset or increase in sputum production or volume?	☐	☐	☐	HRA12
a. Duration of new or increased sputum production or volume	☐ days	HRA12A		
13. New onset or increase in sputum purulence?	☐	☐	☐	HRA13
a. Duration of new or increased sputum purulence	☐ days	HRA13A		
14. New onset or increase in wheezing?	☐	☐	☐	HRA14
a. Duration of new or increased wheezing	☐ days	HRA14A		
15. New onset or increase in cough?	☐	☐	☐	HRA15
a. Duration of new or increased cough	☐ days	HRA15A		
16. New onset or increase in sore throat?	☐	☐	☐	HRA16
a. Duration of new or increased sore throat	☐ days	HRA16A		
17. New onset or increase of fever?	☐	☐	☐	HRA17
a. Duration of new or increased fever	☐ days	HRA17A		
18. New onset or increase in use of rescue bronchodilator?	☐	☐	☐	HRA18
a. Duration of new or increased bronchodilator	☐ days	HRA18A		
19. New onset or increase in chest tightness or chest pain?	☐	☐	☐	HRA19
a. Duration of new or increased chest tightness or pain	☐ days	HRA19A		
20. New onset or increase in leg edema (unilateral or bilateral)?	☐	☐	☐	HRA20
a. Duration of new or increased leg edema	☐ days	HRA20A		
20b. New onset or increase in nasal discharge?	☐	☐	☐	HRA20B
20.b.1. Duration of new or increased nasal discharge	☐ days	HRA20B1		

II. Evidence in Physicians' Notes of Reason for Event

	Yes	No/NR	
21. Was there evidence in the doctor's notes that the reason for this event may be an exacerbation of COPD, chronic bronchitis, or emphysema?	☐	☐	HRA21
22. Was there evidence in the doctor's notes that the reason for this event may be an exacerbation of asthma?	☐	☐	HRA22
23. Was there evidence in the doctor's notes that the reason for this event may be pneumonia?	☐	☐	HRA23
24. Did the patient have new onset or progressive signs/symptoms of any of these conditions after presentation to the ED or hospital?	☐	☐	HRA24

C. MEDICAL HISTORY

25. Prior to this event was there a history of any of the following:	Yes	No/NR	
a. Asthma	☐	☐	HRA25A
b. Chronic bronchitis	☐	☐	HRA25B
c. Emphysema	☐	☐	HRA25C
d. Chronic obstructive pulmonary disease (COPD)	☐	☐	HRA25D
e. Pulmonary fibrosis	☐	☐	HRA25E
f. Sarcoidosis	☐	☐	HRA25F
g. Lung cancer	☐	☐	HRA25G
h. Lung resection or lobectomy	☐	☐	HRA25H
i. Lung transplant	☐	☐	HRA25I
j. Home oxygen (do not include CPAP)	☐	☐	HRA25J
k. Pulmonary embolus	☐	☐	HRA25K
l. Pulmonary hypertension	☐	☐	HRA25L
m. Cor pulmonale	☐	☐	HRA25M
n. Obstructive Sleep Apnea (OSA)	☐	☐	HRA25N
o. Coronary artery disease	☐	☐	HRA25O
p. Heart failure	☐	☐	HRA25P
q. Atrial fibrillation/atrial flutter	☐	☐	HRA25Q
r. Diabetes	☐	☐	HRA25R
s. Pulmonary Tuberculosis	☐	☐	HRA25S

25. Prior to this event was there a history of any of the following: Yes No/NR

t. Bronchiectasis ..... ☐ ☐ HRA25T

26. Were Pulmonary Function Test results prior to this event provided? If so, what was the percent predicted FEV1?

a. Pre-bronchodilator ..... HRA26A .% b. Post-bronchodilator ..... HRA26B .%

27. If prior PFT results were provided, what is the FEV1/FVC ratio

a. Pre-bronchodilator HRA27A ☐☐☐.☐☐ units ☐ HRA27A1
Units: 1=proportion or decimal 2=percent (If percent, then assure not percent predicted for the ratio)

b. Post-bronchodilator HRA27B ☐☐☐.☐☐ units ☐ HRA27B1
Units: 1=proportion or decimal 2=percent (If percent, then assure not percent predicted for the ratio)

D. HOSPITAL COURSE

28. Current or Active Problems anytime during this visit Yes No/NR

a. Upper Respiratory Infection (sinusitis, nasopharyngitis, pharyngitis, epiglottitis, laryngitis, laryngotracheitis, acute bronchitis) ..... ☐ ☐ HRA28A

b. Pneumonia ..... ☐ ☐ HRA28B

c. Pulmonary embolus ..... ☐ ☐ HRA28C

d. Myocardial infarction ..... ☐ ☐ HRA28D

e. Heart failure exacerbation ..... ☐ ☐ HRA28E

f. Atrial fibrillation/atrial flutter ..... ☐ ☐ HRA28F

g. Supraventricular Tachycardia (SVT) or multifocal atrial tachycardia (MAT) ..... ☐ ☐ HRA28G

h. Cardiac Surgery – CABG or Valvular Surgery ..... ☐ ☐ HRA28H

i. Non-cardiac surgery ..... ☐ ☐ HRA28I

j. Acute respiratory failure with no known cause (NOS) ..... ☐ ☐ HRA28J

k. Mechanical ventilation *for respiratory failure only* ..... ☐ ☐ HRA28K

i. Was the mechanical ventilation:..... ☐ HRA28K1

Non-invasive (non-rebreather mask, bipap).....1

Invasive (intubation).....2

Not Recorded.....3

l. Lung transplantation ..... ☐ ☐ HRA28L

i. Was the lung transplant:..... ☐ HRA28L1

Single Right.....1

Single Left.....2

Bilateral.....3

E. PHYSICAL EXAM

29. Vital Signs at arrival to hospital or ED (or at onset of event if began after arrival)

a. Heart rate..... ☐☐☐ bpm HRA29A

b. Respiration rate ..... ☐☐ per minute HRA29B

c. Oxygen Saturation (SpO_2/pulse oximetry) ..... ☐☐☐.% HRA29C

1. Oxygen Sats on room air? HRA29C1 Yes ☐ **Skip to 29d** No ☐ NR ☐ **Skip to 29d**

2. If not on room air, what level oxygen? ..... HRA29C2 ☐☐☐.☐ ☐ 1 = Liters 2 = Percent HRA29C2A

d. Weight..... HRA29D ☐☐☐.☐ ☐ 1 = Lbs 2 = Kg HRA29D1

30. Did the patient have any of the following signs (at the time of the event)?

	Yes	No	NR
a. Use of accessory muscles	☐	☐	☐ HRA30A
b. Cyanosis	☐	☐	☐ HRA30B
c. Clubbing	☐	☐	☐ HRA30C
d. Jugular venous distention (JVD) or distended neck veins	☐	☐	☐ HRA30D
e. Crackles / rales	☐	☐	☐ HRA30E
f. Wheezing or rhonchi	☐	☐	☐ HRA30F
g. Decreased unilateral breath sounds	☐	☐	☐ HRA30G
h. Decreased bilateral breath sounds	☐	☐	☐ HRA30H
i. Prolonged expiratory time	☐	☐	☐ HRA30I
j. Egophony	☐	☐	☐ HRA30J
k. Lower extremity edema (unilateral or bilateral)	☐	☐	☐ HRA30K

F. DIAGNOSTIC TESTS

31. Was a chest X-ray performed during this event? Yes ☐ No/NR ☐ **Skip to 33** HRA31

32. Did the patient have any of the following signs on chest x-ray at any time during this event?

	Yes	No/NR	
a. Hyperinflation	☐	☐	HRA32A
b. Flattened diaphragms	☐	☐	HRA32B
c. Consolidation or infiltrate	☐	☐	HRA32C

d. Scarring ..... ☐ ☐ HRA32D

e. Nodule(s) > 8mm ..... ☐ ☐ HRA32E

f. Mass(es) > 3cm ..... ☐ ☐ HRA32F

	Yes	No/NR	
g. Pulmonary edema, pulmonary vascular congestion (alveolar, interstitial)	☐	☐	HRA32G
h. Bilateral pleural effusion	☐	☐	HRA32H
i. Unilateral pleural effusion	☐	☐	HRA32I
j. Emphysema	☐	☐	HRA32J
k. Cardiomegaly	☐	☐	HRA32K

33. Was a chest CT scan or CT angiogram (CTA) performed during this event? Yes ☐ No/NR ☐ **Skip to 35** HRA33

34. Did the patient have any of the following signs on CT scan at any time during this event?

	Yes	No/NR	
a. Emphysema	☐	☐	HRA34A
b. Nodule(s) > 8mm	☐	☐	HRA34B
c. Mass(es) > 3cm	☐	☐	HRA34C
d. Lymphadenopathy	☐	☐	HRA34D
e. Ground glass changes	☐	☐	HRA34E
f. Pneumonia	☐	☐	HRA34F
g. Fibrosis or honeycombing	☐	☐	HRA34G
h. Filling defect—vascular (PE)	☐	☐	HRA34H
i. Filling defect—mucus plug	☐	☐	HRA34I
j. Cysts or blebs	☐	☐	HRA34J
k. Atelectasis	☐	☐	HRA34K
l. Calcifications	☐	☐	HRA34L
m. Pulmonary embolus	☐	☐	HRA34M
n. Enlarged pulmonary artery	☐	☐	HRA34N
o. Bronchiectasis	☐	☐	HRA34O
p. Pulmonary edema or pulmonary vascular congestion	☐	☐	HRA34P
q. Cardiomegaly	☐	☐	HRA34Q
r. Bilateral pleural effusion	☐	☐	HRA34R
s. Unilateral pleural effusion	☐	☐	HRA34S
t. Airway wall thickening	☐	☐	HRA34T

35. Was spirometry (lung function testing) performed during this hospitalization?

Yes ☐ No/NR ☐ **Skip to 36** HRA35

a1 FEV_1 ☐☐.☐☐ L HRA35A1

a2. FEV_1 Percent Predicted ☐☐☐% HRA35A2

b1. FVC ☐☐.☐☐ L HRA35B1

b2. FVC Percent Predicted ☐☐☐% HRA35B2

c1. FEV_1/FVC ratio ☐☐☐.☐☐ HRA35C1

c2.units ☐ 1 = proportion or decimal HRA35C2
2 = percent (If percent, then assure not percent predicted for the ratio)

36. Was post-bronchodilator spirometry measured? Yes ☐ No/NR ☐ **Skip to 37** HRA36

a1. FEV_1 ☐☐.☐☐ L HRA36A1

a2. FEV_1 Percent Predicted ☐☐☐% HRA36A2

b1. FVC ☐☐.☐☐ L HRA36B1

b2. FVC Percent Predicted ☐☐☐% HRA36B2

c1. FEV_1/FVC ratio ☐☐☐.☐☐ HRA36C1

units ☐ 1 = proportion or decimal HRA36C2
2 = percent (If percent, then assure not percent predicted for the ratio)

37. Was peak expiratory flow rate (PEFR or PEF) obtained at the time of event? HRA37

Yes ☐ No/NR ☐ **Skip to 38**

a. Date of first PEF(R) taken at time of event: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ HRA37A

b. First PEF recording ☐☐☐ HRA37B

c. Worst or lowest PEF recording (anytime during hospitalization) ☐☐☐ HRA37C

38. Was peak expiratory flow rate (PEFR or PEF) obtained at discharge? HRA38

Yes ☐ No/NR ☐ **Skip to 39**

a. Date of last PEF(R) taken at discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ HRA38A

b. Last PEF recording ☐☐☐ HRA38B

39. Was a ventilation perfusion scan (VQ Scan) done? Yes ☐ No/NR ☐ **Skip to 40** HRA39

a. Ventilation perfusion scan results (record number of answer) ☐ HRA39A

1. High probability
2. Intermediate probability
3. Low probability
4. No evidence of Pulmonary Embolus
5. Indeterminate
6. Not Recorded

40. Was an echocardiogram (TTE or TEE) performed? Yes ☐ No/NR ☐ **Skip to 41** HRA40

If more than one ECHO performed, then use the worst value for each question

a. Ejection fraction: ☐☐% HRA40A

b. RVSP (right ventricular systolic pressure) ☐☐☐.☐☐mmHg HRA40B

Record the following if present on echocardiogram:	None	Present	Mild	Mod	Severe	NR	
c. Right Ventricular Hypertrophy	☐	☐	☐	☐	☐	☐	HRA40C
d. Impaired RV systolic function	☐	☐	☐	☐	☐	☐	HRA40D
e. Pulmonary hypertension	☐	☐	☐	☐	☐	☐	HRA40E
f. Tricuspid regurgitation	☐	☐	☐	☐	☐	☐	HRA40F
g. Diastolic dysfunction	☐	☐				☐	HRA40G

G. BIOCHEMICAL TESTS

41. White Blood Cell Count (highest) ☐☐.☐ HRA41

	First (at event)	
42. Hemoglobin (g/dL)	☐☐.☐	HRA42
43. Hematocrit (%)	☐☐.☐	HRA43
44. Sodium (mEq/L)	☐☐☐	HRA44
45. Serum creatinine (mg/dL)	☐☐.☐☐	HRA45
46. BUN (mg/dL)	☐☐.☐	HRA46
47. Bicarbonate (total CO2)	☐☐.☐	HRA47

	First (at event)		Upper limit normal	
48. BNP (pg/mL)	a. ☐☐☐☐☐.☐	HRA48	b. ☐☐☐☐☐.☐	HRA48A
49. ProBNP (pg/mL)	a. ☐☐☐☐☐.☐	HRA49	b. ☐☐☐☐☐.☐	HRA49A

50. Were Arterial Blood Gases (ABGs) obtained? Yes ☐ No/NR ☐ **Skip to 51** HRA50

	First blood gas (at time of event)		Last blood gas	
pH	a1. ☐☐.☐☐	HRA50A1	b1. ☐☐.☐☐	HRA50B1
PaCO2	a2. ☐☐.☐mmHg	HRA50A2	b2. ☐☐.☐mmHg	HRA50B2
PaO2	a3. ☐☐☐.☐mmHg	HRA50A3	b3. ☐☐☐.☐mmHg	HRA50B3

O_2 Saturation a4. ___.___% HRA50A4 b4. ___.___% HRA50B4

c. First blood gas on room air? Yes ☐ **Skip to 51** No ☐ NR ☐ **Skip to 51** HRA50C

1. If not on room air, what level oxygen? ___.___ HRA50C1 ☐ 1 = Liters 2 = Percent HRA50C1A

51. Was a sputum culture done? Yes ☐ No/NR ☐ **Skip to 52** HRA51

a. Culture Results Pos ☐ Neg ☐ **Skip to 52** Not Recorded ☐ **Skip to 52** HRA51A

b. If positive, were any of the following reported in the sputum culture?

	Yes	No	NR	
1. Haemophilus Influenzae	☐	☐	☐	HRA51B1
2. Moraxella Catarrhalis	☐	☐	☐	HRA51B2
3. Streptococcus pneumoniae	☐	☐	☐	HRA51B3
4. Methicillin-resistant Staphylococcus Aureus (MRSA)	☐	☐	☐	HRA51B4
5. Staphylococcus aureus (not MRSA)	☐	☐	☐	HRA51B5
6. Mycoplasma pneumoniae	☐	☐	☐	HRA51B6
7. Pseudomonas Aureginosa	☐	☐	☐	HRA51B7
8. Chlamydophila (or Chlamydia) pneumoniae	☐	☐	☐	HRA51B8
9. Oropharyngeal flora	☐	☐	☐	HRA51B9
10. Klebsiella pneumoniae	☐	☐	☐	HRA51B10
11. Other	☐	☐	☐	HRA51B11

Specify HRA51B11A _____

52. Was a bronchoscopy culture done? Yes ☐ No/NR ☐ **Skip to 53** HRA52

a. Culture Results Pos ☐ Neg ☐ **Skip to 53** Not Recorded ☐ **Skip to 53** HRA52A

b. If positive, were any of the following reported in the bronchoscopy culture?

	Yes	No	NR	
1. Haemophilus Influenzae	☐	☐	☐	HRA52B1
2. Moraxella Catarrhalis	☐	☐	☐	HRA52B2
3. Streptococcus pneumoniae	☐	☐	☐	HRA52B3
4. Methicillin-resistant Staphylococcus Aureus (MRSA)	☐	☐	☐	HRA52B4
5. Staphylococcus aureus (not MRSA)	☐	☐	☐	HRA52B5
6. Mycoplasma pneumoniae	☐	☐	☐	HRA52B6
7. Pseudomonas Aureginosa	☐	☐	☐	HRA52B7
8. Chlamydophila (or Chlamydia) pneumoniae	☐	☐	☐	HRA52B8
9. Oropharyngeal flora	☐	☐	☐	HRA52B9

10. Klebsiella pneumoniae ..... ☐ ☐ ☐ HRA52B10

11. Other ..... ☐ ☐ ☐ HRA52B11

Specify___HRA52B11A_____

53. Was a blood culture done? Yes ☐ No/NR ☐ **Skip to 54** HRA53

a. Culture Results Pos ☐ Neg ☐ **Skip to 54** Not Recorded ☐ **Skip to 54** HRA53A

b. If positive, were any of the following reported in the blood culture?

	Yes	No	NR	
1. Haemophilus Influenzae	☐	☐	☐	HRA53B1
2. Moraxella Catarrhalis	☐	☐	☐	HRA53B2
3. Streptococcus pneumoniae	☐	☐	☐	HRA53B3
4. Methicillin-resistant Staphylococcus Aureus (MRSA)	☐	☐	☐	HRA53B4
5. Staphylococcus aureus (not MRSA)	☐	☐	☐	HRA53B5

6. Other_____ HRA53B6 HRA53B6A

54. Influenza swab Pos ☐ Neg ☐ Not Recorded ☐ HRA54

H. TREATMENTS / MEDICATIONS

	Yes	No/NR	
55. CPAP or BiPAP (non-invasive mechanical ventilation)	☐	☐	HRA55
56. Invasive Mechanical Ventilation	☐	☐	HRA56
57. Inhaled short-acting beta-agonists (ie,albuterol, xopenex)	☐	☐	HRA57
58. Inhaled short-acting anticholinergics (ie, atrovent, ipratropium)	☐	☐	HRA58
59. Inhaled long-acting anticholinergics (ie, spiriva, tudorza pressair)	☐	☐	HRA59
60. Inhaled long-acting beta-agonists (ie: serevent)	☐	☐	HRA60
61. Inhaled Corticosteroid for respiratory event	☐	☐	HRA61
62. Oxygen (continuous or prn)	☐	☐	HRA62
63. Antibiotics for respiratory event (IV or PO)	☐	☐	HRA63
64. Systemic Corticosteroid for respiratory event (IV or PO)	☐	☐	HRA64
65. IV Lasix or Furosemide	☐	☐	HRA65
66. Leukotriene antagonist (ie. singulair, accolate)	☐	☐	HRA66
67. Home oxygen	☐	☐	HRA67

I. EXACERBATION EVALUATION

68. Did this hospitalization meet the SPIROMICS criteria for a COPD exacerbation? ☐ HRA68
    - Yes 1
    - No 0

69. Did this hospitalization meet the SPIROMICS criteria for infiltrate pneumonia?.. ☐ HRA69
    - Yes 1
    - No 0

70. Do you agree with the SPIROMICS event classification?..... ☐ HRA70
    - Yes..... 1
    - No 0

71. If no, explain:

HRA71 _____

_____

72. Should this event be reviewed by the Mortality and Morbidity Committee?..... ☐ HRA72
    - Yes..... 1
    - No 0

73. Are other condition abstractions needed for this case?

	Yes	No	
a. MI / Coronary Artery Disease	☐	☐	HRA73A
b. Venous Thrombosis Disease / Stroke	☐	☐	HRA73B
c. Cancer	☐	☐	HRA73C
d. Hip Fracture / Osteoporosis	☐	☐	HRA73D
e. Diabetes	☐	☐	HRA73E

INFORMANT INTERVIEW

ID NUMBER:					SUBJID	FORM CODE: IFI VERSION: 1.0 06/20/2014	Visit Number	VISIT	SEQ #	

0a. Form Date:..... __ __/__ __/__ __ __ __ IFI0A 0b. Code..... __ __ __ IFI0B

Instructions: *The informant interview form is completed for each informant for an eligible death as determined by the SPIROMICS event investigation protocol.*

Decedent's name: Removed from Blinded Dataset _____ Informant name: Removed from Blinded Dataset _____

Date of death __ __/__ __/__ __ __ __ IFI0E

Age at death: __ __ IFI0F

Date of birth: __ __/__ __/__ __ __ __ Removed from Blinded Dataset

Place of death: Removed from Blinded Dataset _____

Informant Interview Attempt for the: IFI0I
- Primary Informant _____ 1
- Secondary Informant _____ 2
- Additional Informant _____ 3

"Hello, my name is (interviewer's name) *with the SPIROMICS study. I'm calling* (name of informant) *regarding* (name of decedent)*'s involvement with the SPIROMICS study, a medical study in which* (name of decedent) *was enrolled.*

[Once it is established you are speaking with the informant, continue with the script below. If the informant is not available determine a time to call back. If the interviewer determines that the person they are speaking with is knowledgeable of the circumstances surrounding the decedent's death, the interview with this person should continue. See procedure manual for more details.]

*"I'm sorry for your loss. We understand that you might be able to help us complete our documents for (*decedent*), particularly the circumstances surrounding (*his/her*) death. Is now a good time to talk?"* IFI0J

No answer IFIOJ1

First attempt ☐
Second attempt ☐
Third attempt ☐
Fourth attempt ☐
Fifth attempt ☐

No → When would be convenient to call back? IFI0J2 _____

No → Do not contact again **Skip to 19**

Yes → Thank you. If you have any questions, please ask me.

1. Before we get started could you please tell me what was your relationship with (*insert name of decedent*)? (Respondent was deceased's…) IFI1

Spouse ☐
Daughter/Son ☐
Parent ☐
Friend ☐
Workmate ☐
Other relative ☐
Other ☐
Specify relationship of other: IFI1A _____

A. CIRCUMSTANCES SURROUNDING DEATH

"I'd like to ask you a few questions about (*decedent's name)*'s medical history and the events leading up to (*his/her*) death."

2. Please tell me about his/her general health, health on the day s/he died, and about the death itself.

Record a brief synopsis of the events surrounding the death as related by the informant:
Removed from Blinded Dataset

_____

_____

_____

_____

"Some of the remaining questions may repeat information you already provided, but it helps us to ask these items specifically."

3. How long was it between the time (*decedent's name*) was last known to be alive and the time (*he/she*) was found dead? IFI3

   - Less than 5 minutes ☐
   - 5 minutes to 1 hour ☐
   - 1 to 24 hours ☐
   - Longer than 24 hours ☐
   - Unknown ☐

4. Please tell me who was present. (Mark all that apply.)

Self	No	☐	Yes	☐	**Skip to Item 6** IFI4A
Health care person(s)	No	☐	Yes	☐	IFI4B
Other person(s)	No	☐	Yes	☐	IFI4C

5. When was the last time you saw (*decedent's name*) prior to (*his/her*) death? IFI5

   - Less than 5 minutes ☐
   - 5 minutes to 1 hour ☐
   - 1 to 24 hours ☐
   - Longer than 24 hours ☐
   - Unknown ☐

B. MEDICAL HISTORY

"I'd now like to ask you a few questions about (*decedent's name*) medical history."

6. Was (*he/she*) hospitalized within the four weeks prior to death? IFI6

   - No ☐ **Skip to Item 10**
   - Yes ☐
   - Unknown ☐ **Skip to Item 10**

7. What was the reason for the hospitalization? (Select all that apply.)

a. Unknown	Yes	☐	No	☐	IFI7A
b. Respiratory	Yes	☐	No	☐	IFI7B
b1. Emphysema, Chronic Bronchitis, or chronic obstructive pulmonary disease (COPD)	Yes	☐	No	☐	IFI7B1
b2. Pneumonia	Yes	☐	No	☐	IFI7B2
b3. Other respiratory	Yes	☐	No	☐	IFI7B3
c. Cardiac	Yes	☐	No	☐	IFI7C
c1. Heart Attack	Yes	☐	No	☐	IFI7C1
c2. Heart Failure	Yes	☐	No	☐	IFI7C2
c3. Other heart problem	Yes	☐	No	☐	IFI7C3
Specify: IFI7C3A					
d. Cancer	Yes	☐	No	☐	IFI7D
d1. Lung	Yes	☐	No	☐	IFI7D1
d2. Other cancer	Yes	☐	No	☐	IFI7D2 IFI7D2A
e. Other condition	Yes	☐	No	☐	IFI7E
Specify: IFI7E1					

8. What was the date of the hospitalization? IFI8

☐☐/ ☐☐/ ☐☐☐☐
Month Day Year

9. What was the name and location of the hospital? Removed from Blinded Dataset _____

10. Was (insert decedent's name) seen by a doctor any other time in the last four weeks prior to death? IFI10

No ☐ **Skip to Item 12**
Yes ☐
Unknown ☐ **Skip to Item 12**

11. What was the name and address of this doctor?

Removed from Blinded Dataset
_____

_____

C. SYMPTOMS

"Now I'd like to talk about specific symptoms (*decedent's name*) might have experienced just prior to (*his/her*) death."

12. Did (*he/she*) experience an increase in shortness of breath? IFI12

- No ☐
- Yes ☐
- Unknown ☐

13. Did (*he/she*) experience increased coughing? IFI13

- No ☐
- Yes ☐
- Unknown ☐

14. Did (*he/she*) experience increased mucus or sputum production? IFI14

- No ☐
- Yes ☐
- Unknown ☐

D. EMERGENCY MEDICAL CARE

"I now have a few questions about emergency medical care *(insert decedent's name)* may have received prior to or at the time of death. You may have already given this information in an answer to an earlier question, and I apologize if these questions seem repetitive, but it is important to obtain information specifically on emergency medical care."

15. Was a physician, ambulance or other emergency medical team called? IFI15

- No ☐ **Skip to Item 16**
- Yes ☐
- Unknown ☐ **Skip to Item 16**

15a. How long was it from the time the last episode of symptoms started to the time that medical assistance was called for? IFI15A

- 5 minutes or less ☐
- 10 minutes or less ☐
- 1 hour or less ☐
- 6 hours or less ☐
- 24 hours or less ☐
- More than 24 hours ☐
- Unknown ☐

16. Were resuscitation measures, such as CPR attempted? IFI16

- No ☐
- Yes ☐
- Unknown ☐

17. Was (*decedent's name*) taken to the hospital, emergency room or any other emergency care facility? IFI17

- No ☐
- Yes ☐
- Unknown ☐

E. CAUSE OF DEATH

18. To the best of your knowledge, what was the reason for the death? (Select all that apply.)

a. Unknown	Yes	☐	No	☐	IFI18A
b. Respiratory	Yes	☐	No	☐	IFI18B
b1. Emphysema, Chronic Bronchitis, or chronic obstructive pulmonary disease (COPD)	Yes	☐	No	☐	IFI18B1
b2. Pneumonia	Yes	☐	No	☐	IFI18B2
b3. Other respiratory cause	Yes	☐	No	☐	IFI18B3
c. Cardiac	Yes	☐	No	☐	IFI18C
c1. Heart Attack	Yes	☐	No	☐	IFI18C1
c2. Heart Failure	Yes	☐	No	☐	IFI18C2
c3. Other heart problem	Yes	☐	No	☐	IFI18C3
Specify:___ IFI18C3A _____					
d. Cancer	Yes	☐	No	☐	IFI18D
d1. Lung	Yes	☐	No	☐	IFI18D1
d2. Other	Yes	☐	No	☐	IFI18D2 IFI18D2A
e. Other condition	Yes	☐	No	☐	IFI18E
Specify: ___ IFI18E1 _____					

F. ADDITIONAL INFORMANTS

19. Is there anyone else we could contact who might be able to provide additional information about the circumstances surrounding (*decedent's name*) death or (*his/her*) usual state of health? IFI19

No ☐ **Skip to Closing Script**

Yes ☐

Unknown ☐ **Skip to Closing Script**

20. How is (*he/she*) related to (*decedent's name*)? IFI20

- Spouse ☐
- Daughter/Son ☐
- Parent ☐
- Friend ☐
- Workmate ☐
- Other relative ☐
- Other ☐

Specify relationship of other: IFI20A _____

21. What is the name and address of this person?

Removed from Blinded Dataset

_____

_____

G. CLOSING SCRIPT

"Thank you very much for your assistance in this study. This information is very important for advancing our understanding of lung disease. Do you have any questions? Thanks again for your help."

H. RELIABILITY (To be completed after the interview)

22. On the basis of these questions, give your rating of reliability of the interview. IFI22

- Poor ☐
- Fair ☐
- Good ☐

I. COORDINATOR SUMMARY

23. Please provide a narrative summary of the conversation with the informant, describing any pertinent details that may not have been captured by this form that will aid the adjudication committee in determining any circumstances and underlying conditions that may have contributed to a subject's death in addition to determining the ultimate cause of death.

Removed from Blinded Dataset

INDUCED SPUTUM WORKSHEET

For post albuterol FEV_1 <50% Predicted

ID NUMBER:	BLINDID	FORM CODE: **ISP** VERSION: **2.0** 6/12/13	Visit Number	VISIT	SEQ #

0a) Form Date: ..... __ __/__ __/__ __ __ __ ISP0A 0b) Initials..... __ __ __ ISP0B

0c) Date Collected:.... __ __/__ __/__ __ __ __ ISP0C

0d) Time Collected: ...ISP0D __ __:__ __ AM/PM (circle one) ISP0D_AMPM

> ***Instructions:*** *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

1) 10% fall from ISP01A __.__ __ is ISP01B __.__ __ - use this value to determine if saline is to be increased to 3% after the first 7 min. (use best post albuterol FEV_1 to calculate)

2) 20% fall from ISP02A __.__ __ is ISP02B __.__ __ (use best post albuterol FEV_1)
(Discontinue tests, give albuterol. Perform PFTs at 10 minutes)

3) Was the participant given albuterol prior to sputum induction?..... __ ISP03

Yes.....Y
No .....N

3a) Was this a re-dosing (e.g., >165 minutes after initial bronchodilator dose for PFTs)? __ ISP03A

Yes.....Y
No .....N

3b) How many puffs of albuterol was the participant given? ..... __ ISP03B

		FEV_1
4)	Baseline #1	a) ISP04A
5)	Baseline #2	a) ISP05A
6)	Baseline #3	a) ISP06A
7)	Baseline spirometry reviewed by: Removed from Blinded Dataset	

8)	Spirometry ok to continue?	☐ Yes ☐ No ISP08
	10 min post albuterol	a) ISP09A
9)	trial #1	
10)	trial #2	a) ISP10A
11)	trial #3	a) ISP11A
12)	1 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP12A
13)	2 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP13A
14)	5 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP14A
15)	7 min at 0.9% NaCl	a) ISP15A
16)	First 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 27** ISP16
17)	If yes, % NaCl used: NOTE: If FEV_1 <10% drop, then increase to 3% NaCl after sample collected. If FEV_1 =11-19% then continue at .9% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 0.9% NaCL ☐ 3% NaCL ISP17
18)	1 min If FEV_1 <20% drop, continue	a) ISP18A
19)	2 min If FEV_1 <20% drop, continue	a) ISP19A
20)	5 min If FEV_1 <20% drop, continue	a) ISP20A
21)	7 min If FEV_1 <20% drop, continue	a) ISP21A
22)	Second 7 minutes complete, continue induction? NOTE: if continuing, use same saline concentration	☐ Yes ☐ No → **Go to Item 27** ISP22
23)	1 min If FEV_1 <20% drop, continue	a) ISP23A
24)	2 min If FEV_1 <20% drop, continue	a) ISP24A

25)	5 min If FEV_1 <20% drop, continue	a) ISP25A
26)	7 min Third 7 minutes complete. Induction Complete.	a) ISP26A

Remind subject to rinse mouth and cheeks thoroughly, gargle - spit into sink.
Clear throat, scraping throat and roof of mouth - spit into sink. Blow nose – discard
Deep cough from chest and spit into sputum sample cup.
DO NOT HOCK OR SCRAPE when producing sample. Passively bring it past the throat into the cup!

27) Was the participant able to produce sputum? ..... ☐ ISP27

Yes.....Y
No .....N

28) Was the induction terminated early? ..... ☐ ISP28

Yes.....Y
No .....N → **Go to End**

29) Reason terminated early ..... ☐ ISP29

FEV1 dropped >20%.....1
Participant requested to stop.....2
Other 3

Specify Other: ISP29A _____

30) Did the participant require additional albuterol? ..... ☐ ISP30

Yes.....Y
No .....N → **Go to Item 33**

If participant's FEV1 dropped >20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

		FEV_1
31)	Trial #1	ISP31A
32)	Trial #2	ISP36A
33)	Trial #3	ISP33A

34) Note reason and time point obtained: ISP34

_____

_____

INDUCED SPUTUM WORKSHEET

For post albuterol FEV_1 <50% Predicted

ID NUMBER:	BLINDID	FORM CODE: **ISP** VERSION: **1.0** 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date: ..... __ __/__ __/__ __ __ __ ISP0A 0b) Initials..... __ __ __ ISP0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

1) 10% fall from ISP01A __.__ __ is ISP01B __.__ __ - use this value to determine if saline is to be increased to 3% after the first 7 min. (use best post albuterol FEV_1 to calculate)

2) 20% fall from ISP02A __.__ __ is ISP02B __.__ __ (use best post albuterol FEV_1)
(Discontinue tests, give albuterol. Perform PFTs at 10 minutes)

3) Was the participant given albuterol prior to sputum induction? ..... ☐ ISP03
Yes.....Y
No .....N

3a) Was this a re-dosing (e.g., >165 minutes after initial bronchodilator dose for PFTs)? ☐ ISP03A

Yes.....Y
No .....N

3b) How many puffs of albuterol was the participant given? ..... ☐ ISP03B

		FEV_1
4)	Baseline #1	a) ISP04A
5)	Baseline #2	a) ISP05A
6)	Baseline #3	a) ISP06A
7)	Baseline spirometry reviewed by: Variable Removed	
8)	Spirometry ok to continue?	☐ Yes ☐ No ISP08
9)	10 min post albuterol trial #1	a) ISP09A
10)	trial #2	a) ISP10A
11)	trial #3	a) ISP11A

12)	1 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP12A
13)	2 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP13A
14)	5 min at 0.9% NaCl If FEV_1 <20% drop, continue	a) ISP14A
15)	7 min at 0.9% NaCl	a) ISP15A
16)	First 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 27** ISP16
17)	If yes, % NaCl used: NOTE: If FEV_1 <10% drop, then increase to 3% NaCl after sample collected. If FEV_1 =11-19% then continue at .9% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 0.9% NaCL ☐ 3% NaCL ISP17
18)	1 min If FEV_1 <20% drop, continue	a) ISP18A
19)	2 min If FEV_1 <20% drop, continue	a) ISP19A
20)	5 min If FEV_1 <20% drop, continue	a) ISP20A
21)	7 min If FEV_1 <20% drop, continue	a) ISP21A
22)	Second 7 minutes complete, continue induction? NOTE: if continuing, use same saline concentration	☐ Yes ☐ No → **Go to Item 27** ISP22
23)	1 min If FEV_1 <20% drop, continue	a) ISP23A
24)	2 min If FEV_1 <20% drop, continue	a) ISP24A
25)	5 min If FEV_1 <20% drop, continue	a) ISP25A
26)	7 min Third 7 minutes complete. Induction Complete.	a) ISP26A

Remind subject to rinse mouth and cheeks thoroughly, gargle - spit into sink.
Clear throat, scraping throat and roof of mouth - spit into sink. Blow nose – discard
Deep cough from chest and spit into sputum sample cup.
DO NOT HOCK OR SCRAPE when producing sample. Passively bring it past the throat into the cup!

27) Was the participant able to produce sputum? ..... ☐ ISP27

Yes.....Y
No .....N

28) Was the induction terminated early? ..... ☐ ISP28

Yes.....Y
No .....N → **Go to End**

29) Reason terminated early ..... ☐ ISP29

FEV1 dropped >20%.....1
Participant requested to stop.....2
Other 3

Specify Other: ISP29A _____

30) Did the participant require additional albuterol? ..... ☐ ISP30

Yes.....Y
No .....N → **Go to Item 33**

If participant's FEV1 dropped >20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

		FEV_1
31)	Trial #1	ISP31A
32)	Trial #2	ISP36A
33)	Trial #3	ISP33A

34) Note reason and time point obtained: ISP34

_____

_____

INDUCED SPUTUM WORKSHEET

For post albuterol FEV_1 >50% Predicted

ID NUMBER:	BLINDID	FORM CODE: **ISW** VERSION: **2.0** 6/12/13	Visit Number	VISIT	SEQ #

0a) Form Date: ..... __ __/__ __/__ __ __ __ ISW0A 0b) Initials..... __ __ __ ISW0B

0c) Date Collected:.... __ __/__ __/__ __ __ __ ISW0C

0d) Time Collected: ... ISW0D __ __:__ __ AM/PM (circle one) ISW0D_AMPM

> ***Instructions:*** *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

1) 10% fall from ISW01A __.__ __ is ISW01B __.__ __ - Continue at present concentration – do not increase saline concentration (use best post albuterol FEV_1 to calculate)

2) 20% fall from ISW02A __.__ __ is ISW02B __.__ __ (use best post albuterol FEV_1)
(Discontinue tests, give albuterol. Perform PFTs at 10 minutes post administration)

3) Was the participant given albuterol prior to sputum induction?..... ☐ ISW03

Yes.....Y
No .....N

3a) Was this a re-dosing (e.g., >165 minutes after initial bronchodilator dose for PFTs)? ☐ ISW03A

Yes.....Y
No .....N

3b) How many puffs of albuterol was the participant given? ..... ☐ ISW03B

		FEV_1
4)	Baseline #1	a) ISW04A
5)	Baseline #2	a) ISW05A
6)	Baseline #3	a) ISW06A
7)	Baseline spirometry reviewed by:	Removed from Blinded Dataset
8)	Spirometry ok to continue?	☐ Yes ☐ No ISW08

9)	10 min post albuterol trial #1	a) ISW09A
10)	trial #2	a) ISW10A
11)	trial #3	a) ISW11A
12)	2 min at 3% NaCl If FEV_1 <20% drop, continue	a) ISW12A
13)	7 min at 3% NaCl	a) ISW13A
14)	First 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 22** ISW14
15)	If yes, % NaCl used: NOTE: If FEV_1 <10% drop, then increase to 4% NaCl after sample collected. If FEV_1 =11-19% then continue at 3% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 3% NaCL ☐ 4% NaCL ISW15
16)	2 min at 4% NaCl If FEV_1 <20% drop, continue	a) ISW16A
17)	7 min at 4% NaCl	a) ISW17A
18)	Second 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 22** ISW18
19)	If yes, % NaCl used: NOTE: If you did not increase % NaCL in step 15, then continue at 3% unless FEV1 >20% drop. If you did increase NaCL to 4% and FEV_1 <10% drop, then increase to 5%. If FEV_1 =11-19% then continue at 4% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 3% NaCL ☐ 4% NaCL ☐ 5% NaCL ISW19
20)	2 min at 5% NaCl If FEV_1 <20% drop, continue	a) ISW20A
21)	7 min at 5% NaCl Induction complete.	a) ISW21A

Remind subject to rinse mouth and cheeks thoroughly, gargle - spit into sink.
Clear throat, scraping throat and roof of mouth - spit into sink. Blow nose – discard

Deep cough from chest and spit into sputum sample cup.
DO NOT HOCK OR SCRAPE when producing sample. Passively bring it past the throat into the cup!

22) Was the participant able to produce sputum? ..... ☐ ISW22

Yes.....Y
No .....N

23) Was the induction terminated early? ..... ☐ ISW23

Yes.....Y
No .....N → **Go to 25**

24) Reason terminated early ..... ☐ ISW24

FEV1 dropped >20%.....1
Participant requested to stop.....2
Other 3

Specify Other: ISW24A _____

25) Did the participant require additional albuterol? ..... ☐ ISW25

Yes.....Y
No .....N → **Go to End**

If participant's FEV1 dropped >20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

		FEV_1
26)	Trial #1	ISW26A
27)	Trial #2	ISW27A
28)	Trial #3	ISW28A

29) Note reason and time point obtained: ISW29

_____

_____

INDUCED SPUTUM WORKSHEET

For post albuterol FEV_1 >50% Predicted

ID NUMBER:	BLINDID	FORM CODE: ISW VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date:..... ☐☐/☐☐/☐☐☐☐ ISW0A 0b) Initials ..... ☐☐☐ ISW0B

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

1) 10% fall from ISW01A ☐.☐☐ is ISW01B ☐.☐☐ - Continue at present concentration – do not increase saline concentration (use best post albuterol FEV_1 to calculate)

2) 20% fall from ISW02A ☐.☐☐ is ISW02B ☐.☐☐ (use best post albuterol FEV_1)
(Discontinue tests, give albuterol. Perform PFTs at 10 minutes post administration)

3) Was the participant given albuterol prior to sputum induction?..... ☐ ISW03
Yes ..... Y
No ..... N

3a) Was this a re-dosing (e.g., >165 minutes after initial bronchodilator dose for PFTs)? ☐ ISW03A

Yes ..... Y
No ..... N

3b) How many puffs of albuterol was the participant given? ..... ☐ ISW03B

		FEV_1
4)	Baseline #1	a) ISW04A
5)	Baseline #2	a) ISW05A
6)	Baseline #3	a) ISW06A
7)	Baseline spirometry reviewed by: Variable Removed	
8)	Spirometry ok to continue?	☐ Yes ☐ No ISW08
9)	10 min post albuterol trial #1	a) ISW09A
10)	trial #2	a) ISW10A
11)	trial #3	a) ISW11A

12)	2 min at 3% NaCl If FEV_1 <20% drop, continue	a) ISW12A
13)	7 min at 3% NaCl	a) ISW13A
14)	First 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 20** ISW14
15)	If yes, % NaCl used: NOTE: If FEV_1 <10% drop, then increase to 4% NaCl after sample collected. If FEV_1 =11-19% then continue at 3% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 3% NaCL ☐ 4% NaCL ISW15
16)	2 min at 4% NaCl If FEV_1 <20% drop, continue	a) ISW16A
17)	7 min at 4% NaCl	a) ISW17A
18)	Second 7 minutes complete, continue induction?	☐ Yes ☐ No → **Go to Item 20** ISW18
19)	If yes, % NaCl used: NOTE: If you did not increase % NaCL in step 15, then continue at 3% unless FEV1 >20% drop. If you did increase NaCL to 4% and FEV_1 <10% drop, then increase to 5%. If FEV_1 =11-19% then continue at 4% NaCL. If FEV_1 >20% drop, then stop induction procedure.	☐ 3% NaCL ☐ 4% NaCL ☐ 5% NaCL ISW19
20)	2 min at 5% NaCl If FEV_1 <20% drop, continue	a) ISW20A
21)	7 min at 5% NaCl Induction complete.	a) ISW21A

Remind subject to rinse mouth and cheeks thoroughly, gargle - spit into sink.
Clear throat, scraping throat and roof of mouth - spit into sink. Blow nose – discard
Deep cough from chest and spit into sputum sample cup.
DO NOT HOCK OR SCRAPE when producing sample. Passively bring it past the throat into the cup!

22) Was the participant able to produce sputum? ..... ☐ ISW22

Yes ..... Y

No ..... N

23) Was the induction terminated early? ..... ☐ ISW23

Yes ..... Y

No ..... N → **Go to 23**

24) Reason terminated early ..... ☐ ISW24

FEV1 dropped >10% 1

Participant requested to stop 2

Other 3

Specify Other: ISW24A _____

25) Did the participant require additional albuterol? ..... ☐ ISW25

Yes ..... Y

No ..... N → **Go to End**

If participant's FEV1 dropped >20% from baseline and/or if a 2nd dose of albuterol was required, conduct a post-induction spirometry and record values here:

		FEV_1
26)	Trial #1	ISW26A
27)	Trial #2	ISW27A
28)	Trial #3	ISW28A

29) Note reason and time point obtained: ISW29

_____

_____

MONTHLY CONTACT FORM

ID NUMBER:	BLINDID	FORM CODE: MCF VERSION: 1.0 06/17/13	Visit Number	visit	SEQ #	

0a) Form Date..... ☐☐/☐☐/☐☐☐☐ MCF0a 0b) Initials ..... ☐☐☐ MCF0b

> ***Instructions:*** *This form should be completed during the follow up phone conversations with study participants. Read the form carefully to familiarize yourself with the script as well as questions and skip patterns.*

INTERVIEWER: Hello, my name is *(interviewer name),* and I am calling to follow up with *(participant name)* about the Subpopulations and Intermediate Outcome Measures in COPD Study (SPIROMICS), a health study in which s/he is currently enrolled. Is s/he available?

No → When would it be convenient to call back? .....Thank you. I will call again.

Yes → Hello, *(participant name),* this is *(interviewer name)* with the SPIROMICS study. I'm calling to see how you have been since your last (*visit to our center* or *telephone contact)*. Do you have a few minutes to speak on the phone?

No → When would it be convenient to call back?.....Thank you. I will call again.

Yes → We'd like to gather information about your general health and about specific medical conditions that you may have had since your last (*visit to our center* or *telephone contact)*. I will ask you some questions about your health since your last (*visit to our center* or *telephone contact)* on *(date of contact).*

INTERVIEWER: I want you to focus on what happened from *(date of contact)* until today.

1) *(Do not ask participant)* Participant status (choose one): MCF1

Contacted and alive	1 ☐	→ **Go to Item 2**
Contacted and refused interview	2 ☐	→ **End Call**
Not contacted, reported alive	3 ☐	→ **End Call**
Not contacted, reported deceased	4 ☐	→ **Go to Item 1a**
Unknown	5 ☐	→ **End Call**

1a) What was the date of death? ..... ☐☐/☐☐/☐☐☐☐ MCF1a

1b) What city, state, and country did the death occur? Removed from Blinded Dataset

1c) Do you know if (*insert decedent's name*) was hospitalized or visited an emergency room for any reason since (*date of last contact*) and his/her death? MCF1c

Yes 1 ☐ Record date and name of hospitalization in question 21a.
No 0 ☐ End interview

HOSPITALIZATIONS

2) Since your last (*clinic visit* or *telephone contact*) on (*date*), have you had a flare-up of your chest trouble? (Y/N)..... ☐ MCF2
(if 'No' go to item 20)

If Yes:

2a) How many episodes of chest trouble flare ups have you had since (*date*)? ..... ☐ MCF2a

How was/were the episode(s) of breathing problem(s) treated? Please answer for each episode (if more than one) by checking all relevant treatments given for each episode. Starting with the first episode since (*date*):

3) For the first episode of breathing problems you had since *(date)*:

3a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF3a

3b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF3b

3c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF3c

3d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF3d

3e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF3e

During that visit were you given (check all that apply):

3e1) An additional antibiotic ..... ☐ MCF3e1

3e2) Additional steroids ..... ☐ MCF3e2

3e3) Don't know ..... ☐ MCF3e3

3e4) Don't remember..... ☐ MCF3e4

3f) Were you evaluated in an Emergency Department? ..... ☐ MCF3f

During that visit were you given (check all that apply):

3f1) An additional antibiotic ..... ☐ MCF3f1

3f2) Additional steroids ..... ☐ MCF3f2

3f3) Don't know ..... ☐ MCF3f3

3f4) Don't remember..... ☐ MCF3f4

3g) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF3g

3h) What is the name of the medical facility? Removed from Blinded Dataset

3i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

3j) For clarification of our records, under what name is this record?

3j1) First Name: Removed from Blinded Dataset

3j2) Second Name: Removed from Blinded Dataset

3j3) Last Name: Removed from Blinded Dataset

3j4) Maternal Last Name: Removed from Blinded Dataset

3k) Were you admitted to the hospital? ..... ☐ MCF3k

If participant was admitted to hospital:

4a) What was the date of this event? ..... __ __/__ __/__ __ __ __ MCF4a

4b) What is the name of the medical facility? Removed from Blinded Dataset

4c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

4d) For clarification of our records, under what name is this record?

4d1) First Name: Removed from Blinded Dataset

4d2) Second Name: Removed from Blinded Dataset

4d3) Last Name: Removed from Blinded Dataset

4d4) Maternal Last Name: Removed from Blinded Dataset

5) (do not ask) Did the participant have a second episode? (if 'No', go to 20) ..... ☐ MCF5

6) For the second episode of breathing problems you had since *(date)*:

6a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF6a

6b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF6b

6c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF6c

6d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF6d

6e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF6e

During that visit were you given (check all that apply):

6e1) An additional antibiotic ..... ☐ MCF6e1

6e2) Additional steroids ..... ☐ MCF6e2

6e3) Don't know ..... ☐ MCF6e3

6e4) Don't remember ..... ☐ MCF6e4

6f) Were you evaluated in an Emergency Department? ..... ☐ MCF6f

During that visit were you given (check all that apply):

6f1) An additional antibiotic ..... ☐ MCF6f1

6f2) Additional steroids ..... ☐ MCF6f2

6f3) Don't know ..... ☐ MCF6f3

6f4) Don't remember ..... ☐ MCF6f4

6g) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF6g

6h) What is the name of the medical facility? Removed from Blinded Dataset

6i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

6j) For clarification of our records, under what name is this record?

6j1) First Name: Removed from Blinded Dataset

6j2) Second Name: Removed from Blinded Dataset

6j3) Last Name: Removed from Blinded Dataset

6j4) Maternal Last Name: Removed from Blinded Dataset

6k) Were you admitted to the hospital? ..... ☐ MCF6k

If participant was admitted to hospital:

7a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF7a

7b) What is the name of the medical facility? Removed from Blinded Dataset

7c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

7d) For clarification of our records, under what name is this record?

7d1) First Name: Removed from Blinded Dataset

7d2) Second Name: Removed from Blinded Dataset

7d3) Last Name: Removed from Blinded Dataset

7d4) Maternal Last Name: Removed from Blinded Dataset

8) (do not ask) Did the participant have a third episode? (if 'No', go to 20) ..... ☐ MCF8

9) For the third episode of breathing problems you had since *(date)*:

9a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF9a

9b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF9b

9c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF9c

9d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF9d

9e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF9e

During that visit were you given (check all that apply):

9e1) An additional antibiotic ..... ☐ MCF9e1

9e2) Additional steroids ..... ☐ MCF9e2

9e3) Don't know ..... ☐ MCF9e3

9e4) Don't remember..... ☐ MCF9e4

9f) Were you evaluated in an Emergency Department? ..... ☐ MCF9f

During that visit were you given (check all that apply):

9f1) An additional antibiotic ..... ☐ MCF9f1

9f2) Additional steroids ..... ☐ MCF9f2

9f3) Don't know ..... ☐ MCF9f3

9f4) Don't remember..... ☐ MCF9f4

9g) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF9g

9h) What is the name of the medical facility? Removed from Blinded Dataset

9i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

9j) For clarification of our records, under what name is this record?

9j1) First Name: Removed from Blinded Dataset

9j2) Second Name: Removed from Blinded Dataset

9j3) Last Name: Removed from Blinded Dataset

9j4) Maternal Last Name: Removed from Blinded Dataset

9k) Were you admitted to the hospital? ..... ☐ MCF9k

If participant was admitted to hospital:

10a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF10a

10b) What is the name of the medical facility? Removed from Blinded Dataset

10c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

10d) For clarification of our records, under what name is this record?

10d1) First Name: Removed from Blinded Dataset

10d2) Second Name: Removed from Blinded Dataset

10d3) Last Name: Removed from Blinded Dataset

10d4) Maternal Last Name: Removed from Blinded Dataset

11) (do not ask) Did the participant have a fourth episode? (if 'No', go to 20) ..... ☐ MCF11

12) For the fourth episode of breathing problems you had since *(date)*:

12a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF12a

12b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF12b

12c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF12c

12d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF12d

12e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF12e

During that visit were you given (check all that apply):

12e1) An additional antibiotic ..... ☐ MCF12e1

12e2) Additional steroids ..... ☐ MCF12e2

12e3) Don't know ..... ☐ MCF12e3

12e4) Don't remember..... ☐ MCF12e4

12f) Were you evaluated in an Emergency Department? ..... ☐ MCF12f

During that visit were you given (check all that apply):

12f1) An additional antibiotic ..... ☐ MCF12f1

12f2) Additional steroids ..... ☐ MCF12f2

12f3) Don't know ..... ☐ MCF12f3

12f4) Don't remember..... ☐ MCF12f4

12g)What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF12g

12h)What is the name of the medical facility? Removed from Blinded Dataset

12i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

12j) For clarification of our records, under what name is this record?

12j1) First Name: Removed from Blinded Dataset

12j2) Second Name: Removed from Blinded Dataset

12j3) Last Name: Removed from Blinded Dataset

12j4) Maternal Last Name: Removed from Blinded Dataset

12k) Were you admitted to the hospital? ..... ☐ MCF12k

If participant was admitted to hospital:

13a) What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF13a

13b) What is the name of the medical facility? Removed from Blinded Dataset

13c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

13d) For clarification of our records, under what name is this record?

13d1) First Name: Removed from Blinded Dataset

13d2) Second Name: Removed from Blinded Dataset

13d3) Last Name: Removed from Blinded Dataset

13d4) Maternal Last Name: Removed from Blinded Dataset

14) (do not ask) Did the participant have a fifth episode? (if 'No', go to 20)..... ☐ MCF14

15) For the fifth episode of breathing problems you had since *(date)*:

15a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF15a

15b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF15b

15c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF15c

15d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF15d

15e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF15e

During that visit were you given (check all that apply):

15e1) An additional antibiotic ..... ☐ MCF15e1

15e2) Additional steroids ..... ☐ MCF15e2

15e3) Don't know ..... ☐ MCF15e3

15e4) Don't remember ..... ☐ MCF15e4

15f) Were you evaluated in an Emergency Department? ..... ☐ MCF15f

During that visit were you given (check all that apply):

15f1) An additional antibiotic ..... ☐ MCF15f1

15f2) Additional steroids ..... ☐ MCF15f2

15f3) Don't know ..... ☐ MCF15f3

15f4) Don't remember ..... ☐ MCF15f4

15g) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF15g

15h) What is the name of the medical facility? Removed from Blinded Dataset

15i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

15j) For clarification of our records, under what name is this record?

15j1) First Name: Removed from Blinded Dataset

15j2) Second Name: Removed from Blinded Dataset

15j3) Last Name: Removed from Blinded Dataset

15j4) Maternal Last Name: Removed from Blinded Dataset

15k) Were you admitted to the hospital? ..... ☐ MCF15k

If participant was admitted to hospital:

16a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF16a

16b) What is the name of the medical facility? Removed from Blinded Dataset

16c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

16d) For clarification of our records, under what name is this record?

16d1) First Name: Removed from Blinded Dataset

16d2) Second Name: Removed from Blinded Dataset

16d3) Last Name: Removed from Blinded Dataset

16d4) Maternal Last Name: Removed from Blinded Dataset

17) (do not ask) Did the participant have a sixth episode? (if 'No', go to 20) ..... ☐ MCF17

18) For the sixth episode of breathing problems you had since *(date)*:

18a) Did you take additional antibiotics after contacting your healthcare provider by telephone or email? (Y/N) ..... ☐ MCF18a

18b) Did you take additional oral steroids after contacting your healthcare provider by telephone or email? (Y/N)..... ☐ MCF18b

18c) Did you take additional antibiotics but without contacting a healthcare provider? (Y/N) ..... ☐ MCF18c

18d) Did you take additional oral steroids but without contacting a healthcare provider? (Y/N)..... ☐ MCF18d

18e) Were you evaluated in a physician's office or urgent care? (Y/N)..... ☐ MCF18e

During that visit were you given (check all that apply):

18e1) An additional antibiotic ..... ☐ MCF18e1

18e2) Additional steroids ..... ☐ MCF18e2

18e3) Don't know ..... ☐ MCF18e3

18e4) Don't remember..... ☐ MCF18e4

18f) Were you evaluated in an Emergency Department? ..... ☐ MCF18f

During that visit were you given (check all that apply):

18f1) An additional antibiotic ..... ☐ MCF18f1

18f2) Additional steroids ..... ☐ MCF18f2

18f3) Don't know ..... ☐ MCF18f3

18f4) Don't remember..... ☐ MCF18f4

18g)What was the date of this event?..... ☐☐/☐☐/☐☐☐☐ MCF18g

18h)What is the name of the medical facility? Removed from Blinded Dataset

18i) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

18j) For clarification of our records, under what name is this record?

18j1) First Name: Removed from Blinded Dataset

18j2) Second Name: Removed from Blinded Dataset

18j3) Last Name: Removed from Blinded Dataset

18j4) Maternal Last Name: Removed from Blinded Dataset

18k) Were you admitted to the hospital? ..... ☐ MCF18k

If participant was admitted to hospital:

19a) What was the date of this event?..... __ __/__ __/__ __ __ __ MCF19a

19b) What is the name of the medical facility? Removed from Blinded Dataset

19c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

19d) For clarification of our records, under what name is this record?

19d1) First Name: Removed from Blinded Dataset

19d2) Second Name: Removed from Blinded Dataset

19d3) Last Name: Removed from Blinded Dataset

19d4) Maternal Last Name: Removed from Blinded Dataset

20) Since your last (*center visit* or *telephone contact)* on *(date),* have you at any time been admitted to a hospital for any reason other than a chest flare up)? MCF20

No 0 ☐ → **Go to Item 27**
Yes 1 ☐
Unsure 9 ☐ → **Go to Item 27**

20a) How many hospitalizations have you had since *(date)*?..... ☐ MCF20a

INTERVIEWER: The next few questions are about one event. If there were more than one we would like to talk about each one separately. Let's start with the first event after your *(visit* or *teleconference)* on *(date)."*

21a) What was the date of this event? ..... __ __/__ __/__ __ __ __ MCF21a

21b) What is the name of the medical facility? Removed from Blinded Dataset

21c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

21d) For clarification of our records, under what name is this record?

21d1)First Name: Removed from Blinded Dataset

21d2) Second Name: Removed from Blinded Dataset

21d3) Last Name: Removed from Blinded Dataset

21d4) Maternal Last Name: Removed from Blinded Dataset

21e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** MCF21e
Yes 1 ☐

22a) What was the date of this event? ..... __ __/__ __/__ __ __ __ MCF22a

22b) What is the name of the medical facility? Removed from Blinded Dataset

22c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

22d) For clarification of our records, under what name is this record?

22d1)First Name: Removed from Blinded Dataset

22d2) Second Name: Removed from Blinded Dataset

22d3) Last Name: Removed from Blinded Dataset

22d4) Maternal Last Name: Removed from Blinded Dataset

22e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?
No 0 ☐ → **Go to Item 27** MCF22e
Yes 1 ☐

23a) What was the date of this event? ..... __ __/__ __/__ __ __ __ MCF23a

23b) What is the name of the medical facility? Removed from Blinded Dataset

23c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

23d) For clarification of our records, under what name is this record?

23d1)First Name: Removed from Blinded Dataset

23d2) Second Name: Removed from Blinded Dataset

23d3) Last Name: Removed from Blinded Dataset

23d4) Maternal Last Name: Removed from Blinded Dataset

23e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?
No 0 ☐ → **Go to Item 27** MCF23e
Yes 1 ☐

24a) What was the date of this event? ..... __ __/__ __/__ __ __ __ MCF24a

24b) What is the name of the medical facility? Removed from Blinded Dataset

24c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

24d) For clarification of our records, under what name is this record?

24d1)First Name: Removed from Blinded Dataset

24d2) Second Name: Removed from Blinded Dataset

24d3) Last Name: Removed from Blinded Dataset

24d4) Maternal Last Name: Removed from Blinded Dataset

24e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** MCF24e
Yes 1 ☐

25a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF25a

25b) What is the name of the medical facility? Removed from Blinded Dataset

25c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

25d) For clarification of our records, under what name is this record?

25d1) First Name: Removed from Blinded Dataset

25d2) Second Name: Removed from Blinded Dataset

25d3) Last Name: Removed from Blinded Dataset

25d4) Maternal Last Name: Removed from Blinded Dataset

25e) Were you admitted to a hospital at any other time since your last (*center visit* or *telephone contact*)?

No 0 ☐ → **Go to Item 27** MCF25e
Yes 1 ☐

26a) What was the date of this event? ..... ☐☐/☐☐/☐☐☐☐ MCF26a

26b) What is the name of the medical facility? Removed from Blinded Dataset

26c) What is the address of this medical facility? Removed from Blinded Dataset
(Leave blank if unknown)

26d) For clarification of our records, under what name is this record?

26d1)First Name: Removed from Blinded Dataset

26d2) Second Name: Removed from Blinded Dataset

26d3) Last Name: Removed from Blinded Dataset

26d4) Maternal Last Name: Removed from Blinded Dataset

INTERVIEWER: I'd now like to ask you some other questions about your health since your last (*clinic visit* or *telephone contact*) on (*date*).

Since your last (*clinic visit* or *telephone contact*) on (*date*)

27) Did your doctor put you on oxygen? (Y/N) ..... ☐ MCF27

28) Have you been listed for or received a lung transplant? (Y/N) ..... ☐ MCF28

29) Are you currently smoking cigarettes? (Y/N) ..... ☐ MCF29

30) Since your last (*clinic visit* or *telephone contact*) on (*date*), have you been diagnosed with other medical problems or been injured? (Y/ N) ..... ☐ MCF30

If answered 'Yes' to question 30

31) Were you diagnosed with:

31a) Lung cancer (Y/N) ..... ☐ MCF31a

31b) Other type of cancer (Y/N) ..... ☐ MCF31b

If so, what type? MCF31b1 _____

31c) Diabetes (Y/N) ..... ☐ MCF31c

31d) Blood Clots (Y/N) ..... ☐ MCF32

31e) Osteoporosis (Y/N) ..... ☐ MCF33

31f) Broken Hip (Y/N) ..... ☐ MCF34

31g) Heart attack or myocardial infarction (Y/N) ..... ☐ MCF35

31h) Stroke (Y/N) ..... ☐ MCF36

31i) Coronary artery disease (atherosclerosis) (Y/N) ..... ☐ MCF37

QUESTIONNAIRE FOR EASE OF COUGH AND SPUTUM CLEARANCE

| ID NUMBER: | BLINDID | | |

[Do not read]Cough Episodes: Severity on Arising and Throughout the Day

3) How severe were your cough episodes on a typical day during the past week?..... ☐ MCQ03

None: Unaware of coughing 1
Mild: Did not interfere with usual morning or daily activity 2
Moderate: Must stop activity during coughing episode.....3
Marked: Must stop activity during and for a brief period after coughing episode.....4
Severe: Stops all activity for some time and is exhausting; can be accompanied by dizziness, headache or pain 5

[Do not read]Ease of Bringing Up Sputum During the Day

4) How easy is it to cough up sputum when you cough today?..... ☐ MCQ04

None: Unaware of coughing at all.....1
Easy: Sputum comes up without difficulty after only one or two coughs.....2
Somewhat difficult: Most of the sputum comes up but only after several hard coughs.....3
Very difficult: Some sputum comes up after hard coughing but there is the feeling that most is still sticking down there.....4
Impossible: There is sputum down there but no matter how hard the coughing nothing comes up.....5

[Do not read]Chest Discomfort: Tightness and/or Congestion and Arising and Throughout the Day

5) How much chest tightness or discomfort do you have today?..... ☐ MCQ05

None: Unaware of any discomfort.....1
Mild: Noticeable now-and-then but is not bothersome and passes quickly; does not limit activity 2
Moderate: Noticeable during light activity such as walking one block or up one flight of stairs.....3
Marked: Noticeable while washing or dressing in the morning.....4
Severe: Almost constant and limits all activity; present even while resting 5

Rubin BK, Ramirez O, & Ohar JA. Iodinated glycerol has no effect on sputum properties, pulmonary function, or symptom score in patients with stable chronic bronchitis. *Chest* 1996;109;348-352

MEDICAL HISTORY FORM FOR FOLLOW-UP

| ID NUMBER: | BLINDID | | |

f)	Palpitations, irregular heartbeat MHF5F	☐	☐	MHF5F1
g)	Valve disease MHF5G	☐	☐	MHF5G1
h)	Congestive heart failure MHF5H	☐	☐	MHF5H1
i)	Blood clots MHF5I	☐	☐	MHF5I1
j)	Poor circulation (claudication) MHF5J	☐	☐	MHF5J1
k)	Other MHF5K	☐	☐	MHF5K1

6) Gastrointestinal		Yes	No	Explain
a)	Esophageal condition or disease MHF6A	☐	☐	MHF6A1
b)	Ulcers MHF6B	☐	☐	MHF6B1
c)	Hepatitis or jaundice MHF6C	☐	☐	MHF6C1
d)	Crohn's disease or colitis MHF6D	☐	☐	MHF6D1
e)	Gallstones MHF6E	☐	☐	MHF6E1
f)	Cirrhosis MHF6F	☐	☐	MHF6F1
g)	GERD (heart burn) MHF6G	☐	☐	MHF6G1
h)	Hiatal hernia MHF6H	☐	☐	MHF6H1
i)	Other MHF6I	☐	☐	MHF6I1

7) Pulmonary/vascular		Yes	No	Explain
a)	Intubation or respirator MHF7A	☐	☐	MHF7A1
b)	Pneumothorax (collapsed lung) MHF7B	☐	☐	MHF7B1
c)	Tuberculosis MHF7C	☐	☐	MHF7C1
d)	Pulmonary fibrosis MHF7D	☐	☐	MHF7D1
e)	Lung nodules MHF7E	☐	☐	MHF7E1
f)	Pulmonary embolism MHF7F	☐	☐	MHF7F1
g)	Other MHF7G	☐	☐	MHF7G1

8) Oncology/hematology		Yes	No	Explain
a)	Cancer (except basal cell skin cancer) MHF8A	☐	☐	MHF8A1
b)	Anemia MHF8B	☐	☐	MHF8B1
c)	Other MHF8C	☐	☐	MHF8C1

9) Genitourinary and reproductive		Yes	No	Explain
a)	Menstrual symptoms (women) MHF9A	☐	☐	MHF9A1
b)	Enlarged prostate or BPH (men) MHF9B	☐	☐	MHF9B1

c)	Bladder or kidney problems/ kidney stones MHF9C	☐	☐	MHF9C1
d)	Other MHF9D	☐	☐	MHF9D1

10) Endocrine	Yes	No	Explain
a) Diabetes MHF10A	☐	☐	MHF10A1
b) Thyroid MHF10B	☐	☐	MHF10B1
c) Other MHF10C	☐	☐	MHF10C1

11) Neurology	Yes	No	Explain
a) Stroke MHF11A	☐	☐	MHF11A1
b) Headaches MHF11B	☐	☐	MHF11B1
c) Seizure MHF11C	☐	☐	MHF11C1
d) Other MHF11D	☐	☐	MHF11D1

12) Muscular/skeletal	Yes	No	Explain
a) Rheumatoid arthritis MHF12A		☐	MHF12A1
b) Gout MHF12B	☐	☐	MHF12B1
c) Osteoporosis MHF12C	☐	☐	MHF12C1
d) Fractures MHF12D	☐	☐	MHF12D1
e) Joint pain MHF12E	☐	☐	MHF12E1
f) Osteoarthritis MHF12F	☐	☐	MHF12F1
g) Other MHF12G	☐	☐	MHF12G1

13) Dermatology	Yes	No	Explain
a) Rashes/hives/eczema MHF13A		☐	MHF13A1
b) Psoriasis MHF13B	☐	☐	MHF13B1
c) Shingles MHF13C	☐	☐	MHF13C1
d) Other MHF13D	☐	☐	MHF13D1

14) Infectious disease	Yes	No	Explain
a) Atypical mycobacteria (MAC, MAI) MHF14A	☐	☐	MHF14A1
b) Fungal disease MHF14B	☐	☐	MHF14B1
c) Other MHF14C	☐	☐	MHF14C1

15) Psychiatric	Yes	No	Explain
a) Anxiety MHF15A	☐	☐	MHF15A1
b) Depression MHF15B	☐	☐	MHF15B1
c) Other MHF15C	☐	☐	MHF15C1

16) Other significant problems not reported in questions 2-18 Yes ☐ MHF16 No ☐

a) MHF16A _____
b) MHF16B _____
c) MHF16C _____
d) MHF16D _____
e) MHF16E _____

These next questions refer to recent illnesses or problems you may have had.

In the last two weeks have you had any of the following:

17) A fever, cold, flu, or sore throat? (Y/N) ..... ☐ MHF17

18) A urinary tract infection? (Y/N) ..... ☐ MHF18

19) Seasonal allergies? (Y/N)..... ☐ MHF19

20) A sinus infection or sinusitis? (Y/N) ..... ☐ MHF20

21) A tooth infection? (Y/N) ..... ☐ MHF21

22) A flare up of gout? (Y/N)..... ☐ MHF22

23) A flare up of arthritis? (Y/N)..... ☐ MHF23

24) Other? (Y/N)..... ☐ MHF24

25) Please explain: MHF25 _____

26) Are you allergic to any medications, latex, food, or substances? (Y/N)..... ☐ MHF26

If **YES**:

List substance:	Reaction
a) MHF26A	MHF26A1
b) MHF26B	MHF26B1
c) MHF26C	MHF26C1
d) MHF26D	MHF26D1
e) MHF26E	MHF26E1

27) In the past 12 months, how often have you consumed any alcohol containing beverage (beer, wine, wine coolers, liquor, or mixed drinks such as margaritas, martinis, or daiquiris)? *(check only one)* MHF27

- Every Day ..... ☐
- 4 to 6 days per week ..... ☐
- 2 to 3 days per week ..... ☐
- Once per week ..... ☐
- 1 to 3 times per month ..... ☐
- Less than once per month ..... ☐
- No alcohol in the past 12 months ..... ☐ →**Go to 34**

28) When you drink alcohol containing beverages, how many do you usually drink at one sitting? *(check only one)* MHF28

- 1 or 2 ..... ☐
- 3 or 4 ..... ☐
- 5 or 6 ..... ☐
- More than 6 ..... ☐

29) What kind of alcoholic beverages do you usually drink? *(check all that apply)*

- Beer ..... ☐ MHF29A
- Wine ..... ☐ MHF29B
- Drinks containing liquor ..... ☐ MHF29C

30) How often do you have eight or more drinks on one occasion? MHF30

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

31) How often during the last year have you been unable to remember what happened the night before because you had been drinking? MHF31

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

32) How often during the last year have you failed to do what was normally expected of you because of your drinking? MHF32

- Never ..... ☐
- Less than monthly ..... ☐
- Monthly ..... ☐
- Weekly ..... ☐
- Daily or almost daily ..... ☐

33) Has a relative or friend, a doctor or other health worker been concerned about your drinking or suggested you cut down? MHF33

- No ..... ☐
- Yes, but not in the last year ..... ☐
- Yes in the last year ..... ☐

If participant is MALE, skip to 46
If participant is FEMALE, continue

34) Have you reached menopause? ..... ☐ MHF34

- Yes ..... Y
- No ..... N → **Go to 36**
- I don't know ..... U → **Go to 36**

35) If you have reached menopause, at what age did that occur? ..... ☐☐ yrs old MHF35

36) Did you ever use oral contraceptive medications? ..... ☐ MHF36

- Yes ..... Y
- No ..... N → **Go to 38**

37) If you did use oral contraceptives, for how many years? ..... ☐☐ years MHF37

38) Did you ever use hormone replacement therapy? ..... ☐ MHF38

- Yes ..... Y
- No ..... N → **Go to 40**

39) If you did use hormone replacement therapy, for how many years? ..... ☐☐ years MHF39

40) In the last 12-months have you been pregnant? ..... ☐☐ MHF40

41) In the last 12-months did you ever breastfeed? ..... ☐ MHF41

- Yes ..... Y
- No ..... N → **Go to 43**

42) If you did breastfeed, for approximately how many total months did you breastfeed *(total for all pregnancies)*? ..... [ ][ ] months MHF42

43) In the last 12 months have you ever had an ovary removed? ..... [ ] MHF43

Yes ..... Y
No ..... N → **Go to 46**

44) If you had an ovary removed, was one removed or both? ..... [ ] MHF44

One ..... O
Both ..... B

45) At what age was your ovary or ovaries removed? ..... [ ][ ] yrs old MHF45

46) Were you born premature? ..... [ ] MHF46

Yes ..... Y
No ..... N → **Go to 47**
Don't Know ..... D → **Go to 47**

46a) If yes, how many weeks were you premature? ..... [ ][ ] weeks MHF46A

47) What was your birth weight? ..... MHF47A [ ][ ] pounds MHF47B [ ][ ] ounces

48) Did you ever have breathing problems during the first two years of life? ..... [ ] MHF48

Yes ..... Y
No ..... N → **Go to 49**
Don't Know ..... D → **Go to 49**

48a) If yes, were you ever hospitalized for these problems? ..... [ ] MHF48A

Yes ..... Y
No ..... N
Don't Know ..... D

49) Were you ever hospitalized for pneumonia before 18 years of age? ..... [ ] MHF49

Yes ..... Y
No ..... N
Don't Know ..... D

SPIROMICS MYOCARDIAL INFARCTION ABSTRACTION FORM (MIF)

ID NUMBER:	SUBJID	FORM CODE: MIF VERSION: A 2/12/2015	Visit Number	VISIT	SEQ #

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ MIF0A
Month/Day/Year

0b. Staff ID: ☐☐☐ MIF0B

0c.Event ID: ☐☐☐☐☐☐☐☐☐☐ MIF0C

0d. Event Date: ☐☐/☐☐/☐☐☐☐ MIF0D

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received or classified as unobtainable as indicated on the Medical Record Shipping Form.

A. GENERAL INFORMATION

1. Was the event (choose one): ☐ MIF1
   1= In hospital only 2= Emergency Dept. visit only(ED) 3= Both ED and in hospital

2. Date of arrival: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ MIF2

   a. Date of admission ☐☐/☐☐/☐☐☐☐ MIF2A

3. Date of discharge:(mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ MIF3

4. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐ MIF4

5. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐ MIF5

	Yes	No/NR	
6. Did an emergency medical service unit transport the patient to this hospital?	☐	☐	MIF6
7. Was the patient transferred to this hospital from another hospital?	☐	☐	MIF7
8. Was the patient's code status ever "no-code" or "DNR" (do not resuscitate)?	☐	☐	MIF8
9. Was the patient alive at discharge? ***(If Yes, skip to 10)***	☐	☐	MIF9

   a. Was the patient dead on arrival? Yes ☐ No ☐ MIF9A

   b. Did the patient die in the Emergency Department? Yes ☐ No ☐ MIF9B

   c. Was an autopsy performed? Yes ☐ No ☐ MIF9C

B. PRESENTING SIGNS AND SYMPTOMS

		Yes	No	NR (Not recorded)
10. Did the onset of the acute episode occur prior to admission?	MIF10	☐	☐	☐

a. If Yes, estimate the time from onset of symptoms of acute condition to arrival at the hospital: MIF10A

< 1hr ☐ ≥ 1- < 3 hrs ☐ ≥ 3 - < 6 hrs ☐ Unsure ☐

≥ 6 - < 12 hrs ☐ ≥ 12 - < 24 hrs ☐ ≥ 24 hrs ☐

		Yes	No	NR	
11. Was there mention of an acute CHD event with onset after arrival at the hospital?		☐	☐	☐	MIF11
12. Was there an acute episode(s) of pain or discomfort (eg: tightness) anywhere in the chest, arm, shoulder throat or jaw, either within 72 hours prior to arrival to the hospital, or in conjunction with the in-hospital CHD event? ***(If No or NR, skip to 13)***		☐	☐	☐	MIF12
a. Did this pain or discomfort specifically involve the chest?		☐	☐	☐	MIF12A
b. Did the pain get worse (crescendo) over time?		☐	☐	☐	MIF12B
c. Was the pain or discomfort diagnosed as having a non-cardiac origin?		☐	☐	☐	MIF12C
13. Was there nausea or vomiting associated with this event?		☐	☐	☐	MIF13
14. Was there diaphoresis associated with this event?		☐	☐	☐	MIF14
15. Was there fatigue or malaise associated with this event?		☐	☐	☐	

16. Vital Signs at arrival (or event onset) and not during CPR

a. Blood pressure ☐☐☐/☐☐☐ mmHg MIF16A

b. Heart rate ☐☐☐ bpm MIF16B

C. MEDICAL HISTORY

17. Prior to this event was there history of any of the following:		Yes	No/NR
a. Myocardial infarction ***(If No or NR, skip to 17b)***	MIF17A	☐	☐
a1. If history of MI, then MI within 4 weeks of this event?	MIF17A1	☐	☐
b. Angina	MIF17B	☐	☐
c. Percutaneous coronary intervention (PCI)	MIF17C	☐	☐
d. CABG	MIF17D	☐	☐
e. Coronary artery disease (CAD)	MIF17E	☐	☐
f. Heart failure	MIF17F	☐	☐
g. Arrhythmia	MIF17G	☐	☐

If Yes, specify type of arrhythmia

g1 Arial Fibrillation/Flutter MIF17G1 ☐ ☐

g2 Ventricular Fibrillation/Tachycardia MIF17G2 ☐ ☐

g3 Other arrhythmia MIF17G3 ☐ ☐

D. ACTIVE OR CURRENT MEDICAL PROBLEMS (DURING THIS HOSPITALIZATION)

18. Did a physician indicate any of these as being present during the hospitalization?

	Yes	No	
a. Angina	☐	☐	MIF18A
b. Acute myocardial Infarction	☐	☐	MIF18B
c. ST elevation > 1mm with pain that is not present on ECG without pain	☐	☐	MIF18C
d. Congestive heart failure exacerbation or pulmonary edema	☐	☐	MIF18D
e. Shock or cardiogenic shock	☐	☐	MIF18E
f. Ventricular fibrillation, cardiac arrest or asystole	☐	☐	MIF18F
g. Ventricular Tachycardia	☐	☐	MIF18G
h. Atrial fibrillation or atrial flutter	☐	☐	MIF18H

E. BIOMARKERS

19. Were cardiac enzymes reported within days 1-4 after arrival at the hospital or after the in-hospital CHD event? ***(If No/NR skip to 32)*** Yes ☐ No/NR ☐ MIF19

Biomarker Laboratory Standards:

Units: 1= ng/mL 2 = Units/L 3 = µg/L

20. Normal Lab Value Ranges ***(this facility)***

	Upper limit of normal	Units*
a. Total CK (CPK)	a1. ☐☐☐☐☐ MIF20A1	a2. ☐ MIF20A2
b. CK-MB	b1. ☐☐☐.☐☐ MIF20B1	b2. ☐ MIF20B2
c. Troponin	c1. ☐☐☐.☐☐ MIF20C1	c2. ☐ MIF20C2

c3. What type of Troponin was this? ☐ MIF20C3

1= Troponin, type not specified
2= Troponin I
3= Troponin T
4= High Sensitivity Troponin (HS)
5= Unsure

ID NUMBER:								

FORM CODE: MIF
VERSION: A 2/12/2015

Contact Occasion ☐☐ SEQ # ☐☐☐

Daily Biomarkers Measurements:

Note: *When a value is recorded using words rather than numerals, use the following codes to record the value:* ***absent/negative/normal = 1, trace/weak positive = 2, present/positive/abnormal = 3***

Note: *If more than two sets in one event day, pick the two with the highest Troponin values*

21. Event Day 1/Set 1 Date: ☐☐/☐☐/☐☐☐☐ MIF21

			Units* (see pg. 3)	Words Code*	
a. Total CK/CPK		☐☐☐☐ MIF21A0	a1. MIF21A1	a2. ☐	MIF21A2
b. CK-MB		☐☐☐.☐ MIF21B0	b1. MIF21B1	b2. ☐	MIF21B2
c. Troponin	MIF21C <	☐☐☐.☐ MIF21C0	c1. MIF21C1	c2. ☐	MIF21C2

c3. What type of Troponin was this? ☐ MIF21C3

1= Troponin, type not specified
2= Troponin I
3= Troponin T
4= High Sensitivity Troponin (HS)
5= Unsure

22. Event Day 1/Set 2 Date: ☐☐/☐☐/☐☐☐☐ MIF22

			Units* (see pg. 3)	Words Code*	
a. Total CK/CPK		☐☐☐☐ MIF22A0	a1. MIF22A1	a2. ☐	MIF22A2
b. CK-MB		☐☐☐.☐ MIF22B0	b1. MIF22B1	b2. ☐	MIF22B2
c. Troponin	MIF22C <	☐☐☐.☐ MIF22C0	c1. MIF22C1	c2. ☐	MIF22C2

c3. What type of Troponin was this? ☐ MIF22C3

1= Troponin, type not specified
2= Troponin I
3= Troponin T
4= High Sensitivity Troponin (HS)
5= Unsure

23. Event Day 2/Set 1 Date: ☐☐/☐☐/☐☐☐☐ MIF23

			Units* (see pg. 3)	Words Code*	
a. Total CK/CPK		☐☐☐☐ MIF23A0	a1. MIF23A1	a2. ☐	MIF23A2
b. CK-MB		☐☐☐.☐ MIF23B0	b1. MIF23B1	b2. ☐	MIF23B2
c. Troponin	MIF23C <	☐☐☐.☐ MIF23C0	c1. MIF23C1	c2. ☐	MIF23C2

c3. What type of Troponin was this? ☐ MIF23C3

1= Troponin, type not specified
2= Troponin I
3= Troponin T
4= High Sensitivity Troponin (HS)
5= Unsure

24. Event Day 2/Set 2 Date: ☐☐/☐☐/☐☐☐☐ MIF24

			Units* (see pg. 3)	Words Code*	
a. Total CK/CPK		☐☐☐☐ MIF24A0	a1. MIF24A1	a2. ☐	MIF24A2
b. CK-MB		☐☐☐.☐ MIF24B0	b1. MIF24B1	b2. ☐	MIF24B2
c. Troponin	MIF24C <	☐☐☐.☐ MIF24C0	c1. MIF24C1	c2. ☐	MIF24C2

c3. What type of Troponin was this? ☐ MIF24C3

1= Troponin, type not specified
2= Troponin I
3= Troponin T
4= High Sensitivity Troponin (HS)
5= Unsure

25. Is there mention of the patient having had a trauma, a surgical procedure, or rhabdomyolysis within one week prior to measurement of biomarkers? ☐Yes ☐No/NR MIF25
(*If No/NR, skip to 26*)

If Yes, Indicate the type of procedure or trauma:

	Yes	No	Date	
a. Cardiac procedure MIF25A	☐	☐	☐☐/☐☐/☐☐☐☐	MIF25A1
b. CPR or cardioversion MIF25B	☐	☐	☐☐/☐☐/☐☐☐☐	MIF25B1
c. Other cardiac trauma MIF25C	☐	☐	☐☐/☐☐/☐☐☐☐ MIF25C1	c2. Specify: MIF25C2
d. Rhabdomyolysis MIF25D	☐	☐	☐☐/☐☐/☐☐☐☐	MIF25D1
e. Intramuscular Injection MIF25E	☐	☐	☐☐/☐☐/☐☐☐☐	MIF25E1
f. Non-cardiac procedure MIF25F	☐	☐	☐☐/☐☐/☐☐☐☐ MIF25F1	f2. Specify: MIF25F2
g. Non-cardiac trauma MIF25G	☐	☐	☐☐/☐☐/☐☐☐☐	MIF25G1

26. Enter the item number from the biomarkers section (items 21-24) of this form which corresponds to the first biomarker measurement performed after the trauma, cardiac procedure or rhabdomyolysis: ☐☐ MIF26

27. Is there evidence of hemolytic disease during the hospitalization? ☐Yes ☐No/NR MIF27

28. Did participant have active liver disease (cirrhosis, hepatitis, liver cancer, etc.)? ☐Yes ☐No/NR MIF28

F. Procedures and Diagnostics

Were any of the following special procedures or operations performed during this hospitalization?
(Mark all that apply)

	Yes	No	
29. Were any 12 lead ECGs taken during this admission?	☐	☐	MIF29
30. Transthoracic echocardiogram (TTE) performed? (*If No/NR, skip to 31*)	☐	☐	MIF30
a. LV Ejection fraction: ☐☐%			MIF30A
31. Was a Nuclear Medicare Scan (MUGA, SPECT or radionuclide ventriculogram (RVG)) performed? (*If No/NR, skip to 32*)	☐	☐	MIF31
a. Ejection fraction: LV: ☐☐% MIF31A b. RV: ☐☐% MIF31B			
c. Stress test positive for ischemia	☐	☐	MIF31C

32. Was any stress test (treadmill, pharmacologic, or nuclear medicine) performed during this admission: ***(If No/NR, skip to 33)*** ☐ ☐ MIF32

a. Ejection fraction: LV: ☐☐% MIF32A

b. Stress test positive for ischemia ☐ ☐ MIF32B

c. Greater than or equal to 1mm ST depression or elevation ☐ ☐ MIF32C

d. Ischemic pain or equivalent occurred ☐ ☐ MIF32D

33. Was a coronary angiography performed? ***(If No/NR, skip to 34)*** ☐ ☐ MIF33

a. Date: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ MIF33A

b. Ejection fraction: LV: ☐☐% MIF33B

	Yes	No	NR	
c. 70% or greater obstruction of any coronary artery	☐	☐	☐	MIF33C
d. Were coronary bypass grafts present?	☐	☐	☐	MIF33D

d1. If yes, number of occluded grafts: ☐☐ MIF33D1

G. Treatment

	Yes	No/NR	
34. Was coronary reperfusion (CABG, PCI, thrombolysis) attempted? ***(If No/NR, skip to 40)***	☐	☐	MIF34

a. If yes, what was the approximate time from event onset to reperfusion? MIF34A

☐ < 2 hours ☐ 2 - <4 hours ☐ 4 - <6 hours ☐ 6 - <12 hours

☐ 12 - <24 hours ☐ 24+ hours ☐ not sure

35. Where any of the following treatments given during this hospitalization?

	Yes	No	
a. Coronary artery bypass graft surgery (CABG)	☐	☐	MIF35A
a1. If yes, Date: ☐☐/☐☐ ☐☐☐☐			MIF35A1
b. Coronary atherectomy	☐	☐	MIF35B
b1. If yes, Date: ☐☐/☐☐ ☐☐☐☐			MIF35B1
c. Intra-arterial or intravenous thrombolytic	☐	☐	MIF35C
c1. If yes, Date: ☐☐/☐☐ ☐☐☐☐			MIF35C1
d. Coronary angioplasty without stent	☐	☐	MIF35D
d1. If yes, Date: ☐☐/☐☐ ☐☐☐☐			MIF35D1

e. Coronary angioplasty with stent placement ☐ ☐ MIF35E

e1. If yes, Date: ☐☐/☐☐ ☐☐☐☐ MIF35E1

f. Valve surgery ☐ ☐ MIF35F

g. Non-cardiac surgery ☐ ☐ MIF35G

h. Aortic balloon pump ☐ ☐ MIF35H

i. Pacemaker placement (temporary or permanent) ☐ ☐ MIF35I

j. Cardioversion or defibrillation ☐ ☐ MIF35J

j1. If yes, Date: ☐☐/☐☐ ☐☐☐☐ MIF35J1

j2. If cardioversion took place after arrival at the hospital, what rhythm(s) were present prior to cardioversion?

		Yes	No
a.	Ventricular Fibrillation/Flutter (Yes/no) MIF35J2A		
b.	Ventricular Tachycardia (VT)	☐	☐ MIF35J2B
c.	Asystole	☐	☐ MIF35J2C
d.	Complete AV Block (3 HB)	☐	☐ MIF35J2D
e.	Atrial Fibrillation/Flutter	☐	☐ MIF35J2E
f.	Pulseless Electrical Activity (PEA)	☐	☐ MIF35J2F

36. During the hospitalization or at discharge, did the participant receive any of the following medications?

	Admission Meds Yes	Admission Meds No/NR	Discharge Meds Yes	Discharge Meds No/NR
a. Nitroglycerin	☐	☐ MIF36A	☐	☐ MIF36A1
b. Beta Blockers	☐	☐ MIF36B	☐	☐ MIF36B1
c. Calcium Channel Blockers	☐	☐ MIF36C	☐	☐ MIF36C1
d. ACE Inhibitor or ARB	☐	☐ MIF36D	☐	☐ MIF36D1
e. Scheduled aspirin (not PRN)	☐	☐ MIF36E	☐	☐ MIF36E1
f. Heparin or Enoxaparin	☐	☐ MIF36F	☐	☐ MIF36F1
g. Coumadin, warafin, dicumarol	☐	☐ MIF36G	☐	☐ MIF36G1
h. Anti-platelet agents (non-aspirin)	☐	☐ MIF36H	☐	☐ MIF36H1
i. Statin	☐	☐ MIF36I	☐	☐ MIF36I1

37. During this hospitalization was this patient treated with:

	Yes	No/NR
a. IV pressors	☐	☐ MIF37A
b. IV nitroglycerin	☐	☐ MIF37B
c. IIb / IIIa inhibitors or thrombin inhibitors	☐	☐ MIF37C

MODIFIED MEDICAL RESEARCH COUNCIL DYSPNEA SCALE

| ID NUMBER: | BLINDID | | |

PULMONARY FUNCTION ELIGIBILITY FORM

ID NUMBER:	BLINDID	FORM CODE: PFT VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date..... __ __ / __ __ / __ __ __ __ PFT0A 0b) Initials ..... __ __ __

> ***Instructions:*** *This form should be completed prior to conducting pulmonary function testing. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.*

1) Have you eaten a large meal with the last 2 hours?..... ☐ PFT01
   - Yes ..... Y→**If yes, wait a minimum of 15 minutes prior to PFTs**
   - No..... N

2) Have you smoked within the last hour? ..... ☐ PFT02
   - Yes ..... Y→**If yes, wait a minimum of 15 minutes prior to PFTs**
   - No..... N

3) Have you participated in any vigorous exercise in the past 30 minutes? ..... ☐ PFT03
   - Yes ..... Y→**If yes, wait a minimum of 15 minutes prior to PFTs**
   - No..... N

4) Have you consumed any alcoholic beverages within the past 4 hours? ..... ☐ PFT04
   - Yes ..... Y→**If yes, wait to perform eCO but must be before DLCO (if performed)**
   - No..... N

5) Have you taken any inhaled or oral medication for your lungs in the past 48 hours? ..... ☐ PFT05
   - Yes ..... Y
   - No..... N →**Go to item 12**

6) Have you used tiotropium (Spiriva) within in the past 48 hours? ..... ☐ PFT06
   - Yes ..... Y
   - No..... N →**Go to item 7**

6a) Date PFT06A __ __ / __ __ __ __ time PFT06B __ __ AM/PM *(circle one)* PFT06B_AMPM

7) Have you used theophylline (Theo 24, Uniphyl, Theochron) within past 48 hrs? ..... ☐ PFT07
   - Yes ..... Y
   - No..... N →**Go to item 8**

7a) What is the most recent type of theophyline you have used?:..... ☐ PFT07A
   1) a once-a-day preparation (Theo 24, Uniphyl)

2) an extended release preparation (Theochron, generic SR)
3) an immediate release preparation (Elixophyllin, Theolair)

7b) Date PFT07B __ __/__ __ __ __ time PFT07C __ __ AM/PM *(circle one)* PFT07C_AMPM

8) Have you used another once-a-day bronchodilator within in the past 48 hours? ..... ☐ PFT08
Yes ..... Y
No..... N →**Go to item 9**

8a) Date PFT08A __ __/__ __ __ __ time PFT08B __ __ AM/PM *(circle one)* PFT06B_AMPM
8b) Name: PFT08B1 _____

9) Have you used any long-acting (12-hour) beta agonist within in the past 24 hours? ..... ☐ PFT09
Yes ..... Y
No..... N →**Go to item10**

9a) What is the most recent long acting beta agonist you have used?:..... ☐ PFT09A
1) Albuterol sustained release tab. (VoSpire ER):
2) Arformoterol (Brovana):
3) Formoterol (Dulera, Foradil, Perforomist, Symbicort):
4) Salmeterol (Advair Diskus, Advair HFA, Serevent Diskus)
5) Other 12 hour beta agonist: Name: PFT09A1 _____

9b) Time PFT09B __ __ AM/PM *(circle one)* PFT09B_AMPM

10) Have you used ipratropium within the past 8 hours?..... ☐ PFT10
Yes ..... Y
No..... N →**Go to item 11**

10a) What is the most recent ipratropium or ipratropium/albuterol combination have you used? ☐ PFT10A
1) Ipratropium (Atrovent, generic ipratropium nebulizer solution)
2) Ipratropium/albuterol combination (Combivent, Duoneb, generic nebulizer solution)

10b) Time PFT10B __ __ AM/PM *(circle one)* PFT10C_AMPM

If <300 minutes since last ipratropium dose, see partial dosing instruction in the PFT MOP.

11) Have you used any short-acting beta agonist within in the past 6 hours? ..... ☐ PFT11

Yes ..... Y

No..... N → **Go to item 12**

11a) What is the most recent short-acting beta agonist have you used?..... ☐ PFT11A

1) Albuterol (ProAir HFA, Proventil HFA, Ventolin HFA, Acuneb, generic solution, non-sustained release oral tablets)
2) Epinephrine (Epipen, Twinject, S2, generic)
3) Levalbuterol (Xopenex HFA, Xopenex solution, generic solution)
4) Metaproterenol (generic solution, syrup, non-sustained release tablets)
5) Pirbuterol (Maxair)
6) Terbutaline (generic tablets)
7) Other short-acting beta agonist: Name PFT11A7A _____

11b) Time PFT11B ☐ AM/PM *(circle one)* PFT11B_AMPM

If <165 minutes since last short-acting beta agonist dose, see partial dosing instructions in PFT MOP.

12) Have you had more then 18 oz. of coffee (or equivalent caffeine, 200 mg), in the past 6 hours? ☐ PFT12

Yes ..... Y

No..... N

200 mg= (roughly):18 oz of coffee, 4 shots of expresso, 40 oz of tea, 60 oz of a cola soft drink, 16 oz of energy drink

PHYSICIAN QUESTIONNAIRE

ID NUMBER:	SUBJID	FORM CODE: PQE VERSION: 1.0 01/21/2015	Visit Number	VISIT	SEQ #

ADMINISTRATIVE INFORMATION

0a. Completion Date: __ __/__ __/__ __ __ __ PQE0A 0b. Code: __ __ __ PQE0B

DETAILS OF DEATH

1. Are you familiar with the events surrounding the decedent's death? (Y/N) ..... ☐ PQE1

2. Did you witness the death? (Y/N) ..... ☐ PQE2

If you answered "Yes" *to one or both of Items 1 and 2, please skip to Item 4.*

3. If you answered "No" to both Questions, are you aware of another physician who could provide information regarding the death? ..... ☐ PQE3

   No..... N Please sign and date the bottom of this form
   Yes ..... Y

   3a. Provide contact information. Please then sign and date the bottom of this form.

   Name of physician: Removed from Blinded Dataset _____

   Address: _____

   _____

   _____

CIRCUMSTANCES SURROUNDING DEATH

4. What do you believe to be the underlying cause of death? Please select one of the following categories: Respiratory, Cardiovascular, Cancer, Other Known, or Unknown.

(Select only one). ..... ☐ PQE4

Respiratory ..... 1 → Go to 4a
Cardiovascular ..... 2 → Go to 4b
Cancer ..... 3 → Go to 4c
Other, Known ..... 4 → Go to 4d
Unknown…….. 5 → Go to 4e

4a. Respiratory (select only one)? ..... ☐ PQE4A

COPD Exacerbation with pneumonia..... 1
COPD Exacerbation without pneumonia..... 2
COPD without exacerbation……3
Other respiratory 4

Specify:_____ PQE4A1

4b. Cardiovascular (select only one)?..... ☐ PQE4B

Myocardial infarction…….. 1
Heart failure…….. 2
Stroke/aneurysm……3
DVT/PE……4
Other heart problem 5

Specify:_____ PQE4B1

4b1. Type of Cardiovascular death (select only one)?..... ☐ PQE4B2

a. "Sudden Death," defined as death that occurs within 24 hours of being observed alive and without evidence of a deteriorating medical condition)…... 1

b. "Sudden Cardiac Death," defined as death that occurs within 1 hour of being observed alive and without evidence of a deteriorating medical condition……. 2

c. Neither of the above……3

4c. Cancer (select only one)? ..... ☐ PQE4C

Lung 1
Other cancer 2

Specify:_____ PQE4C1

4d. Other, Known

Specify:_____ PQE4D

4e. Reason for Unknown cause of death (select only one)?.....…….. ☐ PQE4E

Information is inadequate..... ……..1
Indeterminate (information available but cause unclear)…….....2

5. Do you believe that a diagnosis of COPD contributed to the death of this individual?..... ☐ PQE5

Yes ……...…..1
No ……..……..2

Comments:

Removed from Blinded Dataset

_____

_____

6. Did you see the participant within one month of death? ..... ☐ PQE6

No……N Please skip to Question 8
Yes……..Y

7. If yes, please fill out the following for the most recent visit:

7a. Date of visit: ☐☐/ ☐☐/ ☐☐☐☐ PQE7A
Month day year

7b. Chief Complaint: _____ PQE7B

_____

7c. Primary Diagnosis: _____ PQE7C

_____

7d. Changes in Medical Management: _____ PQE7D

_____

_____

8. Is there any other pertinent information that you think would help us determine the circumstances and underlying conditions that may have contributed to this individual's death in addition to determining the ultimate cause of death?

Removed from Blinded Dataset

_____

_____

_____

Form completed by: Removed from Blinded Dataset _____ Date: PQE10 _____

PITTSBURGH SLEEP QUALITY INDEX

ID NUMBER:	BLINDID	FORM CODE: **PSQ** VERSION: **1.1** 7/12/11	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ PSQ0A 0b) Initials..... ☐☐☐

> ***Instructions:*** *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Answer all questions.*

The following questions relate to your usual sleep habits during the past month *only.* Your answers should indicate the most accurate reply for the *majority* of days and nights in the past month. Please answer all questions.

1) During the past month, when have you usually gone to bed at night?

   PSQ01 ☐☐:☐☐ AM / PM *(circle one)* PSQ01_AMPM

2) During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   ☐☐☐ minutes PSQ02

3) During the past month, when have you usually gotten up in the morning?

   PSQ03 ☐☐:☐☐ AM / PM *(circle one)* PSQ03_AMPM

4) During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

   ☐☐ hours PSQ04

For each of the remaining questions, choose the one best response. Please answer *all* questions.

5) During the past month, how often have you had trouble sleeping because you:

   a) Cannot get to sleep within 30 minutes ..... ☐ PSQ05A

      Not during the past month .....A
      Less than once a week .....B
      Once or twice a week C
      Three or more times a week.....D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

b) Wake up in the middle of the night or early morning ..... ☐ PSQ05B

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

c) Have to get up to use the bathroom ..... ☐ PSQ05C

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

d) Cannot breathe comfortably ..... ☐ PSQ05D

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

e) Cough or snore loudly ..... ☐ PSQ05E

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

f) Feel too cold ..... ☐ PSQ05F

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

g) Feel too hot ..... ☐ PSQ05G

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

h) Had bad dreams ..... ☐ PSQ05H

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

i) Had pain PSQ05I

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

j) Other reason(s), please describe PSQ05J1 _____

_____

How often during the past month have you had trouble sleeping because of this? PSQ05J

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

6) During the past month, how would you rate your sleep quality overall? PSQ06

Very good ..... A
Fairly good ..... B
Fairly bad C
Very bad ..... D

7) During the past month, how often have you take medicine (prescribed or over-the-counter) to help you sleep? PSAQ7

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

8) During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? PSAQ8

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

9) During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done? ..... ☐ PSAQ9

No problem at all ..... A
Only a very slight problem ..... B
Somewhat of a problem C
A very big problem ..... D

10) Do you have a bed partner or roommate? ..... ☐ PSQ10

No bed partner or roommate ..... A → **End**
Partner/roommate in other room ..... B
Partner in same room, but not same bed C
Partner in same bed ..... D

If you have a roommate or bed partner, ask him/her how often in the past month you have had:

a) Loud Snoring ..... ☐ PSQ10A

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

b) Long pauses between breaths while asleep ..... ☐ PSQ10B

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

c) Legs twitching or jerking while you sleep ..... ☐ PSQ10C

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

d) Episodes of disorientation of confusion during sleep ..... ☐ PSQ10D

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

e) Other restlessness while you sleep; please describe: PSQ10E1 _____

_____

_____ ..... ☐ PSQ10E

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

PITTSBURGH SLEEP QUALITY INDEX

ID NUMBER:	BLINDID	FORM CODE: PSQ VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ PSQ0A 0b) Initials..... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Answer all questions.*

The following questions relate to your usual sleep habits during the past month *only.* Your answers should indicate the most accurate reply for the *majority* of days and nights in the past month. Please answer all questions.

1) During the past month, when have you usually gone to bed at night?

PSQ01 ☐☐:☐☐ AM / PM *(circle one)* PSQ01_AMPM

2) During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

☐☐☐ minutes PSQ02

3) During the past month, when have you usually gotten up in the morning?

PSQ03 ☐☐:☐☐ AM / PM *(circle one)* PSQ03_AMPM

4) During the past month, how many hours of *actual sleep* did you get at night? (This may be different than the number of hours you spend in bed.)

☐☐ hours PSQ04

For each of the remaining questions, choose the one best response. Please answer *all* questions.

5) During the past month, how often have you had trouble sleeping because you:

a) Cannot get to sleep within 30 minutes ..... ☐ PSQ05A

Not during the past month .....A
Less than once a week .....B
Once or twice a week.....C
Three or more times a week.....D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

b) Wake up in the middle of the night or early morning ..... ☐ PSQ05B

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

c) Have to get up to use the bathroom ..... ☐ PSQ05C

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

d) Cannot breathe comfortably..... ☐ PSQ05D

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

e) Cough or snore loudly..... ☐ PSQ05E

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

f) Feel too cold ..... ☐ PSQ05F

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

g) Feel too hot..... ☐ PSQ05G

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

h) Had bad dreams ..... ☐ PSQ05H

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

i) Had pain PSQ05I

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

j) Other reason(s), please describe PSQ05J1 _____

_____

How often during the past month have you had trouble sleeping because of this? PSQ05J

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

6) During the past month, how would you rate your sleep quality overall? PSQ06

Very good ..... A
Fairly good ..... B
Fairly bad C
Very bad ..... D

7) During the past month, how often have you take medicine (prescribed or over-the-counter) to help you sleep? PSAQ7

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

8) During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity? PSAQ8

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

9) During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done? ..... ☐ PSAQ9

No problem at all ..... A
Only a very slight problem ..... B
Somewhat of a problem C
A very big problem ..... D

10) Do you have a bed partner or roommate? ..... ☐ PSQ10

No bed partner or roommate ..... A → **End**
Partner/roommate in other room ..... B
Partner in same room, but not same bed C
Partner in same bed ..... D

If you have a roommate of bed partner, as him/her how often in the past month you have had:

a) Loud Snoring ..... ☐ PSQ10A

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

b) Long pauses between breaths while asleep ..... ☐ PSQ10B

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

c) Legs twitching or jerking while you sleep ..... ☐ PSQ10C

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

d) Episodes of disorientation of confusion during sleep ..... ☐ PSQ10D

Not during the past month ..... A
Less than once a week ..... B
Once or twice a week C
Three or more times a week ..... D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

e) Other restlessness while you sleep; please describe: PSQ10E1 _____

_____

_____ ..... ☐ PSQ10E

Not during the past month .....A
Less than once a week .....B
Once or twice a week C
Three or more times a week.....D

Buysse,D.J., Reynolds,C.F., Monk,T.H., Berman,S.R., & Kupfer,D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213.

RESPIRATORY DISEASE AND SMOKE EXPOSURE QUESTIONNAIRE FOR FOLLOW-UP

ID NUMBER: BLINDID

FORM CODE: **RDF**
VERSION: **1.0** 9/21/11

Visit Number VISIT

SEQ #

0a) Form Date ..... __ __/__ __/__ __ __ __ RDF0A

0b) Code ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please answer all questions.*

I would now like to ask you detailed questions about your experiences with respiratory disease and smoke exposure.

The following questions relate to respiratory symptoms.

1) Do you usually have a cough? (Exclude clearing of throat.) (Y/N) ..... ☐ RDF1

   1a) If **yes (Y)**, do you usually cough as much as 4 times a day, 4 or more days out of the week? ..... ☐ RDF1A

2) Do you usually cough at all on getting up or first thing in the morning? (Y/N) ..... ☐ RDF2

3) Do you usually cough at all during the rest of the day or night? (Y/N) ..... ☐ RDF3

   If **yes (Y)** to any of the above (1, 2, 3), answer the following:

   3a) Do you cough like this on most days, for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDF3A

   3b) For how many years have you had this cough? ..... ☐☐ RDF3B

4) Do you usually bring up phlegm from your chest? (Y/N) ..... ☐ RDF4

   4a) If **yes (Y)**, do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? (Y/N) ..... ☐ RDF4A

5) Do you usually bring up phlegm from your chest on getting up, or first thing in the morning? (Y/N) ..... ☐ RDF5

6) Do you usually bring up phlegm from your chest during the rest of the days or at night? (Y/N) ..... ☐ RDF6

   If **yes (Y)**, to any of the about (4, 5, 6), answer the following:

   6a) Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDF6A

   6b) For how many years have you had trouble with phlegm? ..... ☐☐ RDF6B

7) In the past 12 months, have you had periods or episodes of cough with phlegm that lasted 1 week or more? (If you usually have cough and phlegm, please count only periods or episodes of increased cough and phlegm). (Y/N) ..... ☐ RDF7

7a) If **yes (Y)**, about how many such episodes have you had in the past 12 months? ..... ☐☐ RDF7A

7b) If **yes (Y)**, for how many years have you had at least one such episode per year? ..... ☐☐ RDF7B

8) Have you ever had wheezing or whistling in your chest? (Y/N) (If **NO**, go to 11) ..... ☐ RDF8

8a) If **yes (Y)**, about how old were you when you first had wheezing or whistling in your chest? ..... ☐☐ RDF8A

9) Have you ever had an attack of wheezing or whistling in your chest that made you feel short of breath? (Y/N) ..... ☐ RDF9

9a) If **yes (Y)**, about how old were you when you had your first such attack? ..... ☐☐ RDF9A

9b) Have you ever had 2 or more such attacks? (Y/N) ..... ☐ RDF9B

9c) Have you ever required medicine or treatment for such attacks? (Y/N) ..... ☐ RDF9C

10) In the last 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDF10

10a) If **yes (Y)**, in the last 12 months, does your chest ever sound wheezy or whistling…

When you have a cold?	☐ Yes	☐ No	RDF10A1
Occasionally apart from colds?	☐ Yes	☐ No	RDF10A2
More than once a week?	☐ Yes	☐ No	RDF10A3
Most days or nights?	☐ Yes	☐ No	RDF10A4

11) In the last 12 months, have you been awakened from sleep by coughing, apart from a cough associated with a cold or chest infection? (Y/N) ..... ☐ RDF11

12) In the last 12 months, have you been awakened from sleep by shortness of breath or a feeling of tightness in your chest? (Y/N) ..... ☐ RDF12

Questions 13-14 are about symptoms that occur when you do not have a cold or the flu.

13) In the past 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDF13

14) In the past 12 months, have you been bothered by watery, itchy, or burning eye when you did not have a cold or the flu? (Y/N) ..... ☐ RDF14

15) Are you unable to walk due to a condition other than shortness of breath? (Y/N) ..... ☐ RDF15

Nature of condition: RDF15A _____

These next questions relate to respiratory conditions

16) In the past 12 months, have you been newly diagnosed by a doctor or other health professional with asthma? ☐ RDF16

Yes ..... Y
No ..... N → **Go to Item 17**
Don't know ..... U → **Go to Item 17**

16a) In the past 12 months, have you received medical treatment, taken medications, or used an inhaler for asthma? (Y/N) ☐ RDF16A

17) In the past 12 months, have you had any hay fever (allergy involving the nose and/or eyes)? ☐ RDF17

Yes ..... Y
No ..... N → **Go to Item 18**
Don't know ..... U → **Go to Item 18**

17a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDF17A

17b) In the past 12 months, have you received medical treatment, taken medications, or used a nasal spray for hay fever? (Y/N) ☐ RDF17B

18) In the past 12 months, have you had an attack of bronchitis? ☐ RDF18

Yes ..... Y
No ..... N → **Go to Item 19**
Don't know ..... U → **Go to Item 19**

18a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDF18A

18b) How many times have you had bronchitis in the past 12 months? ☐☐ RDF18B

19) In the past 12 months, have you had pneumonia or bronchopneumonia? ☐ RDF19

Yes ..... Y
No ..... N → **Go to Item 20**
Don't know ..... U → **Go to Item 20**

19a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDF19A

19b) How many times have you had pneumonia or bronchopneumonia in the past 12 months? ☐☐ RDF19B

20) In the past 12 months, were you newly diagnosed by a doctor or other health professional with chronic bronchitis? ☐ RDF20

Yes ..... Y
No ..... N → **Go to Item 21**
Don't know ..... U → **Go to Item 21**

20a) In the past 12 months, have you received medical treatment, taken medications or used an inhaler for chronic bronchitis? (Y/N) ☐ RDF20A

21) In the past 12 months, have you been newly diagnosed by a doctor or other health professional with emphysema?..... ☐ RDF21

Yes ..... Y
No ..... N → **Go to Item 22**
Don't know..... U → **Go to Item 22**

21a) In the past 12 months, have you received medical treatment, taken medications or used an inhaler for emphysema? (Y/N)..... ☐ RDF21A

22) In the past 12 months, have you been newly diagnosed by a doctor or other health professional with COPD (chronic obstructive pulmonary disease)? ..... ☐ RDF22

Yes ..... Y
No ..... N → **Go to Item 23**
Don't know..... U → **Go to Item 23**

22a) In the past 12 months, have you received medical treatment, taken medications or used an inhaler for COPD? (Y/N)..... ☐ RDF22A

23) In the past 12 months, have you been newly diagnosed by a doctor or other health professional with sleep apnea?..... ☐ RDF23

Yes ..... Y
No ..... N → **Go to Item 24**
Don't know..... U → **Go to Item 24**

23a) In the past 12 months, have you received any treatment for sleep apnea? (Y/N)..... ☐ RDF23A

Yes ..... Y
No ..... N→ **Go to Item 24**

23b) Do you use a CPAP or BIPAP? (Y/N) ..... ☐ RDF23B

Yes ..... Y
No ..... N

23c) Did you have surgery for your sleep apnea? (Y/N) ..... ☐ RDF23C

Yes ..... Y
No ..... N

23d) Did you have some other treatment for your sleep apnea? (Y/N)..... ☐ RDF23D

Yes ..... Y
No ..... N→ **Go to Item 24**

23e) Describe RDF23E _____

24) In the past 12 months have you had:

24a) Any other chest illnesses? (Y/N) ..... ☐ RDF24A

If **Yes (Y)**, specify: RDF24A1 _____

24b) Any chest operations? (Y/N) ..... ☐ RDF24B

If **Yes (Y)**, specify: RDF24B1 _____

24c) Any chest injuries? (Y/N) ..... ☐ RDF24C

If **Yes (Y)**, specify: RDF24C1 _____

I am now going to ask you about some common environmental exposures.

[Do not read] Cigarette Smoking

25) In the past 12 months have you smoked cigarettes? ..... ☐ RDF25

Yes ..... Y

No ..... N → **Go to Item 30**

26) Do you still smoke cigarettes as of one month ago? (Y/N) ..... ☐ RDF26

Yes ..... Y

No ..... N → **Go to Item 29**

27) Cigarettes smoke in the past 24 hours: (check here ☐ if does not apply) RDF27

Approximately how many cigarettes have you smoked in the past

☐☐ 24 hours RDF27A

☐☐ 2 hours RDF27B

☐☐ ½ hour RDF27C

28) How many cigarettes do you smoke per day now? ..... ☐☐ RDF28

29) On average over the last 12 months, how many cigarettes did you smoke per day? ..... ☐☐ RDF29

30) Have you ever smoked menthol cigarettes? RDF30

Yes ..... Y

No ..... N → **Go to Item 31**

30a) For how long have you or did you smoke menthol cigarettes? ..... ☐☐ years RDF30A

31) What brands of cigarettes have you smoked?

a) RDF31A _____

b) RDF31B _____

c) RDF31C _____

d) RDF31D _____

e) RDF31E _____

[Do not read] Pipe Smoking

32) In the past twelve months have you smoked a pipe regularly? ..... ☐ RDF32

Yes ..... Y
No ..... N → **Go to Item 36**

33) Do you smoke a pipe (as of one month ago)? (Y/N) ..... ☐ RDF33

Yes ..... Y
No ..... N → **Go to Item 36**

34) How much pipe tobacco do you smoke per day now? ..... ☐☐ RDF34 oz per day

35) On average over the last 12 months, how many ounces of tobacco did you smoke per week? ..... ☐☐ RDF35 oz per week

[Do not read] Cigar Smoking

36) In the past twelve months have you smoked cigars regularly? (**YES** means more than 1 cigar a week for one year at any time in your life) ..... ☐ RDF36

Yes ..... Y
No ..... N → **Go to Item 40**

37) Do you now smoke cigars (as of one month ago)? (Y/N) ..... ☐ RDF37

Yes ..... Y →
No ..... N → **Go to Item 39**

38) How many cigars smoke per day now? ..... ☐☐.☐ RDF38 per day

39) On average over the last 12 months, how many cigars did you smoke per week? ..... ☐☐ RDF39 per week

I'd now like to ask you about your second-hand smoke exposures.

40) Which of the following best describes your approach to tobacco smoking in your home when you are in the house? ..... ☐ RDF40

Never allow smoking in home 1
Smoking is allowed only in certain rooms 2
Smoking is allowed in all rooms of your home 3
Refused ..... R
Don't Know ..... D

41) In the last 12 months, have you lived in the same household with someone who smoked tobacco products? RDF41

Yes 1
No ..... 0→**Go to Item 45**
Refused ..... R→**Go to Item 45**
Don't know ..... D→**Go to Item 45**

42) Do you currently live in the same household with someone who smokes tobacco products? RDF42

Yes ..... Y
No ..... N→**Go to Item 44**
Refused ..... R→**Go to Item 44**
Don't Know ..... D→**Go to Item 44**

43) How many people in your household currently smoke? RDF43

44) In the last 12 months for how many months in total have you lived in the same household with someone else who smoke tobacco products? ..... RDF44 months

Refused ..... R
Don't know ..... D

I would now like to ask you about any smoke exposure that may have occurred in the past seven days.

45) Has anyone smoked tobacco in your home during the past seven days? RDF45

Yes ..... Y
No ..... N→**Go to Item 53**
No Answer ..... U

46) During the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke at home? ..... RDF46 hrs

47) During the past 7 days, did you enter a room in your home that was visibly smoky? RDF47

Yes ..... Y
No ..... N
No Answer ..... U

48) In the past 7 days, did you smell tobacco smoke in your home? (Y/N/U) RDF48

49) During the past 7 days, did you experience red eyes or eye irritation? (Y/N/U) RDF49

50) During the past 7 days, did you experience runny nose or nose irritation? (Y/N/U) RDF50

51) During the past 7 days, did you experience coughing, wheezing or chest tightness? (Y/N/U) RDF51

52) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your home? (Y/N/U) ..... ☐ RDF52

53) In the past 7 days, have you visited another person's home where someone was smoking tobacco products indoors? (Y/N/U) ..... ☐ RDF53 **If N or U skip to 71**

54) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in another person's home? ..... ☐☐ hrs RDF54

55) During the past 7 days, did you enter a room in another person's home that was visibly smoky? (Y/N/U) ..... ☐ RDF55

56) In the past 7 days, did you smell tobacco smoke in another person's home? (Y/N/U) ..... ☐ RDF56

57) In the past 7 days, have you traveled by car or other vehicle with someone else who was smoking tobacco products? (Y/N/U) ..... ☐ RDF57 **If N or U skip to 73**

58) In the past 7 days, how many hours did you spend traveling in a car while someone else was smoking tobacco? ..... ☐☐ hrs RDF58

[Do not read] IF NOT A WORKER SKIP TO 68

59) During the past 7 days, did anyone smoke tobacco inside your workplace, that is, while you were working indoors? (Y/N/U) ..... ☐ RDF59 **If N or U skip to 75**

60) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke inside your workplace? ..... ☐☐ hrs RDF60

61) During the past 7 days, did you enter a room in your workplace that was visibly smoky? ..... ☐ RDF61

62) In the past 7 days, did you smell tobacco smoke in your workplace? ..... ☐ RDF62

63) Is there an outdoor area at your workplace where cigarette smokers routinely gather or congregate to smoke? (Y/N/U) ..... ☐ RDF63 **If N or U skip to 66**

64) In the past 7 days, how many times did you walk through or past this area while others were smoking? (Y/N/U) ..... ☐ RDF64

65) During the past 7 days, how many hours in total did you spend in an outdoor smoking area while people were smoking? (Y/N/U) ..... ☐ RDF65

66) While walking through or past this area, did you smell smoke? (Y/N/U) ..... ☐ RDF66

67) In the past 7 days, how many hours did you spend near coworkers who were smoking tobacco outdoors? ..... ☐ RDF67

68) During the past 7 days, did you smell tobacco smoke while working outdoors? ..... ☐ RDF68

69) In the past seven days, have you been at an outdoor location (besides work) where someone was smoking tobacco products outside? (Y/N/U) ..... ☐ RDF69 **If N or U skip to 70**

70) Where was this location? RDF70 _____

71) During the past 7 days, did you smell tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDF71 **If N or U skip to 72**

72) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke this outdoor location? ..... ☐☐ hrs RDF72

73) In the past seven days or nights, were you in a bar, nightclub, cocktail lounge, sports arena, or concert hall where someone else was smoking tobacco products? (Y/N/U) ..... ☐ RDF73 **If N or U skip to 74**

74) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in a bar or other place of entertainment? ..... ☐☐ hrs RDF74

75) During the past 7 days, did you enter a room in a bar or other place of entertainment that was visibly smoky? (Y/N/U) ..... ☐ RDF75

76) In the past 7 days, did you smell tobacco smoke in a bar or other place of entertainment? ..... ☐ RDF76

You answered that you were exposed to someone else's tobacco smoke in a bar or other place of entertainment. During the past 7 days, did you experience any of the following after this exposure

77) I have asked you about exposure to someone else's tobacco some in your home, friend's home, work, outdoor locations, and bars or nightclubs. In the past 7 days, was there any other location where you were exposed to tobacco smoke? (Y/N/U) ..... ☐ RDF77 **If N or U skip to 80**

78) Where was this location? (Y/N/U) ..... ☐ RDF78

79) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in this location? (Y/N/U) ..... ☐ RDF79

I would now like to ask you about any smoke exposure that may have occurred as a result of marijuana use. Please remember that all information that you give us is confidential, and only certified SPIROMICS personnel will have access to this information.

80) In the last 12 months have you smoked marijuana (cannabis, pot, or hashish)? ..... ☐ RDF80

Yes ..... Y

No ..... N → **Go to 84**

81) In the last 12 months have you smoked marijuana regularly (five times or more in a given year)? ☐ RDF81

Yes ..... Y

No ..... N

82) On average, in the last 12 months about how many joints per week do (did) you smoke? RDF82

83) On average, in the last 12 months about how many pipes per week do (did) you smoke? RDF83

84) How many hours per day do you spend outdoors?

a) In spring..... hrs RDF84A

b) In summer..... hrs RDF84B

c) In fall ..... hrs RDF84C

d) In winter..... hrs RDF84D

85) On average, how many hours per day do you spend in your home? ..... hrs RDF85

a) Do you have a central air conditioner? RDF85A

Yes ..... Y

No ..... N → **Go to Item 85c**

b) How many months out of the year do you use it? RDF85B

c) Do you have a room air conditioner? RDF85C

Yes ..... Y

No ..... N → **Go to Item 85e**

d) How many months out of the year do you use it? RDF85D

e) What kind of range or stove do you have? RDF85E

Gas ..... G

Electric..... E

Other..... O

Specify RDF85E1 _____

f) Does your range or stove have ventilation to the outdoors? RDF85F

Yes ..... Y

No ..... N

Unknown..... U

g) What is the main type of heating you use in your house? RDF85G

Radiator ..... 1 → **Go to Item 85i**

Forced Air ..... 2 → **Go to Item 85h**

Wood stove..... 3→ **Go to Item 85i**

Fireplace..... 4→ **Go to Item 85i**

Other..... 5→ **Go to Item 85i**

h) What is the main type of heating fuel used in your house? RDF85H

Electric..... 1

Natural Gas 2

Oil 3

Coal 4

Wood 5

Other..... 6

Specify RDF85H1 _____

i) How many months out of the year do you use the main type of heating in your house?..... RDF85I

j) Are there any other sources of heat? (check all that apply)

Radiator ..... ☐ RDF85J1

Forced Air ..... ☐ RDF85J2

Wood stove..... ☐ RDF85J3

Fireplace..... ☐ RDF85J4

Other..... ☐ RDF85J5

86) How much time per day do you spend commuting in traffic to work in total (i.e. both ways)? RDF86

None 1

1-30 minutes.....2

30-60 minutes.....3

More than 60 minutes (1 hour) 4

More than 120 minutes (2 hours) 5

a) How many days per week do you commute to work? RDF86A

RESPIRATORY DISEASE AND SMOKE EXPOSURE QUESTIONNAIRE

ID NUMBER: BLINDID

FORM CODE: **RDS**
VERSION: **3.0** 8/2/11

Visit Number VISIT

SEQ #

0a) Form Date ..... __ __/__ __/__ __ __ __ RDS0A

0b) Staff Code..... __ __ __ RDS0BNUM

Instructions: *This form should be completed during the participant's visit. Please answer all questions.*

I would now like to ask you detailed questions about your experiences with respiratory disease and smoke exposure.

The following questions relate to respiratory symptoms.

1) Do you usually have a cough? (Exclude clearing of throat.) (Y/N) ..... ☐ RDS01

1a) If **yes (Y)**, do you usually cough as much as 4 times a day, 4 or more days out of the week? ..... ☐ RDS01A

2) Do you usually cough at all on getting up or first thing in the morning? (Y/N)..... ☐ RDS02

3) Do you usually cough at all during the rest of the day or night? (Y/N) ..... ☐ RDS03

If **yes (Y)** to any of the above (1, 2, 3), answer the following:

3a) Do you cough like this on most days, for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS03A

3b) For how many years have you had this cough?..... ☐☐ RDS03B

4) Do you usually bring up phlegm from your chest? (Y/N) ..... ☐ RDS04

4a) If **yes (Y)**, do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? (Y/N)..... ☐ RDS04A

5) Do you usually bring up phlegm from your chest on getting up, or first thing in the morning? (Y/N) ..... ☐ RDS05

6) Do you usually bring up phlegm form you chest during the rest of the days or at night? (Y/N) ..... ☐ RDS06

If **yes (Y)**, to any of the about (4, 5, 6), answer the following:

6a) Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS06A

6b) For how many years have you had trouble with phlegm?..... ☐☐ RDS06B

7) In the past 12 months, have you had periods or episodes of cough with phlegm that lasted 1 week or more? (If you usually have cough and phlegm, please count only periods or episodes of increased cough and phlegm). (Y/N) ..... ☐ RDS07

7a) If **yes (Y)**, about how many such episodes have you had in the past 12 months? ..... ☐☐ RDS07A

7b) If **yes (Y)**, for how many years have you had at least one such episode per years? ..... ☐☐ RDS07B

8) Have you ever had wheezing or whistling in your chest? (Y/N) (If **NO**, go to 11) ..... ☐ RDS08

8a) If **yes (Y)**, about how old were you when you first had wheezing or whistling in your chest? ..... ☐☐ yrs WHEEZINGAGE

9) Have you ever had an attack of wheezing or whistling in your chest that made you feel short of breath? (Y/N)..... ☐ RDS09

9a) If **yes (Y)**, about how old were you when you had your first such attack? ..... ☐☐ RDS09A

9b) Have you ever had 2 or more such attacks? (Y/N) ..... ☐ RDS09B

9c) Have you ever required medicine or treatment for such attacks? (Y/N) ..... ☐ RDS09C

10) In the last 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDS10

10a) If **yes (Y)**, in the last 12 months, does your chest ever should wheezy or whistling…

When you have a cold?	☐ Yes	☐ No	RDS10A1
Occasionally apart from colds?	☐ Yes	☐ No	RDS10A2
More than once a week?	☐ Yes	☐ No	RDS10A3
Most days or nights?	☐ Yes	☐ No	RDS10A4

11) In the last 12 months, have you been awakened from sleep by coughing, apart from a cough associated with a cold or chest infection? (Y/N) ..... ☐ RDS11

12) In the last 12 months, have you been awakened from sleep by shortness of breath or a feeling of tightness in your chest? (Y/N)..... ☐ RDS12

Questions 13-14 are about symptoms that occur when you do not have a cold of the flu.

13) In the past 12 months, have you had wheezing or whistling in your chest at any time? (Y/N)..... ☐ RDS13

14) In the past 12 months, have you been bothered by watery, itchy, or burning eye when you did now have a cold or the flu? (Y/N)..... ☐ RDS14

15) Are you unable to walk due to a condition other than shortness of breath? (Y/N) ..... ☐ RDS15

Nature of condition: NATURECONDITION _____

These next questions relate to respiratory conditions

16) Have you ever had asthma? ..... ☐ RDS16

Yes ..... Y
No ..... N → **Go to Item 17**
Don't know ..... U → **Go to Item 17**

16a) At about what age did it start? ..... ☐☐ RDS16A

☐ As a child; age not known (Check is appropriate) RDS16A1

16b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS16B

16c) Do you still have it? (Y/N/U) ..... ☐ RDS16C

16d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS16D

☐ As a child; age not known (Check is appropriate) RDS16D1

16e) In the past 12 months, have you received medical treatment, take medications or used an inhaler for asthma? (Y/N) ..... ☐ RDS16E

17) Have you ever had any hay fever (allergy involving the nose and/or eyes)? ..... ☐ RDS17

Yes ..... Y
No ..... N → **Go to Item 18**
Don't know ..... U → **Go to Item 18**

17a) At about what age did it start? ..... ☐☐ RDS17A

☐ As a child; age not known (Check is appropriate) RDS17A1

17b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS17B

17c) Do you still have it? (Y/N/U) ..... ☐ RDS17C

17d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS17D

☐ As a child; age not known (Check is appropriate) RDS17D1

17e) In the past 12 months, have you received medical treatment, take medications or used a nasal spray for hay fever? (Y/N) ..... ☐ RDS17E

18) Have you ever had an attack of bronchitis? ..... ☐ RDS18

Yes ..... Y
No ..... N → **Go to Item 19**
Don't know ..... U → **Go to Item 19**

18a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS18A

18b) At about what age did you first have bronchitis? ..... ☐☐ RDS18B

☐ As a child; age not known (Check is appropriate) RDS18B1

18c) How many time have you had bronchitis? ..... ☐☐ times RDS18C

19) Have you ever had pneumonia or bronchopneumonia? ..... ☐ RDS19

Yes ..... Y
No ..... N → **Go to Item 20**
Don't know ..... U → **Go to Item 20**

19a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS19A

19b) At about what age did you first have pneumonia or bronchopneumonia? ..... ☐☐ RDS19B

☐ As a child; age not known (Check is appropriate) RDS19B1

19c) How many time have you had pneumonia or bronchopneumonia? ..... ☐☐ times RDS19C

20) Have you ever had chronic bronchitis? ..... ☐ RDS20

Yes ..... Y
No ..... N → **Go to Item 21**
Don't know ..... U → **Go to Item 21**

20a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS20A

20b) At about what age did it start? ..... ☐☐ RDS20B

20c) Do you still have it? (Y/N/U) ..... ☐ RDS20C

20d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for chronic bronchitis? (Y/N) ..... ☐ RDS20D

21) Have you ever had emphysema? ..... ☐ RDS21

Yes ..... Y
No ..... N → **Go to Item 22**
Don't know ..... U → **Go to Item 22**

21a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS21A

21b) At about what age did it start? ..... ☐☐ RDS21B

21c) Do you still have it? (Y/N/U) ..... ☐ RDS21C

21d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for emphysema? (Y/N) ..... ☐ RDS21D

22) Have you ever had COPD (chronic obstructive pulmonary disease)? ..... ☐ RDS22

Yes ..... Y
No ..... N → **Go to Item 23**
Don't know ..... U → **Go to Item 23**

22a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS22A

22b) At about what age did it start? ..... ☐☐ RDS22B

22c) Do you still have it? (Y/N/U) ..... ☐ RDS22C

22d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for COPD? (Y/N) ..... ☐ RDS22D

23) Have you ever had sleep apnea? ..... ☐ RDS23

Yes ..... Y
No ..... N → **Go to Item 24**
Don't know ..... U → **Go to Item 24**

23a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS23A

23b) At about what age did it start? ..... ☐☐ RDS23B

23c) Do you still have it? (Y/N/U) ..... ☐ RDS23C

23d) In the past 12 months, have you received any treatment for sleep apnea? (Y/N) ..... ☐ RDS23D

24) Have you ever had:

24a) Any other chest illnesses? (Y/N) ..... ☐ RDS24A

If **Yes (Y)**, specify: RDS24A1 _____

24b) Any chest operations? (Y/N) ..... ☐ RDS24B

If **Yes (Y)**, specify: RDS24B1 _____

24c) Any chest injuries? (Y/N) ..... ☐ RDS24C

If **Yes (Y)**, specify: RDS24C1 _____

I'd now like to ask you about your family history or respiratory disease.

25) Were either of you natural parents told by a doctor they had a chronic lung condition such as:

	Father			Mother		
	YES	NO	Don't Know	YES	NO	Don't Know
Chronic bronchitis	☐	☐	☐ RDS25A1	☐	☐	☐ RDS25B1
Emphysema	☐	☐	☐ RDS25A2	☐	☐	☐ RDS25B2
COPD	☐	☐	☐ RDS25A3	☐	☐	☐ RDS25B3
Asthma	☐	☐	☐ RDS25A4	☐	☐	☐ RDS25B4
Lung Cancer	☐	☐	☐ RDS25A5	☐	☐	☐ RDS25B5

26) Were either of your natural parents ever a cigarette smoker?

Father: ☐ Yes ☐ No ☐ Don't know RDS26A
Mother: ☐ Yes ☐ No ☐ Don't know RDS26B

I am now going to ask you about some common environmental exposes.

[Do not read] Cigarette Smoking

27) Have you ever smoked cigarettes? (No means less than 20 packs of cigarettes of 12 oz. of tobacco in a lifetime of less than 1 cigarette a day for one year at any time in your life) ..... ☐ RDS27

Yes ..... Y
No ..... N → **Go to Item 34**

28) How old were you when you first started regular cigarette smoking? ..... ☐☐ RDS28

29) Do you smoke cigarettes (as of one month ago)? (Y/N) ..... ☐ RDS29

Yes ..... Y → **Go to Item 30**
No ..... N → **Go to Item 31**

30) How many cigarettes do you smoke per day now? ..... ☐☐ RDS30

31) How old were you when you completely stopped smoking? ..... ☐☐ RDS31 yrs old

32) On average of the entire time you smoked, how many cigarettes did you smoke per day? ..... ☐☐ RDS32 per day

33) Cigarettes smoke in the past 24 hours: (check here ☐ if does not apply) RDS33

Approximately how many cigarettes have you smoked in the past

☐☐ in 24 hours RDS33A

☐☐ in 2 hours RDS33B

☐☐ in ½ hour RDS33C

[Do not read] Pipe Smoking

34) Have you ever smoked a pipe regularly? (**YES** means more than 12 oz of tobacco in a lifetime) ..... ☐ RDS34

Yes ..... Y
No ..... N → **Go to Item 40**

35) How old were you when you first started to smoke a pipe regularly? ..... ☐☐ RDS35

36) Do you smoke a pipe (as of one month ago)? (Y/N) ..... ☐ RDS36

Yes ..... Y → **Go to Item 37**
No ..... N → **Go to Item 38**

37) How much pipe tobacco do you smoke per day now? ..... ☐☐ RDS37 oz per day

38) How old were you when you completely stopped smoking a pipe? ..... ☐☐ RDS38 yrs old

39) On average of the entire time you smoked a pipe, how many ounces of tobacco did you smoke per week? ..... ☐☐ RDS39 oz per week

[Do not read] Cigar Smoking

40) Have you ever smoked cigars regularly? (**YES** means more than 1 cigar a week for one year at any time in your life) ..... [ ] RDS40

Yes ..... Y
No ..... N → **Go to Item 46**

41) How old were you when you first started to smoke cigars regularly? ..... [ ][ ] RDS41

42) Do you now smoke cigars (as of one month ago)? (Y/N) ..... [ ] RDS42

Yes ..... Y → **Go to Item 43**
No ..... N → **Go to Item 44**

43) How many cigars smoke per day now? ..... [ ][ ] per day RDS43

44) How old were you when you completely stopped smoking cigars? ..... [ ][ ] yrs old RDS44

45) On average of the entire time you smoked cigars, how many cigars did you smoke per week? ..... [ ][ ] per week RDS45

I'd now like to ask you about your second-hand smoke exposures.

46) Which of the following best describes your approach to tobacco smoking in your home when you are in the house? ..... [ ] RDS46

Never allow smoking in home 1
Smoking is allowed only in certain rooms 2
Smoking is allowed in all rooms of your home 3
Refused ..... R
Don't Know ..... D

47) For how many years has this been your approach to smoking in you home? ..... [ ][ ] yrs RDS47A

Refused ..... R
Don't Know ..... D
RDS47B

48) Do you currently live in the same household with someone who smokes tobacco products? ..... [ ] RDS48

Yes ..... Y → **Go to Item 50**
No ..... N → **Go to Item 49**
Refused ..... R → **Go to Item 52**
Don't Know ..... D → **Go to Item 52**

49) Since age 18, have you ever lived in the same household with someone who smoked tobacco products? ..... [ ][ ] yrs RDS49

Yes ..... 1 → **Go to Item 51**
No ..... 0 → **Go to Item 52**

Refused ..... R→**Go to Item 52**
Don't know ..... D→**Go to Item 52**

50) How many people in your household smoke? ..... ☐☐ RDS50

51) Since age 18, for haw many years in total have you lived in the same household with someone else who smoke tobacco products? ..... ☐☐ yrs RDS51A

Refused ..... R
Don't know ..... D RDS51B

52) Growing up until age 18, were there any adults in your household who smoked at home? ..... ☐ RDS52

Yes ..... Y
No ..... N →**Go to Item 54**
Refused ..... R →**Go to Item 54**
Don't Know ..... D →**Go to Item 54**

53) Was this your father, your mother, or someone else? *(check all that apply)*

Father ..... ☐ RDS53FATHERCBI
Mother ..... ☐ →**Answer Item 54** RDS53MOTHERCBI
Other ..... ☐ RDS53OTHERCBI
Refused ..... ☐ RDS53REFUSEDCBI
Don't Know ..... ☐ RDS53NOTKNOWCBI

54) Did your mother smoke cigarettes when she was pregnant with you before you were born? ..... ☐ RDS55

Yes ..... Y
No ..... N
Refused ..... R
Don't know ..... D

55) Growing up until age 18, for how many years in total did you live in the same household with someone else who smoked tobacco products? ..... ☐☐ yrs RDS55A

Refused ..... R
Don't Know ..... D RDS55B

I would now like to ask you about any smoke exposure that may have occurred in the past seven days.

56) Has anyone smoked tobacco in your home during the past seven days? ..... ☐ RDS56

Yes ..... Y
No ..... N→**Go to Item 64**
No Answer ..... U

57) During the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke at home? ..... ☐☐ hrs RDS57

58) During the past 7 days, did you enter a room in your home that was visibly smoky? ..... ☐ RDS58

Yes ..... Y
No..... N
No Answer ..... U

59) In the past 7 days, did you smell tobacco smoke in your home? (Y/N/U) ..... ☐ RDS59

60) During the past 7 days, did you experience red eyes or eye irritation? (Y/N/U)..... ☐ RDS60

61) During the past 7 days, did you experience runny nose or nose irritation? (Y/N/U)..... ☐ RDS61

62) During the past 7 days, did you experience coughing, wheezing or chest tightness? (Y/N/U) ..... ☐ RDS62

63) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your home? (Y/N/U)..... ☐ RDS63

64) In the past 7 days, have you visited another person's home where someone was smoking tobacco products indoors? (Y/N/U)..... ☐ RDS64 **If N or U skip to 66**

65) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in another person's home?..... ☐☐ hrs RDS65

66) During the past 7 days, did you enter a room in another person's home that was visibly smoky? (Y/N/U)..... ☐ RDS66

67) In the past 7 days, did you smell tobacco smoke in another person's home? (Y/N/U) ..... ☐ RDS67

[Do not read] Skip to Question 72 RDS68-RDS71 removed 08/02/11

72) In the past 7 days, have you traveled by car or other vehicle with someone else who was smoking tobacco products? (Y/N/U) ..... ☐ RDS72 **If N or U skip to 78**

73) In the past 7 days, how many hours did you spend traveling in a car while someone else was smoking tobacco? ..... ☐☐ hrs RDS73

[Do not read] Skip to Question 78 RDS74-RDS77 removed 08/02/11

[Do not read] IF NOT A WORKER SKIP TO 102

78) During the past 7 days, did anyone smoke tobacco inside your workplace, that is, while you were working indoors? (Y/N/U) ..... ☐ RDS78 **If N or U skip to 80**

79) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke inside your workplace?..... ☐☐ hrs RDS79

80) During the past 7 days, did you enter a room in your workplace that was visibly smoky?..... ☐ RDS80

81) In the past 7 days, did you smell tobacco smoke in your workplace? ..... ☐ RDS81

[Do not read] Skip to Question 86 RDS82-RDS85 removed 08/02/11

86) Is there an outdoor area at your workplace where cigarette smokers routinely gather or congregate to smoke? (Y/N/U) ..... ☐ RDS86 **If N or U skip to 95**

87) In the past 7 days, how many times did you walk through or past this area while others were smoking? (Y/N/U) ..... ☐ RDS87

88) During the past 7 days, how many hours in total did you spend in an outdoor smoking area while people were smoking? (Y/N/U) ..... ☐ RDS88

89) While walking through or past this area, did you smell smoke? (Y/N/U) ..... ☐ RDS89

[Do not read] Skip to Question 95 RDS90-RDS94 removed 08/02/11

95) In the past 7 days, how many hours did you spend near coworkers who were smoking tobacco outdoors?. ☐ RDS95

96) During the past 7 days, did you smell tobacco smoke while working outdoors? ..... ☐ RDS96

[Do not read] Skip to Question 101 RDS97-RDS100 removed 08/02/11

101) In the past seven days, have you been at an outdoor location (besides work) where someone was smoking tobacco products outside? (Y/N/U) ..... ☐ RDS101 **If N or U skip to 103**

102) Where was this location? RDS102 _____

103) During the past 7 days, did you smell tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDS103 **If N or U skip to 109**

104) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke this outdoor location? ..... ☐☐ hrs RDS104

[Do not read] Skip to Question 109 RDS105-RDS108 removed 08/02/11

109) In the past seven days or nights, were you in a bar, nightclub, cocktail lounge, sports arena, or concert hall where someone else was smoking tobacco products? (Y/N/U) ..... ☐ RDS109 **If N or U skip to 111**

110) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in a bar or other place of entertainment? ..... ☐☐ hrs RDS110

111) During the past 7 days, did you enter a room in a bar or other place of entertainment that was visibly smoky? (Y/N/U) ..... ☐ RDS111

112) In the past 7 days, did you smell tobacco smoke in a bar or other place of entertainment? ..... ☐ RDS112

[Do not read] Skip to Question 117 RDS113-RDS116 removed 08/02/11

You answered that you were exposed to someone else's tobacco smoke in a bar or other place of entertainment. During the past 7 days, did you experience any of the following after this exposure

117) I have asked you about exposure to someone else's tobacco some in your home, friend's home, work, outdoor locations, and bars or nightclubs. In the past 7 days, was there any other location where you were exposed to tobacco smoke? (Y/N/U) ..... ☐ RDS117 **If N or U skip to 124**

118) Where was this location? (Y/N/U)..... ☐ RDS118

119) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in this location? (Y/N/U)..... ☐ RDS119

[Do not read] Skip to Question 124 RDS120-RDS123 removed 08/02/11

I would now like to ask you about any smoke exposure that may have occurred as a result of marijuana use. Please remember that all information that you give us is confidential, and only certified SPIROMICS personnel will have access to this information.

124) Have you ever smoked marijuana (cannabis, pot, or hashish)? ..... ☐ RDS124

Yes .....Y
No.....N →**Go to END**

125) Have you ever smoked marijuana regularly (five times or more in a given year)? ..... ☐ RDS125

Yes .....Y
No.....N

126) On average over the entire time that you smoke(d) about how many joints per week do (did) you smoke? ..... ☐☐ RDS126

127) On average over the entire time that you smoke(d) about how many pipes per week do (did) you smoke? ..... ☐☐ RDS127

128) How many years have you smoked pot/marijuana? ..... ☐☐ yrs RDS128

[Do not read] Skip to Question 130

130) When was the last time you smoked marijuana? ..... ☐ RDS130

In the last week.....1
In the last month.....2
In the last six months 3
In the last 12 months.....4
More than 12 months ago 5
Don't know.....6
Declines to answer.....7

RESPIRATORY DISEASE AND SMOKE EXPOSURE QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: RDS VERSION: 2.0 11/09/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... __ __/__ __/__ __ __ __ RDS0A 0b) Initials..... __ __ __ RDS0BNUM

Instructions: *This form should be completed during the participant's visit. Please answer all questions.*

I would now like to ask you detailed questions about your experiences with respiratory disease and smoke exposure.

The following questions relate to respiratory symptoms.

1) Do you usually have a cough? (Exclude clearing of throat.) (Y/N) ..... ☐ RDS01

   1a) If **yes (Y)**, do you usually cough as much as 4 times a day, 4 or more days out of the week? ..... ☐ RDS01A

2) Do you usually cough at all on getting up or first thing in the morning? (Y/N) ..... ☐ RDS02

3) Do you usually cough at all during the rest of the day or night? (Y/N) ..... ☐ RDS03

   If **yes (Y)** to any of the above (1, 2, 3), answer the following:

   3a) Do you cough like this on most days, for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS03A

   3b) For how many years have you had this cough? ..... ☐☐ y RDS03B

4) Do you usually bring up phlegm from your chest? (Y/N) ..... ☐ RDS04

   4a) If **yes (Y)**, do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? (Y/N) ..... ☐ RDS04A

5) Do you usually bring up phlegm from your chest on getting up, or first thing in the morning? (Y/N) ..... ☐ RDS05

6) Do you usually bring up phlegm form you chest during the rest of the days or at night? (Y/N) ..... ☐ RDS06

   If **yes (Y)**, to any of the about (4, 5, 6), answer the following:

   6a) Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS06A

   6b) For how many years have you had trouble with phlegm? ..... ☐☐ y RDS06B

7) In the past 12 months, have you had periods or episodes of cough with phlegm that lasted 1 week or more? (If you usually have cough and phlegm, please count only periods or episodes of increased cough and phlegm). (Y/N) ..... ☐ RDS07

7a) If **yes (Y)**, about how many such episodes have you had in the past 12 months? ..... ☐☐ RDS07A

7b) If **yes (Y)**, for how many years have you had at least one such episode per years? ..... ☐☐ RDS07B

8) Have you ever had wheezing or whistling in your chest? (Y/N) (If **NO**, go to 11) ..... ☐ RDS08

8a) If **yes (Y)**, about how old were you when you first had wheezing or whistling in your chest? ..... ☐☐ yrs WHEEZINGAGE

9) Have you ever had an attack of wheezing or whistling in your chest that made you feel short of breath? (Y/N) ..... ☐ RDS09

9a) If **yes (Y)**, about how old were you when you had your first such attack? ..... ☐☐ RDS09A

9b) Have you ever had 2 or more such attacks? (Y/N) ..... ☐ RDS09B

9c) Have you ever required medicine or treatment for such attacks? (Y/N) ..... ☐ RDS09C

10) In the last 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDS10

10a) If **yes (Y)**, in the last 12 months, does your chest ever should wheezy or whistling…

When you have a cold?	☐ Yes	☐ No	RDS10A1
Occasionally apart from colds?	☐ Yes	☐ No	RDS10A2
More than once a week?	☐ Yes	☐ No	RDS10A3
Most days or nights?	☐ Yes	☐ No	RDS10A4

11) In the last 12 months, have you been awakened from sleep by coughing, apart from a cough associated with a cold or chest infection? (Y/N) ..... ☐ RDS11

12) In the last 12 months, have you been awakened from sleep by shortness of breath or a feeling of tightness in your chest? (Y/N) ..... ☐ RDS12

Questions 13-14 are about symptoms that occur when you do not have a cold of the flu.

13) In the past 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDS13

14) In the past 12 months, have you been bothered by watery, itchy, or burning eye when you did now have a cold or the flu? (Y/N) ..... ☐ RDS14

15) Are you unable to walk due to a condition other than shortness of breath? (Y/N) ..... ☐ RDS15

Nature of condition: NATURECONDITION _____

These next questions relate to respiratory conditions

16) Have you ever had asthma? ..... ☐ RDS16

Yes ..... Y
No ..... N → **Go to Item 17**
Don't know ..... U → **Go to Item 17**

16a) At about what age did it start? ..... ☐☐ RDS16A

☐ As a child; age not known (Check is appropriate) RDS16A1

16b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS16B

16c) Do you still have it? (Y/N/U) ..... ☐ RDS16C

16d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS16D

☐ As a child; age not known (Check is appropriate) RDS16D1

16e) In the past 12 months, have you received medical treatment, take medications or used an inhaler for asthma? (Y/N) ..... ☐ RDS16E

17) Have you ever had any hay fever (allergy involving the nose and/or eyes)? ..... ☐ RDS17

Yes ..... Y
No ..... N → **Go to Item 18**
Don't know ..... U → **Go to Item 18**

17a) At about what age did it start? ..... ☐☐ RDS17A

☐ As a child; age not known (Check is appropriate) RDS17A1

17b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS17B

17c) Do you still have it? (Y/N/U) ..... ☐ RDS17C

17d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS17D

☐ As a child; age not known (Check is appropriate) RDS17D1

17e) In the past 12 months, have you received medical treatment, take medications or used a nasal spray for hay fever? (Y/N) ..... ☐ RDS17E

18) Have you ever had an attack of bronchitis? ..... ☐ RDS18

Yes ..... Y
No ..... N → **Go to Item 19**
Don't know ..... U → **Go to Item 19**

18a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS18A

18b) At about what age did you first have bronchitis? ..... ☐☐ RDS18B

☐ As a child; age not known (Check is appropriate) RDSB1

18c) How many time have you had bronchitis? ..... ☐☐ times RDS18C

19) Have you ever had pneumonia or bronchopneumonia? ☐ RDS19

Yes ..... Y
No ..... N → **Go to Item 20**
Don't know ..... U → **Go to Item 20**

19a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDS19A

19b) At about what age did you first have pneumonia or bronchopneumonia? ☐☐ RDS19B

☐ As a child; age not known (Check is appropriate) RDS19B1

19c) How many time have you had pneumonia or bronchopneumonia? ☐☐ times RDS19C

20) Have you ever had chronic bronchitis? ☐ RDS20

Yes ..... Y
No ..... N → **Go to Item 21**
Don't know ..... U → **Go to Item 21**

20a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDS20A

20b) At about what age did it start? ☐☐ RDS20B

20c) Do you still have it? (Y/N/U) ☐ RDS20C

20d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for chronic bronchitis? (Y/N) ☐ RDS20D

21) Have you ever had emphysema? ☐ RDS21

Yes ..... Y
No ..... N → **Go to Item 22**
Don't know ..... U → **Go to Item 22**

21a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDS21A

21b) At about what age did it start? ☐☐ RDS21B

21c) Do you still have it? (Y/N/U) ☐ RDS21C

21d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for emphysema? (Y/N) ☐ RDS21D

22) Have you ever had COPD (chronic obstructive pulmonary disease)? ☐ RDS22

Yes ..... Y
No ..... N → **Go to Item 23**
Don't know ..... U → **Go to Item 23**

22a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ☐ RDS22A

22b) At about what age did it start? ☐☐ RDS22B

22c) Do you still have it? (Y/N/U) ☐ RDS22C

22d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for COPD? (Y/N) ☐ RDS22D

23) Have you ever had sleep apnea? ..... ☐ RDS23

Yes ..... Y
No ..... N → **Go to Item 24**
Don't know ..... U → **Go to Item 24**

23a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS23A

23b) At about what age did it start? ..... ☐☐ RDS23B

23c) Do you still have it? (Y/N/U) ..... ☐ RDS23C

23d) In the past 12 months, have you received any treatment for sleep apnea? (Y/N) ..... ☐ RDS23D

24) Have you ever had:

24a) Any other chest illnesses? (Y/N) ..... ☐ RDS24A

If **Yes (Y)**, specify: RDS24A1 _____

24b) Any chest operations? (Y/N) ..... ☐ RDS24B

If **Yes (Y)**, specify: RDS24B1 _____

24c) Any chest injuries? (Y/N) ..... ☐ RDS24C

If **Yes (Y)**, specify: RDS24C1 _____

I'd now like to ask you about your family history or respiratory disease.

25) Were either of you natural parents told by a doctor they had a chronic lung condition such as:

	Father			Mother		
	YES	NO	Don't Know	YES	NO	Don't Know
Chronic bronchitis	☐	☐	☐ RDS25A1	☐	☐	☐ RDS25B1
Emphysema	☐	☐	☐ RDS25A2	☐	☐	☐ RDS25B2
COPD	☐	☐	☐ RDS25A3	☐	☐	☐ RDS25B3
Asthma	☐	☐	☐ RDS25A4	☐	☐	☐ RDS25B4
Lung Cancer	☐	☐	☐ RDS25A5	☐	☐	☐ RDS25B5

26) Were either of your natural parents ever a cigarette smoker?

Father: ☐ Yes ☐ No ☐ Don't know RDS26A
Mother: ☐ Yes ☐ No ☐ Don't know RDS26B

I am now going to ask you about some common environmental exposes.
[Do not read] Cigarette Smoking

27) Have you ever smoked cigarettes? (No means less than 20 packs of cigarettes of 12 oz. of tobacco in a lifetime of less than 1 cigarette a day for one year at any time in your life) ..... ☐ RDS27

Yes ..... Y
No ..... N → **Go to Item 34**

28) How old were you when you first started regular cigarette smoking? ..... ☐☐ RDS28

29) Do you smoke cigarettes (as of one month ago)? (Y/N)..... ☐ RDS29

Yes ..... Y → **Go to Item 30**
No ..... N → **Go to Item 31**

30) How many cigarettes do you smoke per day now? ..... ☐☐ RDS30

31) How old were you when you completely stopped smoking? ..... ☐☐ RDS31 yrs old

32) On average of the entire time you smoked, how many cigarettes did you smoke per day? ..... ☐☐ RDS32 per day

33) Cigarettes smoke in the past 24 hours: (check here ☐ if does not apply) RDS33

Approximately how many cigarettes have you smoked in the past

☐☐ in 24 hours RDS33A

☐☐ in 2 hours RDS33B

☐☐ in ½ hour RDS33C

[Do not read] Pipe Smoking

34) Have you ever smoked a pipe regularly? (**YES** means more than 12 oz of tobacco in a lifetime)..... ☐ RDS34

Yes ..... Y
No ..... N → **Go to Item 40**

35) How old were you when you first started to smoke a pipe regularly?..... ☐☐ RDS35

36) Do you smoke a pipe (as of one month ago)? (Y/N) ..... ☐ RDS36

Yes ..... Y → **Go to Item 37**
No ..... N → **Go to Item 38**

37) How much pipe tobacco do you smoke per day now? ..... ☐☐ RDS37 oz per day

38) How old were you when you completely stopped smoking a pipe? ..... ☐☐ RDS38 yrs old

39) On average of the entire time you smoked a pipe, how many ounces of tobacco did you smoke per week?..... ☐☐ RDS39 oz per week

[Do not read] Cigar Smoking

40) Have you ever smoked cigars regularly? (**YES** means more than 1 cigar a week for one year at any time in your life) ..... [ ] RDS40

Yes ..... Y
No ..... N → **Go to Item 46**

41) How old were you when you first started to smoke cigars regularly? ..... [ ][ ] RDS41

42) Do you now smoke cigars (as of one month ago)? (Y/N) ..... [ ] RDS42

Yes ..... Y → **Go to Item 43**
No ..... N → **Go to Item 44**

43) How many cigars smoke per day now? ..... [ ][ ] per day RDS43

44) How old were you when you completely stopped smoking cigars? ..... [ ][ ] yrs old RDS44

45) On average of the entire time you smoked cigars, how many cigars did you smoke per week? ..... [ ][ ] per week RDS45

I'd now like to ask you about your second-hand smoke exposures.

46) Which of the following best describes your approach to tobaccos smoking your home when you are in the house? ..... [ ] RDS46

Never allow smoking in home 1
Smoking is allowed only in certain rooms 2
Smoking is allowed in all rooms of your home 3
Refused ..... R
Don't Know ..... D

47) For how many years has this been your approach to smoking in you home? ..... [ ][ ] yrs RDS47A

Refused ..... R RDS47B
Don't Know ..... D

48) Do you currently live in the same household with someone who smokes tobacco products? ..... [ ] RDS48

Yes ..... Y → **Go to Item 50**
No ..... N → **Go to Item 49**
Refused ..... R → **Go to Item 52**
Don't Know ..... D → **Go to Item 52**

49) Since age 18, have you ever lived in the same household with someone who smoked tobacco products? ..... [ ][ ] yrs RDS49

Yes ..... 1 → **Go to Item 51**
No ..... 0 → **Go to Item 52**

Refused ..... R → **Go to Item 52**
Don't know ..... D → **Go to Item 52**

50) How many people in your household smoke? ..... ☐☐ RDS50

51) Since age 18, for haw many years in total have you lived in the same household with someone else who smoke tobacco products? ..... ☐☐ yrs RDS51A

Refused ..... R
Don't know ..... D RDS51B

52) Growing up until age 18, were there any adults in your household who smoked at home? ..... ☐ RDS52

Yes ..... Y
No ..... N → **Go to Item 54**
Refused ..... R → **Go to Item 54**
Don't Know ..... D → **Go to Item 54**

53) Was this your father, your mother, or someone else? *(check all that apply)*

Father ..... ☐ RDS53FATHERCBI
Mother ..... ☐ → **Answer Item 54** RDS53MOTHERCBI
Other ..... ☐ RDS53OTHERCBI
Refused ..... ☐ RDS53REFUSEDCBI
Don't Know ..... ☐ RDS53NOTKNOWCBI

54) Did your mother smoke cigarettes when she was pregnant with you before you were born? ..... ☐ RDS55

Yes ..... Y
No ..... N
Refused ..... R
Don't know ..... D

55) Growing up until age 18, for how many years in total did you live in the same household with someone else who smoked tobacco products? ..... ☐☐ yrs RDS55A

Refused ..... R
Don't Know ..... D RDS55B

I would now like to ask you about any smoke exposure that may have occurred in the past seven days.

56) Has anyone smoked tobacco in your home during the past seven days? ..... ☐ RDS56

Yes ..... Y
No ..... N → **Go to Item 64**
No Answer ..... U

57) During the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke at home? ..... ☐☐ hrs RDS57

58) During the past 7 days, did you enter a room in your home that was visibly smoky? ..... ☐ RDS58

Yes ..... Y
No..... N
No Answer ..... U

59) In the past 7 days, did you smell tobacco smoke in your home? (Y/N/U) ..... ☐ RDS59

60) During the past 7 days, did you experience red eyes or eye irritation? (Y/N/U)..... ☐ RDS60

61) During the past 7 days, did you experience runny nose or nose irritation? (Y/N/U)..... ☐ RDS61

62) During the past 7 days, did you experience coughing, wheezing or chest tightness? (Y/N/U) ..... ☐ RDS62

63) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your home? (Y/N/U)..... ☐ RDS637

64) In the past 7 days, have you visited another person's home where someone was smoking tobacco products indoors? (Y/N/U)..... ☐ RDS64 **If N or U skip to 66**

65) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in another person's home?..... ☐☐ hrs RDS65

66) During the past 7 days, did you enter a room in another person's home that was visibly smoky? (Y/N/U)..... ☐ RDS66

67) In the past 7 days, did you smell tobacco smoke in another person's home? (Y/N/U) ..... ☐ RDS67

You answered that you were exposed to someone else's tobacco smoke in another person's home. During the past 7 days, did you experience any of the following after this exposure?

If No to Q64, Q66, and Q67, skip questions 68-71:

68)Red eyes or eye irritations? (Y/N/U)..... ☐ RDS68

69) Runny nose or nose irritation? (Y/N/U)..... ☐ RDS69

70) Coughing, wheezing, or chest tightness? (Y/N/U)..... ☐ RDS70

71) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in another person's home? (Y/N/U)..... ☐ RDS71

72) In the past 7 days, have you traveled by car or other vehicle with someone else who was smoking tobacco products? (Y/N/U) ..... ☐ RDS72 **If N or U skip to 78**

73) In the past 7 days, how many hours did you spend traveling in a car while someone else was smoking tobacco? ..... ☐☐ hrs RDS73

You answered that you were exposed to someone else's tobacco smoke while traveling by car. During the pas 7 days, did you experience any of the following after this exposure?

If No to Q72, skip questions 74-77:

74) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS74

75) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS75

76) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS76

77) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in a car? (Y/N/U) ..... ☐ RDS77

[Do not read] IF NOT A WORKER SKIP TO 102

78) During the past 7 days, did anyone smoke tobacco inside your workplace, that is, while you were working indoors? (Y/N/U) ..... ☐ RDS78 **If N or U skip to 80**

79) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke inside your workplace? ..... ☐☐ hrs RDS79

80) During the past 7 days, did you enter a room in your workplace that was visibly smoky? ..... ☐ RDS80

81) In the past 7 days, did you smell tobacco smoke in your workplace? ..... ☐ RDS81

You answered that you were exposed to someone else's tobacco smoke in your workplace. During the past 7 days, did you experience any of the following after this exposure?

If No to Q78, Q80, and Q81, skip questions 82-85:

82) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS82

83) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS83

84) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS84

85) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your workplace? (Y/N/U) ..... ☐ RDS85

86) Is there an outdoor area at your workplace where cigarette smokers routinely gather or congregate to smoke? (Y/N/U) ..... ☐ RDS86 **If N or U skip to 94**

87) In the past 7 days, how many times did you walk through or past this area while others were smoking? (Y/N/U) ..... ☐ RDS87

88) During the past 7 days, how many hours in total did you spend in an outdoor smoking area while people were smoking? (Y/N/U) ..... ☐ RDS88

89) While walking through or past this area, did you smell smoke? (Y/N/U) ..... ☐ RDS89

In the past 7 days, did you walking through or past this area result in your experiencing any of the following:

If No to Q86, skip questions 90-93:

90) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS90

91) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS91

92) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS92

93) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after walking through or past this area? (Y/N/U) ..... ☐ RDS93

94) Do your job duties directly involve working outdoors one or more hours per week? ..... ☐ RDS94

95) In the past 7 days, how many hours did you spend near coworkers who were smoking tobacco outdoors? ..... ☐ RDS95

96) During the past 7 days, did you smell tobacco smoke while working outdoors? ..... ☐ RDS96

You answered that you were exposed to your coworker's tobacco smoke while working outdoors. During the past 7 days, did you experience any of the following after this exposure?

If No to Q95 and Q96, skip questions 97-100:

97) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS97

98) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS98

99) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS99

100) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke outside? (Y/N/U) ..... ☐ RDS100

101) In the past seven days, have you been at an outdoor location (besides work) where someone was smoking tobacco products outside? (Y/N/U) ..... ☐ RDS101 **If N or U skip to 103**

102) Where was this location? RDS102 _____

103) During the past 7 days, did you smell tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDS103 **If N or U skip to 103**

104) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke this outdoor location? ..... ☐☐ hrs RDS104

During the past 7 days, did you experience any of the following after this outdoor exposure:
If No to Q101 and Q103, skip questions 105-108:

105) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS105

106) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS106

107) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS107

108) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDS108

109) In the past seven days or nights, were you in a bar, nightclub, cocktail lounge, sports arena, or concert hall where someone else was smoking tobacco products? (Y/N/U) ..... ☐ RDS109 **If N or U skip to 111**

110) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in a bar or other place of entertainment? ..... ☐☐ hrs RDS110

111) During the past 7 days, did you enter a room in a bar or other place of entertainment that was visibly smoky? (Y/N/U) ..... ☐ RDS111

112) In the past 7 days, did you smell tobacco smoke in a bar or other place of entertainment? ..... ☐ RDS112

You answered that you were exposed to someone else's tobacco smoke in a bar or other place of entertainment. During the past 7 days, did you experience any of the following after this exposure
If No to Q109, Q111, and Q112. skip questions 113-116:

113) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS113

114) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS114

115) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS115

116) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in a bar or other place of entertainment? (Y/N/U) ..... ☐ RDS116

117) I have asked you about exposure to someone else's tobacco some in your home, friend's home, work, outdoor locations, and bars or nightclubs. In the past 7 days, was there any other location where you were exposed to tobacco smoke? (Y/N/U) ..... ☐ RDS117 **If N or U skip to end**

118) Where was this location? (Y/N/U) ..... ☐ RDS118

119) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in this location? (Y/N/U) ..... ☐ RDS119

During the past 7 days, did you experience any of the following after this outdoor exposure:

120) Red eyes or eye irritation? (Y/N/U) RDS120

121) Runny nose or nose irritation? (Y/N/U) RDS121

122) Coughing, wheezing, or chest tightness? (Y/N/U) RDS122

123) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in this location? (Y/N/U) RDS123

I would now like to ask you about any smoke exposure that may have occurred as a result of marijuana use. Please remember that all information that you give us is confidential, and only certified SPIROMICS personnel will have access to this information.

124) Have you ever smoked marijuana (cannabis, pot, or hashish)? RDS124

Yes .....Y

No.....N →**Go to END**

125) Have you ever smoked marijuana regularly (five times or more in a given year)? RDS125

Yes .....Y

No.....N

126) On average over the entire time that you smoke(d) about how many joints per week do (did) you smoke?..... RDS126

127) On average over the entire time that you smoke(d) about how many pipes per week do (did) you smoke?..... RDS127

128) How many years have you smoked pot/marijuana?..... yrs RDS128

129) Have you smoked marijuana in the last 12 months?..... RDS129

Yes .....Y

No.....N

RESPIRATORY DISEASE AND SMOKE EXPOSURE QUESTIONNAIRE

ID NUMBER: BLINDID

FORM CODE: RDS
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a) Form Date ..... __ __/__ __/__ __ __ __ RDS0A

0b) Initials..... __ __ __ RDS0BNUM

Instructions: *This form should be completed during the participant's visit. Please answer all questions.*

I would now like to ask you detailed questions about your experiences with respiratory disease and smoke exposure.

The following questions relate to respiratory symptoms.

1) Do you usually have a cough? (Exclude clearing of throat.) (Y/N) ..... ☐ RDS01

1a) If **yes (Y)**, do you usually cough as much as 4 times a day, 4 or more days out of the week? ..... ☐ RDS01A

2) Do you usually cough at all on getting up or first thing in the morning? (Y/N) ..... ☐ RDS02

3) Do you usually cough at all during the rest of the day or night? (Y/N) ..... ☐ RDS03

If **yes (Y)** to any of the above (1, 2, 3), answer the following:

3a) Do you cough like this on most days, for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS03A

3b) For how many years have you had this cough? ..... ☐☐ RDS03B

4) Do you usually bring up phlegm from your chest? (Y/N) ..... ☐ RDS04

4a) If **yes (Y)**, do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week? (Y/N) ..... ☐ RDS04A

5) Do you usually bring up phlegm from your chest on getting up, or first thing in the morning? (Y/N) ..... ☐ RDS05

6) Do you usually bring up phlegm form you chest during the rest of the days or at night? (Y/N) ..... ☐ RDS06

If **yes (Y)**, to any of the about (4, 5, 6), answer the following:

6a) Do you bring up phlegm like this on most days for 3 consecutive months or more during the year? (Y/N) ..... ☐ RDS06A

6b) For how many years have you had trouble with phlegm? ..... ☐☐ RDS06B

7) In the past 12 months, have you had periods or episodes of cough with phlegm that lasted 1 week or more? (If you usually have cough and phlegm, please count only periods or episodes of increased cough and phlegm). (Y/N) ..... ☐ RDS07

7a) If **yes (Y)**, about how many such episodes have you had in the past 12 months? ..... ☐☐ RDS07A

7b) If **yes (Y)**, for how many years have you had at least one such episode per years? ..... ☐☐ RDS07B

8) Have you ever had wheezing or whistling in your chest? (Y/N) (If **NO**, go to 11) ..... ☐ RDS08

8a) If **yes (Y)**, about how old were you when you first had wheezing or whistling in your chest? ..... ☐☐ yrs WHEEZINGAGE

9) Have you ever had an attack of wheezing or whistling in your chest that made you feel short of breath? (Y/N) ..... ☐ RDS09

9a) If **yes (Y)**, about how old were you when you had your first such attack? ..... ☐☐ RDS09A

9b) Have you ever had 2 or more such attacks? (Y/N) ..... ☐ RDS09B

9c) Have you ever required medicine or treatment for such attacks? (Y/N) ..... ☐ RDS09C

10) In the last 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDS10

10a) If **yes (Y)**, in the last 12 months, does your chest ever should wheezy or whistling…

When you have a cold?	☐ Yes	☐ No	RDS10A1
Occasionally apart from colds?	☐ Yes	☐ No	RDS10A2
More than once a week?	☐ Yes	☐ No	RDS10A3
Most days or nights?	☐ Yes	☐ No	RDS10A4

11) In the last 12 months, have you been awakened from sleep by coughing, apart from a cough associated with a cold or chest infection? (Y/N) ..... ☐ RDS11

12) In the last 12 months, have you been awakened from sleep by shortness of breath or a feeling of tightness in your chest? (Y/N) ..... ☐ RDS12

Questions 13-14 are about symptoms that occur when you do not have a cold of the flu.

13) In the past 12 months, have you had wheezing or whistling in your chest at any time? (Y/N) ..... ☐ RDS13

14) In the past 12 months, have you been bothered by watery, itchy, or burning eye when you did now have a cold or the flu? (Y/N) ..... ☐ RDS14

15) Are you unable to walk due to a condition other than shortness of breath? (Y/N) ..... ☐ RDS15

Nature of condition: NATURECONDITION _____

These next questions relate to respiratory conditions

16) Have you ever had asthma? ..... ☐ RDS16

Yes ..... Y
No ..... N → **Go to Item 17**
Don't know ..... U → **Go to Item 17**

16a) At about what age did it start? ..... ☐☐ RDS16A

☐ As a child; age not known (Check is appropriate) RDS16A1

16b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS16B

16c) Do you still have it? (Y/N/U) ..... ☐ RDS16C

16d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS16D

☐ As a child; age not known (Check is appropriate) RDS16D1

16e) In the past 12 months, have you received medical treatment, take medications or used an inhaler for asthma? (Y/N) ..... ☐ RDS16E

17) Have you ever had any hay fever (allergy involving the nose and/or eyes)? ..... ☐ RDS17

Yes ..... Y
No ..... N → **Go to Item 18**
Don't know ..... U → **Go to Item 18**

17a) At about what age did it start? ..... ☐☐ RDS17A

☐ As a child; age not known (Check is appropriate) RDS17A1

17b) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS17B

17c) Do you still have it? (Y/N/U) ..... ☐ RDS17C

17d) If you no longer have it, at what age did it stop? ..... ☐☐ RDS17D

☐ As a child; age not known (Check is appropriate) RDS17D1

17e) In the past 12 months, have you received medical treatment, take medications or used a nasal spray for hay fever? (Y/N) ..... ☐ RDS17E

18) Have you ever had an attack of bronchitis? ..... ☐ RDS18

Yes ..... Y
No ..... N → **Go to Item 19**
Don't know ..... U → **Go to Item 19**

18a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS18A

18b) At about what age did you first have bronchitis? ..... ☐☐ RDS18B

☐ As a child; age not known (Check is appropriate) RDSB1

18c) How many time have you had bronchitis? ..... ☐☐ times RDS18C

19) Have you ever had pneumonia or bronchopneumonia? ..... ☐ RDS19

Yes ..... Y
No ..... N → **Go to Item 20**
Don't know ..... U → **Go to Item 20**

19a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS19A

19b) At about what age did you first have pneumonia or bronchopneumonia? ..... ☐☐ RDS19B

☐ As a child; age not known (Check is appropriate) RDS19B1

19c) How many time have you had pneumonia or bronchopneumonia? ..... ☐☐ times RDS19C

20) Have you ever had chronic bronchitis? ..... ☐ RDS20

Yes ..... Y
No ..... N → **Go to Item 21**
Don't know ..... U → **Go to Item 21**

20a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS20A

20b) At about what age did it start? ..... ☐☐ RDS20B

20c) Do you still have it? (Y/N/U) ..... ☐ RDS20C

20d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for chronic bronchitis? (Y/N) ..... ☐ RDS20D

21) Have you ever had emphysema? ..... ☐ RDS21

Yes ..... Y
No ..... N → **Go to Item 22**
Don't know ..... U → **Go to Item 22**

21a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS21A

21b) At about what age did it start? ..... ☐☐ RDS21B

21c) Do you still have it? (Y/N/U) ..... ☐ RDS21C

21d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for emphysema? (Y/N) ..... ☐ RDS21D

22) Have you ever had COPD (chronic obstructive pulmonary disease)? ..... ☐ RDS22

Yes ..... Y
No ..... N → **Go to Item 23**
Don't know ..... U → **Go to Item 23**

22a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS22A

22b) At about what age did it start? ..... ☐☐ RDS22B

22c) Do you still have it? (Y/N/U) ..... ☐ RDS22C

22d) In the past 12 months, have you received medical treatment, take medications or used a inhaler for COPD? (Y/N) ..... ☐ RDS22D

23) Have you ever had sleep apnea? ..... ☐ RDS23

Yes ..... Y
No ..... N → **Go to Item 24**
Don't know ..... U → **Go to Item 24**

23a) Was it diagnosed by a doctor or other health professional? (Y/N/U) ..... ☐ RDS23A

23b) At about what age did it start? ..... ☐☐ RDS23B

23c) Do you still have it? (Y/N/U) ..... ☐ RDS23C

23d) In the past 12 months, have you received any treatment for sleep apnea? (Y/N) ..... ☐ RDS23D

24) Have you ever had:

24a) Any other chest illnesses? (Y/N) ..... ☐ RDS24A

If **Yes (Y)**, specify: RDS24A1 _____

24b) Any chest operations? (Y/N) ..... ☐ RDS24B

If **Yes (Y)**, specify: RDS24B1 _____

24c) Any chest injuries? (Y/N) ..... ☐ RDS24C

If **Yes (Y)**, specify: RDS24C1 _____

I'd now like to ask you about your family history or respiratory disease.

25) Were either of you natural parents told by a doctor they had a chronic lung condition such as:

	Father				Mother			
	YES	NO	Don't Know		YES	NO	Don't Know	
Chronic bronchitis	☐	☐	☐	RDS25A1	☐	☐	☐	RDS25B1
Emphysema	☐	☐	☐	RDS25A2	☐	☐	☐	RDS25B2
COPD	☐	☐	☐	RDS25A3	☐	☐	☐	RDS25B3
Asthma	☐	☐	☐	RDS25A4	☐	☐	☐	RDS25B4
Lung Cancer	☐	☐	☐	RDS25A5	☐	☐	☐	RDS25B5

26) Were either of your natural parents ever a cigarette smoker?

Father: ☐ Yes ☐ No ☐ Don't know RDS26A
Mother: ☐ Yes ☐ No ☐ Don't know RDS26B

I am now going to ask you about some common environmental exposes.
[Do not read] Cigarette Smoking

27) Have you ever smoked cigarettes? (No means less than 20 packs of cigarettes of 12 oz. of tobacco in a lifetime of less than 1 cigarette a day for one year at any time in your life) ..... ☐ RDS27

Yes ..... Y
No ..... N → **Go to Item 34**

28) How old were you when you first started regular cigarette smoking? ..... ☐☐ RDS28

29) Do you smoke cigarettes (as of one month ago)? (Y/N)..... ☐ RDS29

Yes ..... Y → **Go to Item 30**
No ..... N → **Go to Item 31**

30) How many cigarettes do you smoke per day now? ..... ☐☐ RDS30

31) How old were you when you completely stopped smoking? ..... ☐☐ RDS31 yrs old

32) On average of the entire time you smoked, how many cigarettes did you smoke per day? ..... ☐☐ RDS32 per day

33) Cigarettes smoke in the past 24 hours: (check here ☐ if does not apply) RDS33

Approximately how many cigarettes have you smoked in the past

☐☐ in 24 hours RDS33A

☐☐ in 2 hours RDS33B

☐☐ in ½ hour RDS33C

[Do not read] Pipe Smoking

34) Have you ever smoked a pipe regularly? (**YES** means more than 12 oz of tobacco in a lifetime)..... ☐ RDS34

Yes ..... Y
No ..... N → **Go to Item 40**

35) How old were you when you first started to smoke a pipe regularly?..... ☐☐ RDS35

36) Do you smoke a pipe (as of one month ago)? (Y/N) ..... ☐ RDS36

Yes ..... Y → **Go to Item 37**
No ..... N → **Go to Item 38**

37) How much pipe tobacco do you smoke per day now? ..... ☐☐ RDS37 oz per day

38) How old were you when you completely stopped smoking a pipe? ..... ☐☐ RDS38 yrs old

39) On average of the entire time you smoked a pipe, how many ounces of tobacco did you smoke per week?..... ☐☐ RDS39 oz per week

[Do not read] Cigar Smoking

40) Have you ever smoked cigars regularly? (**YES** means more than 1 cigar a week for one year at any time in your life) ..... [ ] RDS40

Yes ..... Y
No ..... N → **Go to Item 46**

41) How old were you when you first started to smoke cigars regularly? ..... [ ][ ] RDS41

42) Do you now smoke cigars (as of one month ago)? (Y/N) ..... [ ] RDS42

Yes ..... Y → **Go to Item 43**
No ..... N → **Go to Item 44**

43) How many cigars smoke per day now? ..... [ ][ ] per day RDS43

44) How old were you when you completely stopped smoking cigars? ..... [ ][ ] yrs old RDS44

45) On average of the entire time you smoked cigars, how many cigars did you smoke per week? ..... [ ][ ] per week RDS45

I'd now like to ask you about your second-hand smoke exposures.

46) Which of the following best describes your approach to tobaccos smoking your home when you are in the house? ..... [ ] RDS46

Never allow smoking in home 1
Smoking is allowed only in certain rooms 2
Smoking is allowed in all rooms of your home 3
Refused ..... R
Don't Know ..... D

47) For how many years has this been your approach to smoking in you home? ..... [ ][ ] yrs RDS47A

Refused ..... R
Don't Know ..... D
RDS47B

48) Do you currently live in the same household with someone who smokes tobacco products? ..... [ ] RDS48

Yes ..... Y → **Go to Item 50**
No ..... N → **Go to Item 49**
Refused ..... R → **Go to Item 52**
Don't Know ..... D → **Go to Item 52**

49) Since age 18, have you ever lived in the same household with someone who smoked tobacco products? ..... [ ][ ] yrs RDS49

Yes ..... 1 → **Go to Item 51**
No ..... 0 → **Go to Item 52**

Refused ..... R→**Go to Item 52**
Don't know ..... D→**Go to Item 52**

50) How many people in your household smoke? ..... ☐☐ RDS50

51) Since age 18, for haw many years in total have you lived in the same household with someone else who smoke tobacco products? ..... ☐☐ yrs RDS51A

Refused ..... R RDS51B
Don't know ..... D

52) Growing up until age 18, were there any adults in your household who smoked at home? ..... ☐ RDS52

Yes ..... Y
No ..... N →**Go to Item 54**
Refused ..... R →**Go to Item 54**
Don't Know ..... D →**Go to Item 54**

53) Was this your father, your mother, or someone else? *(check all that apply)*

Father ..... ☐ RDS53FATHERCBI
Mother ..... ☐ →**Answer Item 54** RDS53MOTHERCBI
Other ..... ☐ RDS53OTHERCBI
Refused ..... ☐ RDS53REFUSEDCBI
Don't Know ..... ☐ RDS53NOTKNOWCBI

54) Did your mother smoke cigarettes when she was pregnant with you before you were born? ..... ☐ RDS55

Yes ..... Y
No ..... N
Refused ..... R
Don't know ..... D

55) Growing up until age 18, for how many years in total did you live in the same household with someone else who smoked tobacco products? ..... ☐☐ yrs RDS55A

Refused ..... R RDS55B
Don't Know ..... D

I would now like to ask you about any smoke exposure that may have occurred in the past seven days.

56) Has anyone smoked tobacco in your home during the past seven days? ..... ☐ RDS56

Yes ..... Y
No ..... N→**Go to Item 64**
No Answer ..... U

57) During the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke at home? ..... ☐☐ hrs RDS57

58) During the past 7 days, did you enter a room in your home that was visibly smoky? ..... ☐ RDS58

Yes ..... Y
No..... N
No Answer ..... U

59) In the past 7 days, did you smell tobacco smoke in your home? (Y/N/U) ..... ☐ RDS59

60) During the past 7 days, did you experience red eyes or eye irritation? (Y/N/U)..... ☐ RDS60

61) During the past 7 days, did you experience runny nose or nose irritation? (Y/N/U)..... ☐ RDS61

62) During the past 7 days, did you experience coughing, wheezing or chest tightness? (Y/N/U) ..... ☐ RDS62

63) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your home? (Y/N/U)..... ☐ RDS637

64) In the past 7 days, have you visited another person's home where someone was smoking tobacco products indoors? (Y/N/U)..... ☐ RDS64 **If N or U skip to 66**

65) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in another person's home?..... ☐☐ hrs RDS65

66) During the past 7 days, did you enter a room in another person's home that was visibly smoky? (Y/N/U)..... ☐ RDS66

67) In the past 7 days, did you smell tobacco smoke in another person's home? (Y/N/U) ..... ☐ RDS67

You answered that you were exposed to someone else's tobacco smoke in another person's home. During the past 7 days, did you experience any of the following after this exposure?

If No to Q64, Q66, and Q67, skip questions 68-71:

68)Red eyes or eye irritations? (Y/N/U)..... ☐ RDS68

69) Runny nose or nose irritation? (Y/N/U)..... ☐ RDS69

70) Coughing, wheezing, or chest tightness? (Y/N/U)..... ☐ RDS70

71) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in another person's home? (Y/N/U)..... ☐ RDS71

72) In the past 7 days, have you traveled by car or other vehicle with someone else who was smoking tobacco products? (Y/N/U) ..... ☐ RDS72 **If N or U skip to 78**

73) In the past 7 days, how many hours did you spend traveling in a car while someone else was smoking tobacco? ..... ☐☐ hrs RDS73

You answered that you were exposed to someone else's tobacco smoke while traveling by car. During the pas 7 days, did you experience any of the following after this exposure?

If No to Q72, skip questions 74-77:

74) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS74

75) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS75

76) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS76

77) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in a car? (Y/N/U) ..... ☐ RDS77

[Do not read] IF NOT A WORKER SKIP TO 102

78) During the past 7 days, did anyone smoke tobacco inside your workplace, that is, while you were working indoors? (Y/N/U) ..... ☐ RDS78 **If N or U skip to 80**

79) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke inside your workplace? ..... ☐☐ hrs RDS79

80) During the past 7 days, did you enter a room in your workplace that was visibly smoky? ..... ☐ RDS80

81) In the past 7 days, did you smell tobacco smoke in your workplace? ..... ☐ RDS81

You answered that you were exposed to someone else's tobacco smoke in your workplace. During the past 7 days, did you experience any of the following after this exposure?

If No to Q78, Q80, and Q81, skip questions 82-85:

82) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS82

83) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS83

84) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS84

85) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in your workplace? (Y/N/U) ..... ☐ RDS85

86) Is there an outdoor area at your workplace where cigarette smokers routinely gather or congregate to smoke? (Y/N/U) ..... ☐ RDS86 **If N or U skip to 94**

87) In the past 7 days, how many times did you walk through or past this area while others were smoking? (Y/N/U) ..... ☐ RDS87

88) During the past 7 days, how many hours in total did you spend in an outdoor smoking area while people were smoking? (Y/N/U) ..... ☐ RDS88

89) While walking through or past this area, did you smell smoke? (Y/N/U) ..... ☐ RDS89

In the past 7 days, did you walking through or past this area result in your experiencing any of the following:

If No to Q86, skip questions 90-93:

90) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS90

91) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS91

92) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS92

93) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after walking through or past this area? (Y/N/U) ..... ☐ RDS93

94) Do your job duties directly involve working outdoors one or more hours per week? ..... ☐ RDS94

95) In the past 7 days, how many hours did you spend near coworkers who were smoking tobacco outdoors? ..... ☐ RDS95

96) During the past 7 days, did you smell tobacco smoke while working outdoors? ..... ☐ RDS96

You answered that you were exposed to your coworker's tobacco smoke while working outdoors. During the past 7 days, did you experience any of the following after this exposure?

If No to Q95 and Q96, skip questions 97-100:

97) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS97

98) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS98

99) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS99

100) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke outside? (Y/N/U) ..... ☐ RDS100

101) In the past seven days, have you been at an outdoor location (besides work) where someone was smoking tobacco products outside? (Y/N/U) ..... ☐ RDS101 **If N or U skip to 103**

102) Where was this location? RDS102 _____

103) During the past 7 days, did you smell tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDS103 **If N or U skip to 103**

104) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke this outdoor location? ..... ☐☐ hrs RDS104

During the past 7 days, did you experience any of the following after this outdoor exposure:
If No to Q101 and Q103, skip questions 105-108:

105) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS105

106) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS106

107) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS107

108) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in this outdoor location? (Y/N/U) ..... ☐ RDS108

109) In the past seven days or nights, were you in a bar, nightclub, cocktail lounge, sports arena, or concert hall where someone else was smoking tobacco products? (Y/N/U) ..... ☐ RDS109 **If N or U skip to 111**

110) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in a bar or other place of entertainment? ..... ☐☐ hrs RDS110

111) During the past 7 days, did you enter a room in a bar or other place of entertainment that was visibly smoky? (Y/N/U) ..... ☐ RDS111

112) In the past 7 days, did you smell tobacco smoke in a bar or other place of entertainment? ..... ☐ RDS112

You answered that you were exposed to someone else's tobacco smoke in a bar or other place of entertainment. During the past 7 days, did you experience any of the following after this exposure
If No to Q109, Q111, and Q112. skip questions 113-116:

113) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS113

114) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS114

115) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS115

116) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in a bar or other place of entertainment? (Y/N/U) ..... ☐ RDS116

117) I have asked you about exposure to someone else's tobacco some in your home, friend's home, work, outdoor locations, and bars or nightclubs. In the past 7 days, was there any other location where you were exposed to tobacco smoke? (Y/N/U) ..... ☐ RDS117 **If N or U skip to end**

118) Where was this location? (Y/N/U)..... ☐ RDS118

119) In the past 7 days, how many hours in total were you exposed to someone else's tobacco smoke in this location? (Y/N/U)..... ☐ RDS119

During the past 7 days, did you experience any of the following after this outdoor exposure:

120) Red eyes or eye irritation? (Y/N/U) ..... ☐ RDS120

121) Runny nose or nose irritation? (Y/N/U) ..... ☐ RDS121

122) Coughing, wheezing, or chest tightness? (Y/N/U) ..... ☐ RDS122

123) In the past 7 days, did you take any extra handheld spray inhalers for breathing or lung problems after exposure to tobacco smoke in this location? (Y/N/U) ..... ☐ RDS123

RESPIRATORY MEDICATION USE QUESTIONNAIRE

ID NUMBER: BLINDID

FORM CODE: RMU
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a) Form Date __/__/____ RMU0A 0b) Initials..... ___

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box.*

The following questions ask what medications you currently take or have taken in the past.

1) Are you currently using theophylline (Uniphyl, Theo-24, Slo-Bid)? (Y/N) ..... ☐ RMU01

2) Are you currently using oral corticosteroids (prednisone, Medrol, dexamethasone)? (Y/N)..... ☐ RMU02

   2a) How long have you been on this medication? ..... RMU02A1 years RMU02A2 days

3) Do you use supplemental oxygen (prescribed by your doctor) at home? RMU03

   Yes..... ☐
   No ..... ☐
   Only at Night..... ☐

   3a) Approximately how many hours in a 24 hour period?..... ☐☐ hours per day RMU03A

4) In the past 3 months, have you used inhaled steroids (not nasal steroids)? ..... ☐ RMU04

   Yes.....Y
   No .....N → **Go to Item 5**
   Don't know .....U → **Go to Item 5**

4a) Which inhaled steroid(s) have you used in the past 3 months?

		Yes		Puffs/day	No
1) Azmacort (triamcinolone)	RMU04A1	☐	→	RMU04A1A	☐
2) Beclovent (beclomethasone).....	RMU04A2	☐	→	RMU04A2A	☐
3) Vanceril (beclomethasone)	RMU04A3	☐	→	RMU04A3A	☐
☐ Regular Strength ☐ Double Strength	RMU04A3B				
4) AeroBid (blunisolide).....	RMU04A4	☐	→	RMU04A4A	☐

		Yes		Puffs/Day	No
5) Flovent (fluticasone).....	RMU04A5	☐	→	RMU04A5A	☐
☐ 44 Aerosol ☐ 110 Aerosol ☐ 220 Aerosol ☐ 100 Diskus ☐ 250 Diskus	RMU04A5B				
6) Pulmicort (budesonide)	RMU04A6	☐	→	RMU04A6A	☐
☐ 90 ☐ 180	RMU04A6B				
7) Qvar (beclomethasone).....	RMU04A7	☐	→	RMU04A7A	☐
☐ 40 ☐ 80	RMU04A7B				
8) Advair (bluticasone/salmeterol).....	RMU04A8	☐	→	RMU04A8A	☐
☐ 100/50 ☐ 250/50 ☐ 500/50 ☐ HFA 45/21 ☐ HFA 115/21 ☐ HFA 230/21	RMU04A8B				
9) Symbicort.....	RMU04A9	☐	→	RMU04A9A	☐
☐ 80/4.5 ☐ 160/4.5	RMU04A9B				
10) Other, specify:.....	RMU04A10	☐	→	RMU04A10A	☐

RMU04A10B

_____

5) Have you used inhaled bronchodilators in the past 3 months? ..... ☐ RMU05

Yes.....Y
No.....N → **Go to Item 6**
Don't know.....U → **Go to Item 6**

5a) Which bronchodilators have you used in the past 3 months?

	Yes		Puffs/day	No	
1) albuterol (Proventil, Ventolin, ProAir). RMU05A1	☐	→	RMU05A1A	☐	
2) ipratropium bromide (Atrovent)..... RMU05A2	☐	→	RMU05A2A	☐	
3) ipratropium bromide/albuterol sulfate (Combivent)	☐	→	RMU05A3A	☐	RMU05A3
4) terbutaline (Brethaire, Brethine, Bricanyl).....	☐	→	RMU05A4A	☐	RMU05A4
5) formoterol (Foradil)..... RMU05A5	☐	→	RMU05A5A	☐	
6) tiotropium (Spiriva)..... RMU05A6	☐	→	RMU05A6A	☐	
7) salmeterol (Serevent Diskus)..... RMU05A7	☐	→	RMU05A7A	☐	
8) pirbuterol (Maxair)..... RMU05A8	☐	→	RMU05A8A	☐	
9) metaproterenol (Alupent, Metaprel).. RMU05A9	☐	→	RMU05A9A	☐	
10) levalbuterol (Tomalate)..... RMU05A10	☐	→	RMU05A10A	☐	
11) bitolterol (Tornalate)..... RMU05A11	☐	→	RMU05A11A	☐	
12) epinephrine (Primatene, Bronkaid). RMU05A12	☐	→	RMU05A12A	☐	
13) fluticasone/salmeterol (Advair Discus).....	☐	→	RMU05A13A	☐	RMU05A13
14) budesonide/formoterol (Symbicort) RMU05A14	☐	→	RMU05A14A	☐	
15) Other, specify..... RMU05A15.	☐	→	RMU05A15A	☐	

RMU05A15B _____

6) Have you used nebulized bronchodilators in the past 3 months? ..... ☐ RMU06

Yes.....Y
No.....N →**Go to Item 7**
Don't know.....U →**Go to Item 7**

6a) Which nebulized bronchodilators have you used in the past 3 months?

	Yes	No	
1) formoterol (Perforomist).....	☐	☐	RMU06A1
2) arformoterol (Brovana)	☐	☐	RMU06A2
3) albuterol and ipratropium bromide (DuoNeb).....	☐	☐	RMU06A3
4) albuterol (Proventil, Ventolin, ProAir).....	☐	☐	RMU06A4
5) ipratropium bromide (Atrovent).....	☐	☐	RMU06A5

7) Have you used a leukotriene antagonist (zafirlukast [Accolate], zileuton [Zyflo] or montelukast [Singulair]) in the past 3 months? ..... ☐ RMU07

Yes.....Y
No.....N
Don't know.....U

8) Have you used any statin medications in the past 3 months?..... ☐ RMU08

Yes.....Y
No.....N →**Go to Item 9**
Don't know.....U →**Go to Item 9**

8a) Which statin medications have you used in the past 3 months?

	Yes	No	
1) Crestor (resuvastatin).....	☐	☐	RMU08A1
2) Lescol (fluvastatin)	☐	☐	RMU08A2
3) Lipitor (atorvastatin).....	☐	☐	RMU08A3
4) Mevacor (lovastatin).....	☐	☐	RMU08A4
5) Pravachol (pravastatin).....	☐	☐	RMU08A5
6) Vytorin (ezetimibe, simvastatin).....	☐	☐	RMU08A6
7) Zocor (simvastatin).....	☐	☐	RMU08A7
8) Other, specify.....	☐	☐	RMU08A8

RMU08A8B _____

9) Have you used any beta-blocker medications in the past 3 months? ..... ☐ RMU09

Yes ..... Y
No ..... N → **Go to Item 10**
Don't know ..... U → **Go to Item 10**

9a) Which beta-blocker medications have you used in the past 3 months?

	Yes	No	
1) Atenolol (tenormin, tenoretic)	☐	☐	RMU09A1
2) Metoprolol (lopressor, toprol)	☐	☐	RMU09A2
3) Carvedilol (coreg)	☐	☐	RMU09A3
4) Labetalol (trandate, normodyne)	☐	☐	RMU09A4
5) Propranalol (Inderal, Inderide)	☐	☐	RMU09A5
6) Sotalol (Betapace, Sorine)	☐	☐	RMU09A6
7) timolol (Blocardren, timolide)	☐	☐	RMU09A7
8) bisoprolol (zebeta, ziac)	☐	☐	RMU09A8
9) pindolol (visken)	☐	☐	RMU09A9
10) Other, specify	☐	☐	RMU09A10

RMU09A10B _____

10) Have you used any oral anti-oxidant supplements in the past 3 months? ..... ☐ RMU10

Yes ..... Y
No ..... N → **Go to Item 11**
Don't know ..... U → **Go to Item 11**

10a) Which antioxidant medications have you used in the past 3 months?

	Yes	No	
1) Vitamin C (ascorbic acid)	☐	☐	RMU10A1
2) Vitamin E (alpha-tocopherol)	☐	☐	RMU10A2
3) beta carotene	☐	☐	RMU10A3
4) zinc	☐	☐	RMU10A4
5) copper	☐	☐	RMU10A5
6) fish oil	☐	☐	RMU10A6
7) omega 3	☐	☐	RMU10A7
8) Other, specify	☐	☐	RMU10A8

RMU10A8B _____

11) Are you currently using aspirin on a daily basis? ..... ☐ RMU11

Yes ..... Y
No ..... N

12) Please list any other medications you have used in the past 3 months that are not listed above:

12a) RMU12A _____

12b) RMU12B _____

12c) RMU12C _____

12d) RMU12D _____

12e) RMU12E _____

12f) RMU12F _____

12g) RMU12G _____

12h) RMU12H _____

12i) RMU12I _____

13) Please list any other supplements you have used in the past 3 months that are not listed above:

13a) RMU13A _____

13b) RMU13B _____

13c) RMU13C _____

13d) RMU13D _____

13e) RMU13E _____

13f) RMU13F _____

13g) RMU13G _____

13h) RMU13H _____

13i) RMU13I _____

REVIEW TRACKING FORM

ID NUMBER:									FORM CODE: **RTF** VERSION: **1.0** 01/20/16	Visit Number	VISIT	SEQ #	

0a. Form Completion Date.... ☐☐/☐☐/☐☐☐☐ RTF0A 0b. Staff Code ..... ☐☐☐ RTF0B

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ RTF0C 0d. Event Date: ☐☐/☐☐/☐☐☐☐ RTF0D

PART A: Reviewer Assignment

1. Reviewer 1: ☐☐☐ RTF1
2. Date Assigned: ☐☐/☐☐/☐☐☐☐ RTF2
3. Review Complete: Yes ☐ No ☐ RTF3
4. Reviewer 2: ☐☐☐ RTF4
5. Date assigned: ☐☐/☐☐/☐☐☐☐ RTF5
6. Review Complete: Yes ☐ No ☐ RTF6

PART B: Adjudication

7. Adjudication Required: Yes ☐ No ☐ RTF7
8. Reviewer 3: ☐☐☐ RTF8
9. Date assigned: ☐☐/☐☐/☐☐☐☐ RTF9
10. Adjudication Complete: Yes ☐ No ☐ RTF10

PART C: Special Review and Event Classification

11. Special Review was completed: Yes ☐ No ☐ RTF11
12. Event Classification Complete: Yes ☐ No ☐ Pending ☐ Not Required ☐ RTF12

SPIROMETRY DATA FORM

ID NUMBER: BLINDID

FORM CODE: SDF
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ SDF0A

0b) Initials ..... __ __ __

Instructions: *This form should be completed during the participant's visit. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. DO NOT begin pulmonary function testing prior to completing the Inclusion/Exclusion Criteria Form and the PFT Eligibility form.*

1) Was exhaled carbon monoxide measured? ..... __ SDF01

Yes ..... Y
No ..... N → **Go to Item 2**

a) Monitor number (1-15) ..... __ __ SDF01A

b) Measurement 1 ..... __ __ __ ppm SDF01B

c) Measurement 2 ..... __ __ __ ppm SDF01C

2) Was pre-bronchodilator spirometry measured? ..... __ SDF02

Yes ..... Y
No ..... N → **Go to Item 4**

a) Time slow vital capacity procedure began: ..... SDF02A __ __ AM/PM *(circle one)* SDF01A_AMPM

3) Pre-bronchodilator spirometry values (reported/best):

a) Inspiratory capacity ..... __ . __ __ L-BTPS SDF03A

b) Expiratory slow vital capacity ..... __ . __ __ L-BTPS SDF03B

c) FEV_1 ..... __ . __ __ L-BTPS SDF03C

d) FVC ..... __ . __ __ L-BTPS SDF03D

4) Was post-bronchodilator (ipratropium & albuterol) spirometry measured? ..... ☐ SDF04

Yes.....Y

No.....N → **Go to Item 7**

a) Time first puff of bronchodilator (ipratropium) administered: . SDF04A ☐☐☐☐ SDF04A_AMPM AM/PM *(circle one)*

b)Time slow vital capacity procedure began: ..... SDF04B ☐☐☐☐ SDF04B_AMPM AM/PM *(circle one)*

5) Post-bronchodilator spirometry values:

a) Inspiratory capacity..... ☐.☐☐ L-BTPS SDF05A

b) Expiratory slow vital capacity ..... ☐☐.☐ L-BTPS SDF05B

c) FEV_1..... ☐.☐☐ L-BTPS SDF05C

d) FVC..... ☐.☐☐ L-BTPS SDF05D

6) Did the post-bronchodilator spirometry (FEV_1 and FVC) meet the ATS-ERS requirements for acceptability and repeatability? (Y/N) ..... ☐ SDF06

7) Were there any complications during spirometry? (Y/N) ..... ☐ SDF07

a) If yes, please explain: SDF07A _____

8) Other comments: SDF08 _____

_____

SF12v2 HEALTH SURVEY

ID NUMBER:	BLINDID	FORM CODE: **SFH** VERSION: **2.0** 7/18/11	Visit Number	VISIT	SEQ #

0a) Form Date ..... __ __ / __ __ / __ __ __ __ SFH0A 0b) Initials..... __ __ __

> ***Instructions:*** *This form should be completed during the participant's visit. Please read the script exactly as written.*

The first question is about your health now.

Please try to answer as accurately as you can.

1) **In general, would you say your health is** *(Choose one number)*..... ☐ SFH01

Excellent.....1
Very good 2
Good.....3
Fair 4
Poor.....5

Now I'm going to read a list of activities that you might do during a typical day.

As I read each item, please tell me if your health now limits you a lot, limits you a little, or does not limit you at all in these activities.

2a) **…moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. Does your health now limit you a lot, limit you a little, or not limit you at all?**

[*READ RESPONSE CHOICES*]..... ☐ SFH02A

[*IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]*

(Choose one number)

Yes, Limited a lot 1
Yes, Limited a little 2
No, Not at all limited. 3

2b) **…climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all?** [*READ RESPONSE CHOICES*]..... ☐ SFH02B

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE*: Is that because of your health?]*

(Choose one number)

Yes, Limited a lot 1
Yes, Limited a little.....2
No, Not at all limited. 3

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The following two questions ask you about your physical health and your daily activities.

3a) **During the past four weeks, how much of the time have you accomplished less than you would like as a result of your physical health?** [*READ RESPONSE CHOICES*] ..... ☐ SFH03A
(*Choose one number*)

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

3b) **During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health?**
[*READ RESPONSE CHOICES*] ..... ☐ SFH03B
(*Choose one number*)

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

The following two questions ask you about your emotions and your daily activities.

4a) **During the past four weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?**
[*READ RESPONSE CHOICES*] ..... ☐ SFH04A
(*Choose one number*)

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

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4b) **During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of any emotional problems, such as feeling depressed or anxious?** [*READ RESPONSE CHOICES*] SFH04B
(*Choose one number*)

All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
Or None of the time 5

5) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

[*READ RESPONSE CHOICES*] SFH05
(*Choose one number*)

Not at all 1
A little bit 2
Moderately 3
Quite a bit 4
Or Extremely 5

The next questions are about how you feel and how things have been with you during the past 4 weeks.

As I read each statement, please give me the one answer that comes closest to the way you have been feeling; is it all of the time, most of the time, some of the time, a little of the time, or none of the time?

6a) **How much of the time during the past four weeks…have you felt calm and peaceful?** [*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Choose one number)* SFH06A

All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
Or None of the time 5

6b) **How much of the time during the past four weeks…did you have a lot of energy?** [*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Choose one number)* SFH06B

All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
Or None of the time 5

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6c) **How much of the time during the past four weeks…have you felt downhearted and depressed?**

[*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Circle one number)*..... SFH06C

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

7) **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?** [*READ RESPONSE CHOICES*] (Choose one number) SFH07

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

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SF12v2 HEALTH SURVEY

ID NUMBER:	BLINDID	FORM CODE: SFH VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date ..... __ __/__ __/__ __ __ __ SFH0A 0b) Initials..... __ __ __

Instructions: *This form should be completed during the participant's visit. Please read the script exactly as written.*

The first question is about your health now.

Please try to answer as accurately as you can.

1) **In general, would you say your health is** *(Choose one number)*..... ☐ SFH01

Excellent.....1
Very good.....2
Good.....3
Fair.....4
Poor.....5

Now I'm going to read a list of activities that you might do during a typical day.

As I read each item, please tell me if your health now limits you a lot, limits you a little, or does not limit you at all in these activities.

2a) **…moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. Does your health now limit you a lot, limit you a little, or not limit you at all?**

[*READ RESPONSE CHOICES*]..... ☐ SFH02A

[*IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE: Is that because of your health?]*

(Choose one number)

Yes, Limited a lot.....1
Yes, Limited a little.....2
or No, Not at all limited. 3

2b) **…climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all?** [*READ RESPONSE CHOICES*]..... ☐ SFH02B

[IF RESPONDENT SAYS S/HE DOES NOT DO ACTIVITY, PROBE*: Is that because of your health?]*

(Choose one number)

Yes, Limited a lot.....1
Yes, Limited a little.....2
Or No, Not at all limited. 3

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The following two questions ask you about your physical health and your daily activities.

3a) **During the past four weeks, how much of the time have you accomplished less than you would like as a result of your physical health?** [*READ RESPONSE CHOICES*] ..... ☐ SFH03A
(*Choose one number*)

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

3b) **During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of your physical health?**
[*READ RESPONSE CHOICES*] ..... ☐ SFH03B
(*Choose one number*)

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

The following two questions ask you about your emotions and your daily activities.

4a) **During the past four weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?**
[*READ RESPONSE CHOICES*] ..... ☐ SFH04A
(*Choose one number*)

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

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4b) **During the past four weeks, how much of the time were you limited in the kind of work or other regular daily activities you do as a result of any emotional problems, such as feeling depressed or anxious?** [*READ RESPONSE CHOICES*] SFH04B
(*Choose one number*)

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

5) During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

[*READ RESPONSE CHOICES*]..... SFH05
(*Choose one number*)

Not at all 1
Slightly 2
Moderately.....3
Quite a bit 4
Or Extremely.....5

The next questions are about how you feel and how things have been with you during the past 4 weeks.

As I read each statement, please give me the one answer that comes closest to the way you have been feeling; is it all of the time, most of the time, some of the time, a little of the time, or none of the time?

6a) **How much of the time during the past four weeks…have you felt calm and peaceful?** [*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Choose one number)* SFH06A

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

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6b) **How much of the time during the past four weeks…did you have a lot of energy?** [*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Choose one number)* ……..……..... SFH06B

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

6c) **How much of the time during the past four weeks…have you felt downhearted and depressed?** [*READ RESPONSE CHOICES ONLY IF NECESSARY*] *(Circle one number)*..... SFH06C

All of the time 1
Most of the time 2
A good bit of the time 3
Some of the time.....4
A little of the time 5
Or None of the time.....6

7) **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?** [*READ RESPONSE CHOICES*] (Choose one number) SFH07

All of the time 1
Most of the time 2
Some of the time.....3
A little of the time 4
Or None of the time.....5

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ST. GEORGE'S RESPIRATORY QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: **SGR** VERSION: **2.0** 8/3/2011	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ SGR0A 0b) Staff Code .... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Please read the script exactly as written.*

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 listen carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

0c) [Do not read] *Before completing the rest of the questionnaire:* SGR0
Please pick one response to show how you describe your current health:

Very good	Good	Fair	Poor	Very Poor
☐	☐	☐	☐	☐

I'm going to read you a series of questions about your chest trouble. Please answer as it applies to you.

PART 1

Questions about how much chest trouble you have.

	most days a week	several days a week	a few days a month	only with respiratory infections	not at all	
1) I cough:	☐	☐		☐	☐	SGR01
2) I bring up phlegm (sputum):	☐	☐		☐	☐	SGR02
3) I have had shortness of breath:	☐	☐			☐	SGR03
4) I have attacks of wheezing:	☐	☐	☐	☐	☐	SGR04

5) How many attacks of chest trouble did you have during the last year? ..... ☐ SGR05

3 or more attacks .....A
1 or 2 attacks .....B
None C

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P.W. Jones, PhD FRCP, St. George's University of London, London SW17 ORE, UK.

6) How often do you have good days (with few respiratory problems)? ..... ☐ SGR06

No good days ..... A
A few good days ..... B
Most days are good C
Every day is good ..... D

7) If you have a wheeze, is it worse when you get up in the morning? ..... ☐ SGR07

Yes ..... Y
No ..... N

PART 2

8) How would you describe your respiratory problems? ..... ☐ SGR08

Causes me a lot of problems or are the most important physical problem I have ..... A
Causes me a few problems ..... B
Cause no problems C

9) Questions about what activities usually make you feel breathless.
For each statement please tell me which applies to you these days.

	True	False	
Washing or dressing yourself	☐	☐	SGR09A
Walking around the house	☐	☐	SGR09B
Walking outside on the level ground	☐	☐	SGR09C
Walking up a flight of stairs	☐	☐	SGR09D
Walking up hills	☐	☐	SGR09E

10) Some more questions about your cough and breathlessness.
For each statement please tell me which applies to you these days.

	True	False	
Coughing hurts	☐	☐	SGR10A
Coughing makes me tired	☐	☐	SGR10B
I am short of breath when I talk	☐	☐	SGR10C
I am short of breath when I bend over	☐	☐	SGR10D
My cough or breathing disturbs my sleep	☐	☐	SGR10E
I get exhausted easily	☐	☐	SGR10F

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11) Questions about other effects that your chest trouble may have on you.
For each statement please tell me which applies to you these days.

	True	False	
My cough or breathing is embarrassing in public	☐	☐	SGR11A
My respiratory problems are a nuisance to my family, friends or neighbors	☐	☐	SGR11B
I get afraid or panic when I cannot catch my breath	☐	☐	SGR11C
I feel that I am not in control of my respiratory problems	☐	☐	SGR11D
I have become frail or an invalid because of my respiratory problems	☐	☐	SGR11E
Exercise is not safe for me	☐	☐	SGR11F
Everything seems too much of an effort	☐	☐	SGR11G

12) These are questions about how your activities might be affected by your respiratory problems.
For each statement please tell me which applies to you because of your breathing.

	True	False	
I take a long time to get washed or dressed	☐	☐	SGR12A
I cannot take a bath or shower, or I take a long time to do it	☐	☐	SGR12B
I walk slower than other people, or I stop to rest	☐	☐	SGR12C
Jobs such as house chores take a long time, or I have to stop to rest	☐	☐	SGR12D
If I walk up one flight of stairs, I have to go slowly or stop	☐	☐	SGR12E
If I hurry or walk fast, I have to stop or slow down	☐	☐	SGR12F
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, bowl or play golf	☐	☐	SGR12G
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim	☐	☐	SGR12H

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13) We would like to know how your chest usually affects your daily life.
For each statement please tell me which applies to you because of your breathing.

	True	False	
I cannot play sports or do other physical activities	☐	☐	SGR13A
I cannot go out for entertainment or recreation	☐	☐	SGR13B
I cannot go out of the house to do the shopping	☐	☐	SGR13C
I cannot do household chores	☐	☐	SGR13D
I cannot move far from my bed or chair	☐	☐	SGR13E

14) How does your respiratory problems affect you? SGR14
Please pick ONE:

They do not stop me doing anything I would like to do	☐
They stop from me doing one or two things I would like to do	☐
They stop from me doing most of the things I would like to do	☐
They stop from me doing everything I would like to do	☐

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ST. GEORGE'S RESPIRATORY QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: SGR VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ SGR0A 0b) Initials..... ☐☐☐

Instructions: *This form should be completed during the participant's visit. Please read the script exactly as written.*

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 listen carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

0c) [Do not read] *Before completing the rest of the questionnaire:* SGR0
Please pick one response to show how you describe your current health:

Very good	Good	Fair	Poor	Very Poor
☐	☐	☐	☐	☐

I'm going to read you a series of questions about your chest trouble. Please answer as it applies to you.

PART 1

Questions about how much chest trouble you have.

	most days a week	several days a week	a few days a month	only with chest infections	not at all	
1) I cough:	☐	☐	☐	☐	☐	SGR01
2) I bring up phlegm (sputum):	☐	☐	☐	☐	☐	SGR02
3) I have had shortness of breath:	☐	☐	☐	☐	☐	SGR03
4) I have attacks of wheezing:	☐	☐	☐	☐	☐	SGR04

5) How many attacks of chest trouble did you have during the last year? ..... ☐ SGR05

more than 3 attacks.....A
1 or 2 attacks .....B
None C

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6) How often do you have good days (with little chest trouble)? ..... ☐ SGR06

No good days .....A
A few good days .....B
Most days are good.....C
Every day is good.....D

7) If you have a wheeze, is it worse in the morning?..... ☐ SGR07

Yes.....Y

No .....N

PART 2

8) How would you describe you chest condition?..... ☐ SGR08

Causes me quite a lot of problems or
is the most important problem I have.....A
Causes me a few problems.....B
Causes no problem C

9) Questions about what activities usually make you feel breathless.
For each statement please tell me which applies to you these days.

	True	False	
Getting washed or dressed	☐	☐	SGR09A
Walking around the home	☐	☐	SGR09B
Walking outside on the level	☐	☐	SGR09C
Walking up a flight of stairs	☐	☐	SGR09D
Walking up hills	☐	☐	SGR09E

10) Some more questions about your cough and breathlessness.
For each statement please tell me which applies to you these days.

	True	False	
My cough hurts	☐	☐	SGR10A
My cough makes me tired	☐	☐	SGR10B
I am breathless when I talk	☐	☐	SGR10C
I am breathless when I bend over	☐	☐	SGR10D
My cough or breathing disturbs my sleep	☐	☐	SGR10E
I get exhausted easily	☐	☐	SGR10F

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11) Questions about other effects that your chest trouble may have on you.
For each statement please tell me which applies to you these days.

	True	False	
My cough or breathing is embarrassing in public	☐	☐	SGR11A
My chest trouble is a nuisance to my family, friends or neighbors	☐	☐	SGR11B
I get afraid or panic when I cannot get my breath	☐	☐	SGR11C
I feel that I am not in control of my chest problem	☐	☐	SGR11D
I have become frail or an invalid because of my chest	☐	☐	SGR11E
Exercise is not safe for me	☐	☐	SGR11F
Everything seems too much or an effort	☐	☐	SGR11G

12) These are questions about how your activities might be affected by your breathing.
For each statement please tell me which applies to you because of your breathing.

	True	False	
I take a long time to get washed or dressed	☐	☐	SGR12A
I cannot take a bath or shower, or I take a long time	☐	☐	SGR12B
I walk slower than other people, or I stop for rests	☐	☐	SGR12C
Jobs such as house work take a long time, or I have to stop for rests	☐	☐	SGR12D
If I walk up one flight of stairs, I have to go slowly or stop	☐	☐	SGR12E
If I hurry or walk fast, I have to stop or slow down	☐	☐	SGR12F
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf	☐	☐	SGR12G
My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim	☐	☐	SGR12H

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13) We would like to know how your chest usually affects your daily life.
For each statement please tell me which applies to you because of your breathing.

	True	False	
I cannot play sports or games	☐	☐	SGR13A
I cannot go out for entertainment or recreation	☐	☐	SGR13B
I cannot go out of the house to do the shopping	☐	☐	SGR13C
I cannot do housework	☐	☐	SGR13D
I cannot move far from my bed or chair	☐	☐	SGR13E

14) How does your chest trouble effect you? SGR14
Please pick ONE:

- It does not stop me doing anything I would like to do ☐
- It stops me doing one or two things I would like to do ☐
- It stops me doing most of the things I would like to do ☐
- It stops me doing everything I would like to do ☐

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SIX MINUTE WALK TEST

ID NUMBER: BLINDID

FORM CODE: SMW
VERSION: 1.0 10/26/10

Visit Number VISIT

SEQ #

0a) Form Date..... __ __ / __ __ / __ __ __ __ SMW0A

0b) Initials ..... __ __ __

Instructions: *Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. Please read the script exactly as written, including the encouragement prompts.*

1) Any medications taken **since** the post-bronchodilator spirometry?..... ☐ SMW01

Yes.....Y

No .....N→**Go to 2**

a) Medication name: SMW01A1 _____ Dose: SMW01A2 _____ Time SMW01A3 SMW01A3_AMPM __ __ AM/PM

b) Medication name: SMW01B1 _____ Dose: SMW01B2 _____ Time SMW01B3 SMW01B3_AMPM __ __ AM/PM

c) Medication name: SMW01C1 _____ Dose: SMW01C2 _____ Time SMW01C3 SMW01C3_AMPM __ __ AM/PM

2) Was the blood pressure for this visit taken more than 4 hours prior to the 6MW? ☐ SMW02

Yes.....Y

No .....N→**Go to 3**

a) Systolic ..... __ __ __ mm Hg SMW02A

b) Diastolic ..... __ __ __ mm Hg SMW02B

3) Supplemental Oxygen **during** test (see MOP for criteria) (Y/N) ..... ☐ SMW03

Yes.....Y

No .....N→**Go to 4**

a) If yes, flow..... __ . __ L/min SMW03A

b) Type ..... ☐ SMW03B

Continuous flow nasal canula 1

Pulsed delivery system (conserver) 2

4) At rest prior to 6MW

a) SpO2 ..... __ __ __ % SMW04A

b) Pulse..... __ __ __ min^{-1} SMW04B

5) Continuous oximetry recorded? (Y/N) SMW05

6) Start time of 6-minute walk: SMW06 AM/PM *(circle one)* SMW06_AMPM

7) Immediately following 6MW

a) SpO2 ..... % SMW07A

b) Pulse..... min^{-1} SMW07B

c) Breathlessness..... SMW07C

d) Exertion SMW07D

8a) Type of course used..... SMW08A

i) 30 meters x 2 lengths 1
ii) 100 feet x 2 lengths 2
iii) Other..... 3
Specify SMW08A1 _____

8b) Number of full laps (2 lengths or legs): SMW08B

8c) Distance walked final partial lap (in meters if 8a is meters, feet if 8a is in feet): SMW08C

9) Stopped before 6 minutes? (Y/N) SMW09

Yes.....Y

No .....N→**Go to 10**

a) Duration (minutes:seconds): SMW09A1 . SMW09A2

10) Give primary reason for stopping or not walking faster: .....

1. Desaturation to <80% SMW09B1
2. Foot, knee, hip or other orthopedic pain SMW09B2
3. Muscle fatigue or pain SMW09B3
4. Breathlessness SMW09B4
5. Adverse event SMW09B5

If yes to adverse event, select all that apply (this does not replace completing the Adverse Event Form):

a. Angina..... SMW09B5A

b. Lightheadedness..... SMW09B5B

c. Intolerable dyspnea (required rescue inhaler)..... SMW09B5C

d. Leg cramps SMW09B5D

e. Staggering..... SMW09B5E

f. Diaphoresis ..... ☐ SMW09B5F

g. Pale or ashen appearance ..... ☐ SMW09B5G

h. Mental confusion or headache ..... ☐ SMW09B5H

i. Other ..... ☐ SMW09B5I

please explain SMW09B5ISP _____

SPUTUM PROCESSING WORKSHEET

ID NUMBER: BLINDID

FORM CODE: **SPW**
VERSION: 3.**0** 6/12/13

Visit Number VISIT

SEQ #

0a) Form Date ..... __ __/__ __/__ __ __ __ SPW0A 0b) Initials..... __ __ __

0c) Date Collected..... __ __/__ __/__ __ __ __ SPW0C

0d) Processing Started..... SPW0D __ __ AM/PM (circle one) SPW0D_AMPM

0e) Processing Ended ..... SPW0E __ __ AM/PM (circle one) SPW0E_AMPM

Instructions: *Complete this form while processing the sputum sample. Carefully record all data in the space provided.*

1) Weight of Entire Sample..... __ __ __.__ __ grams SPW01

Color and Description of Sample:

2) Salivary Contamination:

- ☐ Minimal SPW02A
- ☐ Mild SPW02B
- ☐ Moderate SPW02C
- ☐ Excessive SPW02D

3) Consistency:

- ☐ Watery SPW03A
- ☐ Mucoid SPW03B
- ☐ Purulent (puss) SPW03C

4) Mucus "plugs":

- ☐ Numerous SPW04A
- ☐ Moderate number SPW04B
- ☐ Sparse SPW04C
- ☐ Large SPW04D
- ☐ Small SPW04E
- ☐ Dense/flocculent SPW04F
- ☐ Diffuse opacity SPW04G

5) Color of plugs:

- ☐ Clear SPW05A
- ☐ White SPW05B
- ☐ Yellow/Tan SPW05C
- ☐ Brown SPW05D
- ☐ Green SPW05E

6) General Notes/Comments: SPW06

6a) Sputum processing method ..... [ ] SPW06A

Method 1 (remove three aliquots then process with EDTA)..... 1
Method 2 (Immediately process with EDTA)..... 2 → **Go to Item 10**

7) Processing Whole Sample using the Mucin Method (Complete only for method 1)

Mucin Sample	Weight (g)
Weighing tray	a) SPW07A
Whole sputum	b) SPW07B
Guanidine vol.	c) SPW07C

*Sample size should be from 0.100-0.500g. If sample is 0.500g, 1mL of guanidine reduction buffer added. If less than 0.500g, 0.5mL guanidine reduction buffer added. Sample transferred from weighing tray to microcentrifuge tube. Sample should be stored in 4ºC refrigerator.

8) Processing Microbiology sample (Complete only for method 1)

Micro Sample	Weight (g)
Microcentrifuge tube	a) SPW08A
Whole sputum	b) SPW08B

*Weigh an empty microcentrifuge tube. Zero the balance. Measure 0.250g of whole sputum sample. Record the weight of sputum and store in -80ºC. Ship sample on dry ice.

9) Processing Viscoelastic Sample (Complete only for method 1)

Viscoelastic Sample	Weight (g)
Microcentrifuge tube	a) SPW09A
Whole Sputum	b) SPW09B

*Weigh an empty microcentrifuge tube. Zero the balance. Pipet 100uL of sample, drawing up whatever can be achieved. Transfer sample to microcentrifuge tube. Record the weight of sample and store in -80ºC. Sample can be transferred to -20ºC prior to delivery.

10)Processing Whole Sample using EDTA:

Weight of Centrifuge tube	a) SPW10A
Weight of Sputum	b) SPW10B

1% sputolysin volume	c) SPW10C
Volume EDTA added to make 0.1% sputolysin	d) SPW10D
Time of 15 minute tumble	e) SPW10E
Volume EDTA added after 15 minute tumble	f) SPW10F
Time of 5 minute tumble	g) SPW10G

*****Weigh a 50mL centrifuge tube. Zero the balance. Add remaining sample to centrifuge tube and record weight in grams. Add 0.1% Sputolysin in mLs equal to 4X selected sample weight in grams (For example, 2g of sample would need 8mL of 0.1% sputolysin). Place sample on tumble for 15 minutes. Dilute sample with EDTA. Use the same volume that was added above. Continue to tumble for an additional 5 minutes. After 5 minute tumble, sample is filtered through 53µm nylon mesh into new 50mL tube. Cells are spun down at 500Xg for 10 minutes.

11)Supernatants for Nucleotides and Cytokines

Supernatants	Number of aliquots	Volume stored
Nucleotides	a) SPW11A	b) SPW11B
Cytokines	c) SPW11C	d) SPW11D

*If sample volume is greater than 8mL, obtain 4 1 mL aliquots for nucleotides, 4 1 mL aliquots for cytokines. When there is a limited volume, start by getting a nucleotide sample between 200-500uL, one cytokine sample at 200uL. If there is sample leftover after that, then continue alternating between nucleotide and cytokine aliquots (i.e. 200-500uL for nucleotides, 200uL for cytokines) until finished. Nucleotide and Cytokine samples are stored in -80ºC freezer.

Volume of Hanks added	e) SPW11E

12)Cell Counts

Cell Counts:	# Dead	#Live	Total
a) Square 1	1) SPW12A1	2) SPW12A2	3) SPW12A3
b) Square 2	1) SPW12B1	2) SPW12B2	3) SPW12B3
c) Square 3	1) SPW12C1	2) SPW12C2	3) SPW12C3
d) Square 4	1) SPW12D1	2) SPW12D2	3) SPW12D3
e) Totals:	1) SPW12E1	2) SPW12E2	3) SPW12E3

*Count live (clear) and dead (blue) cells in each 4 corner grids. Count BEC's, but exclude RBC's and squamous.

TCC= (sum 4 grids/4 X 2 X 10^4 X vol. sample	f) SPW12F
=TCC/weight of selected sample	g) SPW12G
Viability = (live cells/total cells) X 100%	h) SPW12H

13)Cytospins:

	# slides stored
Hema 3 stained slides	a) SPW13

*Slides are made using 60µL of cell suspension ($1X10^6$/mL). Spin 6 min. at 450rpm (program 6 on cytospin). If possible, fix and stain 2 slides in Hema 3 stain (10 dips in each) and fix 2 slides in 95% ethanol. After air drying, stained slides are fixed with cytoseal and a cover slip. All slides stored at room temperature.

14)Cells for RNA

Trizol cell pellet	SPW14

*Cells are spun down at 500Xg for 5 minutes, HBSS's is discarded and 1mL Trizol is added. Add 10uL of GGD. The number of cells left in the Trizol pellet will be equal to the TCC (12f) minus the total number of cells used to make slides in 13.

SPUTUM PROCESSING WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: **SPW** VERSION: **2.0** 9/12/11	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ SPW0A 0b) Initials..... ☐☐☐

Instructions: *Complete this form while processing the sputum sample. Carefully record all data in the space provided.*

1) Weight of Entire Sample..... ☐☐☐.☐☐ grams SPW01

Color and Description of Sample:

2) Salivary Contamination:

- ☐ Minimal SPW02A
- ☐ Mild SPW02B
- ☐ Moderate SPW02C
- ☐ Excessive SPW02D

3) Consistency:

- ☐ Watery SPW03A
- ☐ Mucoid SPW03B
- ☐ Purulent (puss) SPW03C

4) Mucus "plugs":

- ☐ Numerous SPW04A
- ☐ Moderate number SPW04B
- ☐ Sparse SPW04C
- ☐ Large SPW04D
- ☐ Small SPW04E
- ☐ Dense/flocculent SPW04F
- ☐ Diffuse opacity SPW04G

5) Color of plugs:

- ☐ Clear SPW05A
- ☐ White SPW05B
- ☐ Yellow/Tan SPW05C
- ☐ Brown SPW05D
- ☐ Green SPW05E

6) General Notes/Comments: SPW06

6a) Sputum processing method ..... ☐ SPW06A

Method 1 (remove three aliquots then process with EDTA)..... 1
Method 2 (Immediately process with EDTA)..... 2 → **Go to Item 10**

7) Processing Whole Sample using the Mucin Method (Complete only for method 1)

Mucin Sample	Weight (g)
Weighing tray	a) SPW07A
Whole sputum	b) SPW07B
Guanidine vol.	c) SPW07C

*Sample size should be from 0.100-0.500g. If sample is 0.500g, 1mL of guanidine reduction buffer added. If less than 0.500g, 0.5mL guanidine reduction buffer added. Sample transferred from weighing tray to microcentrifuge tube. Sample should be stored in 4ºC refrigerator.

8) Processing Microbiology sample (Complete only for method 1)

Micro Sample	Weight (g)
Microcentrifuge tube	a) SPW08A
Whole sputum	b) SPW08B

*Weigh an empty microcentrifuge tube. Zero the balance. Measure 0.250g of whole sputum sample. Record the weight of sputum and store in -80ºC. Ship sample on dry ice.

9) Processing Viscoelastic Sample (Complete only for method 1)

Viscoelastic Sample	Weight (g)
Microcentrifuge tube	a) SPW09A
Whole Sputum	b) SPW09B

*Weigh an empty microcentrifuge tube. Zero the balance. Pipet 100uL of sample, drawing up whatever can be achieved. Transfer sample to microcentrifuge tube. Record the weight of sample and store in -80ºC. Sample can be transferred to -20ºC prior to delivery.

10)Processing Whole Sample using EDTA:

Weight of Centrifuge tube	a) SPW10A
Weight of Sputum	b) SPW10B
1% sputolysin volume	c) SPW10C

Volume EDTA added to make 0.1% sputolysin	d) SPW10D
Time of 15 minute tumble	e) SPW10E
Volume EDTA added after 15 minute tumble	f) SPW10F
Time of 5 minute tumble	g) SPW10G

*****Weigh a 50mL centrifuge tube. Zero the balance. Add remaining sample to centrifuge tube and record weight in grams. Add 0.1% Sputolysin in mLs equal to 4X selected sample weight in grams (For example, 2g of sample would need 8mL of 0.1% sputolysin). Place sample on tumble for 15 minutes. Dilute sample with EDTA. Use the same volume that was added above. Continue to tumble for an additional 5 minutes. After 5 minute tumble, sample is filtered through 53µm nylon mesh into new 50mL tube. Cells are spun down at 500Xg for 10 minutes.

11)Supernatants for Nucleotides and Cytokines

Supernatants	Number of aliquots	Volume stored
Nucleotides	a) SPW11A	b) SPW11B
Cytokines	c) SPW11C	d) SPW11D

*If sample volume is greater than 8mL, obtain 4 1 mL aliquots for nucleotides, 4 1 mL aliquots for cytokines. When there is a limited volume, start by getting a nucleotide sample between 200-500uL, one cytokine sample at 200uL. If there is sample leftover after that, then continue alternating between nucleotide and cytokine aliquots (i.e. 200-500uL for nucleotides, 200uL for cytokines) until finished. Nucleotide and Cytokine samples are stored in -80ºC freezer.

Volume of Hanks added	e) SPW11E

12)Cell Counts

Cell Counts:	# Dead	#Live	Total
a) Square 1	1) SPW12A1	2) SPW12A2	3) SPW12A3
b) Square 2	1) SPW12B1	2) SPW12B2	3) SPW12B3
c) Square 3	1) SPW12C1	2) SPW12C2	3) SPW12C3
d) Square 4	1) SPW12D1	2) SPW12D2	3) SPW12D3
e) Totals:	1) SPW12E1	2) SPW12E2	3) SPW12E3

*Count live (clear) and dead (blue) cells in each 4 corner grids. Count BEC's, but exclude RBC's and squamous.

TCC= (sum 4 grids/4 X 2 X 10^4 X vol. sample	f) SPW12F
=TCC/weight of selected sample	g) SPW12G
Viability = (live cells/total cells) X 100%	h) SPW12H

13)Cytospins:

	# slides stored

Hema 3 stained slides	a) SPW13

*Slides are made using 60µL of cell suspension ($1X10^6$/mL). Spin 6 min. at 450rpm (program 6 on cytospin). If possible, fix and stain 2 slides in Hema 3 stain (10 dips in each) and fix 2 slides in 95% ethanol. After air drying, stained slides are fixed with cytoseal and a cover slip. All slides stored at room temperature.

14)Cells for RNA

Trizol cell pellet	SPW14

*Cells are spun down at 500Xg for 5 minutes, HBSS's is discarded and 1mL Trizol is added. Add 10uL of GGD. The number of cells left in the Trizol pellet will be equal to the TCC (12f) minus the total number of cells used to make slides in 13.

SPUTUM PROCESSING WORKSHEET

ID NUMBER:	BLINDID	FORM CODE: SPW VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #

0a) Form Date ..... ☐☐/☐☐/☐☐☐☐ SPW0A 0b) Initials..... ☐☐☐

Instructions: *Complete this form while processing the sputum sample. Carefully record all data in the space provided.*

1) Weight of Entire Sample..... ☐☐☐.☐☐ grams SPW01

Color and Description of Sample:

2) Salivary Contamination:

- ☐ Minimal SPW02A
- ☐ Mild SPW02B
- ☐ Moderate SPW02C
- ☐ Excessive SPW02D

3) Consistency:

- ☐ Watery SPW03A
- ☐ Mucoid SPW03B
- ☐ Purulent (puss) SPW03C

4) Mucus "plugs":

- ☐ Numerous SPW04A
- ☐ Moderate number SPW04B
- ☐ Sparse SPW04C
- ☐ Large SPW04D
- ☐ Small SPW04E
- ☐ Dense/flocculent SPW04F
- ☐ Diffuse opacity SPW04G

5) Color of plugs:

- ☐ Clear SPW05A
- ☐ White SPW05B
- ☐ Yellow/Tan SPW05C
- ☐ Brown SPW05D
- ☐ Green SPW05E

6) General Notes/Comments: SPW06

7) Processing Whole Sample using the Mucin Method

Mucin Sample	Weight (g)
Weighing tray	a) SPW07A
Whole sputum	b) SPW07B
Guanidine vol.	c) SPW07C

*Sample size should be from 0.100-0.500g. If sample is 0.500g, 1mL of guanidine reduction buffer added. If less than 0.500g, 0.5mL guanidine reduction buffer added. Sample transferred from weighing tray to microcentrifuge tube. Sample should be stored in 4ºC refrigerator.

8) Processing Microbiology sample

Micro Sample	Weight (g)
Microcentrifuge tube	a) SPW08A
Whole sputum	b) SPW08B

*Weigh an empty microcentrifuge tube. Zero the balance. Measure 0.250g of whole sputum sample. Record the weight of sputum and store in -80ºC. Ship sample on dry ice.

9) Processing Viscoelastic Sample

Viscoelastic Sample	Weight (g)
Microcentrifuge tube	a) SPW09A
Whole Sputum	b) SPW09B

*Weigh an empty microcentrifuge tube. Zero the balance. Pipet 100uL of sample, drawing up whatever can be achieved. Transfer sample to microcentrifuge tube. Record the weight of sample and store in -80ºC. Sample can be transferred to -20ºC prior to delivery.

10)Processing Whole Sample using EDTA:

Weight of Centrifuge tube	a) SPW10A
Weight of Sputum	b) SPW10B
1% sputolysin volume	c) SPW10C
Volume EDTA added to make 0.1% sputolysin	d) SPW10D
Time of 15 minute tumble	e) SPW10E
Volume EDTA added after 15 minute tumble	f) SPW10F

Time of 5 minute tumble	g) SPW10G

*****Weigh a 50mL centrifuge tube. Zero the balance. Add remaining sample to centrifuge tube and record weight in grams. Add 0.1% Sputolysin in mLs equal to 4X selected sample weight in grams (For example, 2g of sample would need 8mL of 0.1% sputolysin). Place sample on tumble for 15 minutes. Dilute sample with EDTA. Use the same volume that was added above. Continue to tumble for an additional 5 minutes. After 5 minute tumble, sample is filtered through 53µm nylon mesh into new 50mL tube. Cells are spun down at 500Xg for 10 minutes.

11)Supernatants for Nucleotides and Cytokines

Supernatants	Number of aliquots	Volume stored
Nucleotides	a) SPW11A	b) SPW11B
Cytokines	c) SPW11C	d) SPW11D

*If sample volume is greater than 8mL, obtain 4 1 mL aliquots for nucleotides, 4 1 mL aliquots for cytokines. When there is a limited volume, start by getting a nucleotide sample between 200-500uL, one cytokine sample at 200uL. If there is sample leftover after that, then continue alternating between nucleotide and cytokine aliquots (i.e. 200-500uL for nucleotides, 200uL for cytokines) until finished. Nucleotide and Cytokine samples are stored in -80ºC freezer.

Volume of Hanks added	e) SPW11E

12)Cell Counts

Cell Counts:	# Dead	#Live	Total
a) Square 1	1) SPW12A1	2) SPW12A2	3) SPW12A3
b) Square 2	1) SPW12B1	2) SPW12B2	3) SPW12B3
c) Square 3	1) SPW12C1	2) SPW12C2	3) SPW12C3
d) Square 4	1) SPW12D1	2) SPW12D2	3) SPW12D3
e) Totals:	1) SPW12E1	2) SPW12E2	3) SPW12E3

*Count live (clear) and dead (blue) cells in each 4 corner grids. Count BEC's, but exclude RBC's and squamous.

TCC= (sum 4 grids/4 X 2 X 10^4 X vol. sample	f) SPW12F
=TCC/weight of selected sample	g) SPW12G
Viability = (live cells/total cells) X 100%	h) SPW12H

13)Cytospins:

	# slides stored
Hema 3 stained slides	a) SPW13

*Slides are made using 60µL of cell suspension (1X10^6/mL). Spin 6 min. at 450rpm (program 6 on cytospin). If possible, fix and stain 2 slides in Hema 3 stain (10 dips in each) and fix 2 slides in 95% ethanol. After air drying, stained slides are fixed with cytoseal and a cover slip. All slides stored at room temperature.

14)Cells for RNA

Trizol cell pellet	SPW14

*Cells are spun down at 500Xg for 5 minutes, HBSS's is discarded and 1mL Trizol is added. Add 10uL of GGD. The number of cells left in the Trizol pellet will be equal to the TCC (12f) minus the total number of cells used to make slides in 13.

STROKE ABSTRACTION FORM

ID NUMBER: SUBJID

FORM CODE: STR
VERSION: A 6/25/15

Visit VISIT SEQ #

0a. Completion Date: __/__/____ (Month Day Year) STR0A

0b. Staff ID: STR0B

0c. Event ID: STR0C

0d. Event Date: __/__/____ STR0D

Instructions: Answers are derived from the medical records received. Do not complete this form until all records are received (or classified as unobtainable) as indicated on the Medical Records Shipping Cover Sheet

A. GENERAL INFORMATION

1. Was the event (choose one): STR1
   - ED, ED Observation or 23hr Observation 1
   - Hospitalization (with or without preceding ED visit) 2

2. Date of admission: (mm/dd/yyyy) __/__/____ STR2

3. Date of discharge/or death: (mm/dd/yyyy) __/__/____ STR3

4. What was the primary admitting diagnosis code? ____.____ STR4

5. What was the primary discharge diagnosis code? ____.____ STR5

B. MEDICAL HISTORY

6. Is there a history of previous stroke? Yes No/NR ***(Skip to 7)*** STR6

   a. Date of most recent stroke: (mm/dd/yyyy) __/__/____ STR6A

   b. Is the type of stroke recorded? Yes No/NR ***(Skip to 7)*** STR6B

   (If Yes, mark all that apply)

   1. Ischemic/Infarct No Yes STR6B1
   2. Intracranial hemorrhage No Yes STR6B2
   3. Subarachnoid hemorrhage No Yes STR6B3

7. Is there a history of previous TIA? ☐ Yes ☐ No/NR ***(Skip to 8)*** STR7

a. Date of most recent TIA: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ STR7A

8. History of myocardial infarction prior to this event? ☐ Yes ☐ No/NR STR8

9. Does the patient have a history of diabetes? ☐ Yes ☐ No/NR STR9

10. Are any of the following recent conditions documented as having been present <u>within four weeks prior</u> to onset or during this hospitalization?

	Yes	No/NR	
a. myocardial infarction	☐	☐	STR10A
b. intracardiac thrombus or intracardiac tumor	☐	☐	STR10B
c. atrial fibrillation	☐	☐	STR10C
d. rheumatic heart disease	☐	☐	STR10D
e. subacute bacterial endocarditis	☐	☐	STR10E
f. systemic embolus	☐	☐	STR10F
g. hypercoagulative state	☐	☐	STR10G
h. hemorrhagic abnormality	☐	☐	STR10H
i. brain tumor	☐	☐	STR10I
j. major head trauma	☐	☐	STR10J
k. seizure disorder	☐	☐	STR10K
l. migraine headaches	☐	☐	STR10L

C. SIGNS AND SYMPTOMS

11. Were new neurological signs/symptoms present upon admission? ☐ Yes ☐ No/NR ***(Skip to 12)*** STR11

a. Length of time between onset of new neurological signs/symptoms and presentation: ☐ STR11A
1 = < 10 min, 2 = 10 - 59 min, 3 = 60 min.- 24 hrs, 4 = 24 hrs+, 5 = unknown

12. Were any of the following present at onset prior to admission or during this hospitalization?

	Yes	No/NR	
a. Headache	☐	☐	STR12A
b. Vomiting	☐	☐	STR12B
c. Vertigo	☐	☐	STR12C
d. Seizure	☐	☐	STR12D
e. Altered level of consciousness	☐	☐	STR12E
f. Aphasia	☐	☐	STR12F
g. Anesthesia, dysesthesia or paresthesias of the face	☐	☐	STR12G
h. Anesthesia, dysesthesia or paresthesias of the extremities	☐	☐	STR12H
i. Visual field disturbance, diploplia	☐	☐	STR12I
j. Gait disturbance	☐	☐	STR12J
k. Cranial nerve III palsy	☐	☐	STR12K
l. Meningeal signs (ie: Brudinski's sign, Kernig's sign)	☐	☐	STR12L

.

13. Did new neurological symptoms develop during this hospitalization? ☐ Yes ☐ No/NR ***(Skip to 14)*** STR13

a. If yes, did the event occur in the setting of a procedure? ☐ Yes ☐ No/NR ***(Skip to 14)*** STR13A

b. If yes, what procedure?

	Yes	No/NR	
1. Angiogram	☐	☐	STR13B1
2. Cardiac surgery	☐	☐	STR13B2
3. Carotid endarterectomy	☐	☐	STR13B3
4. Other	☐	☐	STR13B4

i. Specify _____ STR13B4A

D. DIAGNOSTIC TESTS

14. Admission Blood pressure ☐☐☐/☐☐☐mmHg STR14

15. Was cerebrovascular imaging performed? ☐ Yes ☐ No/NR ***(Skip to 19)*** STR15

16. Was cerebrovascular angiography performed? ☐ Yes ☐ No/NR ***(Skip to 17)*** STR16

a. Angiography Diagnosis ☐ STR16A

1 = normal, 2 = ruptured aneurysm, 3 = Occlusion or Stenosis, 4 = Dissection, 5 = Venous Occlusion, 6 = Arteriovenous Malformation, 7 = Other

17. Was a CT scan of the head performed during this hospitalization? ☐ Yes ☐ No/NR ***(Skip to 18)*** STR17

a. CT Diagnosis ☐ STR17A

1 = normal, 2 = normal, but done within 48 hrs of symptom onset, 3 = subarachnoid hemorrhage, 4 = intracerebral hematoma, 5 = ischemic infarction, with no evidence of hemorrhage, 6 = hemorrhagic infarction

18. Was magnetic resonance imaging (MRI) of the head performed? ☐ Yes ☐ No/NR ***(Skip to 19)*** STR18

a. MRI Diagnosis ☐ STR18A

1 = normal, 2 = normal, but done within 48 hrs of symptom onset, 3 = subarachnoid hemorrhage, 4 = intracerebral hematoma, 5 = ischemic infarction, with no evidence of hemorrhage, 6 = hemorrhagic infarction

19. Was carotid magnetic resonance angiography (MRA) performed? ☐ Yes ☐ No/NR ***(Skip to 20)*** STR19

a. If Yes, what is the greatest degree of carotid stenosis demonstrated: STR19A

1. 0 – 49% ☐
2. 50 – 69% ☐
3. 70 – 99% ☐
4. 100% (occlusion) ☐

20. Was an echocardiography study performed? ☐ Yes ☐ No/NR ***(Skip to 21)*** STR20

a. If Yes, were the following present:

1. intracardiac thrombus ☐ Yes ☐ No STR20A1
2. valvular heart disease ☐ Yes ☐ No STR20A2

3. dilated ventricle or poor ventricular function ☐ Yes ☐ No STR20A3
4. aortic arch atheroma ☐ Yes ☐ No STR20A4
5. atrioseptal aneurysm ☐ Yes ☐ No STR20A5
6. patent foramen ovale (PFO) ☐ Yes ☐ No STR20A6
7. valve vegetations ☐ Yes ☐ No STR20A7
8. artificial valve ☐ Yes ☐ No STR20A8

E. TREATMENT

21. Did the patient receive thrombolytic treatment for stroke? ☐ Yes ☐ No/NR STR21

F. DISCHARGE

22. Was the patient alive at discharge? ☐ Yes ☐ No/NR ***(End form)*** STR22

23. At the time of discharge, did the patient have deficits in completing everyday activities compared to status prior to event? STR23 ☐ Yes ☐ No/NR

24. Where was the patient discharged to: ☐ STR24

1 = home, 2 = rehabilitation unit or facility, 3 = nursing home or other long term care facility

VETERANS SPECIFIC ACTIVITY QUESTIONNAIRE

ID NUMBER:	BLINDID	FORM CODE: VSA VERSION: 1.0 10/26/10	Visit Number	VISIT	SEQ #	

0a) Form Date..... ☐☐/☐☐/☐☐☐☐ VSA0A 0b) Initials..... ☐

Instructions: Questionnaire should be completed during the study visit. Mark only one answer, and read questions exactly as written.

The following is a list of activities that increase in difficulty as you read down the page. Think carefully, then select the first activity that, if you performed it for a period of time, would typically cause fatigue, shortness of breath, chest discomfort, or otherwise cause you to want to stop. If you do not normally perform a particular activity, try to imagine what it would be like if you did.

1) 1 METS Eating, getting dressed, working at a desk ..... ☐ VSA01

2) 2 METS Taking a shower, shopping, cooking
Walking down 8 steps ..... ☐ VSA02

3) 3 METS Walking slowly on a flat surface for 1 or 2 blocks
A moderate amount of work around the house, such as vacuuming, sweeping the floors, or carrying groceries ..... ☐ VSA03

4) 4 METS Light yard work (ie, raking leaves, weeding, sweeping, or pushing a power mower), painting, or light carpentry..... ☐ VSA04

5) 5 METS Walking briskly
Social dancing, washing the car ..... ☐ VSA05

6) 6 METS Play 9 holes of golf carrying your own clubs. Heavy carpentry, mow lawn with push mower ..... ☐ VSA06

7) 7 METS Carrying 60 pounds, perform heavy outdoor work (ie, digging, spading soil, etc)
Walking uphill..... ☐ VSA07

8) 8 METS Carrying groceries upstairs, move heavy furniture
Jog slowly on flat surface, climb stairs quickly..... ☐ VSA08

9) 9 METS Bicycling at a moderate pace, sawing wood, jumping rope (slowly)..... ☐ VSA09

10) 10 METS Brisk swimming, bicycle up a hill, jog 6 miles per hour ..... ☐ VSA10

11) 11 METS Carry a heavy load (ie, a child or firewood) up 2 flights of stairs..... ☐ VSA11

12) 12 METS Running briskly, continuously (level ground, 8 min per mile) ..... ☐ VSA12

13) 13 METS Any competitive activity, including those that involve intermittent sprinting
Running competitively, rowing competitively, bicycle riding ..... ☐ VSA13

Myers J, Bader D, Madhavan R, et al. Validation of a specific activity questionnaire to estimate exercise tolerance in patients referred for exercise testing. Am Heart J 2001; 142:1041-1046

SPIROMICS VENOUS THROMBOEMBOLIC DISEASE ABSTRACTION FORM (VTD)

ID NUMBER:	SUBJID	FORM CODE: VTD VERSION A 2/12/2015	Visit Number	VISIT	SEQ #	

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ VTD0A 0b. Staff ID: ☐☐☐ VTD0B
Month/Day/Year

0c. Event ID: ☐☐☐☐☐☐☐☐☐☐☐☐ VTD0C 0d. Event Date: ☐☐/☐☐/☐☐☐☐ VTD0D

Instructions: *Answers are derived from the medical records received. Do not complete this form until all records are received or classified as unobtainable as indicated on the Medical Record Shipping Form.*

A. GENERAL INFORMATION

1. Was the event ***(choose one)***: ☐ VTD1

   1= In hospital only 2= Emergency Dept. visit only (ED) 3= Both ED and in hospital

2. Date of admission: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ VTD2

3. Date of discharge: (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ VTD3

4. What was the primary admitting diagnosis code? ☐☐☐☐.☐☐☐☐ VTD4

5. What was the primary discharge diagnosis code? ☐☐☐☐.☐☐☐☐ VTD5

B. DEEP VEIN THROMBOSIS (DVT)

6. Was DVT confirmed? Yes ☐ No ☐ [***skip to 10***] VTD6

7. Diagnosis: ***(Mark the one that applies best)*** VTD7

   a. ☐ Deep vein thrombosis of lower extremities **not resulting from a procedure** within 60 days
   b. ☐ Deep vein thrombosis of lower extremities **during or following a procedure** within 60 days

8. Diagnosis of deep vein thrombosis is based on: ***(Mark all that apply)***

   a. ☐ Hospital discharge summary with a diagnosis of deep vein thrombosis VTD8A
   b. ☐ Positive findings on a venogram VTD8B
   c. ☐ Positive findings using impedance plethysmography VTD8C
   d. ☐ Positive findings on Doppler duplex, ultrasound, sonogram or other non-invasive test VTD8D
   e. ☐ Positive findings on isotope scan VTD8E

9. Diagnosis of deep vein thrombosis reporting source ***(Mark the one category that applies best)*** VTD9

a. ☐ Hospital inpatient
b. ☐ Hospital outpatient facility or clinic
c. ☐ Radiology or imaging facility
d. ☐ Physician's office / private medical practitioner
e. ☐ Nursing/convalescent home/hospice
f. ☐ Autopsy only
g. ☐ Death Certificate only
h. ☐ Other, specify_____ VTD9A

10. Was a work-up for pulmonary embolism performed? Yes ☐ No ☐ ***(End Form)*** Unknown ☐ ***(End Form)***
VTD10

C. PULMONARY EMBOLISM (PE)

11. Diagnosis: ***(Mark the one that applies best)*** VTD11

a. ☐ Pulmonary embolism **not resulting from a procedure** within 60 days
b. ☐ Pulmonary embolism **during or following a procedure** within 60 days
c. ☐ No Pulmonary embolism diagnosed or diagnosis is not recorded

12. Diagnosis of pulmonary embolism is based on: ***(Mark all that apply)***

a. ☐ Hospital discharge summary with a diagnosis of pulmonary embolism VTD12A
b. ☐ High probability on ventilation-perfusion lung scan VTD12B
c. ☐ Positive findings on pulmonary angiogram or spiral CT VTD12C
d. ☐ Diagnosis of deep vein thrombosis (DVT) based on at least one DVT criteria on Q7 plus signs and symptoms suggestive of PE (i.e. acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest X-ray findings suggestive of PE) VTD12D
e. ☐ Other, including autopsy VTD12E

13. Does patient have a history of: ***(Mark all that apply)***

a. ☐ Factor V Leiden deficiency VTD13A
b. ☐ Polycythemia VTD13B
c. ☐ Cancer VTD13C
d. ☐ Smoking VTD13D
e. ☐ Obesity VTD13E
f. ☐ Recent estrogen or birth control pill use VTD13F