

## BRONCHOSCOPY SPECIMEN COLLECTION WORKSHEET

| ID NUMBER: FORM CODE: BCW Visit VERSION: 2.0 6/10/14 Number SEQ#  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 0a. Form Completion Date 0b. Initials   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| <u>Instructions:</u> 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 []   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| VITAL SIGNS TAKEN PRIOR TO BRONCHOSOCPY   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. O <sub>2</sub> Saturation on room air:   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| HISTORY AND PHYSICAL  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2a. Does your center require lab work prior to bronchoscopy? (Y/N)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2b. If yes, please describe:  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2c. Were the results of the lab work abnormal? (Y/N)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 2d. Do the results of blood work described in 2b and 2c make the participant ineligible   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| to proceed with a bronchoscopy? (Y/N)   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3a. Did the doctor perform a limited physical exam? (Y/N)   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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)   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3c. Please describe:  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Female Participants Only  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4a. Is the participant of child-bearing potential? (Y/N)  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4b. If yes, what was the result of the pregnancy test   |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Negative  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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|----|---|--------|--------|-----------|------|-------|--------|--|--|--|--|--|--|--|
| PR | PRE-BRONCHOSCOPY PULMONARY FUNCTION   |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 5. | 5. Pre-bronchodilator FEV <sub>1</sub> (reported/best): L-BTPS  |        |        |           |      |       |        |  |  |  |  |  |  |  |
|    |   |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 6. | 6. Post-bronchodilator (4 puffs albuterol) FEV <sub>1</sub> (reported/best):LLL-BTPS  |        |        |           |      |       |        |  |  |  |  |  |  |  |
| BL | BLOOD COLLECTION:   |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 7. | Date of blood   | d col  | lectio | on:       |      |       |        | m m / d d / y y y y  |  |  |  |  |  |  |
| 8. | Collection tim  | ne:    |        |           |      |       |        | h h: m m (Circle One)  |  |  |  |  |  |  |
| 9. | Number of venipuncture attempts:  |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 10 | 0. Any blood drawing incidents or problems? (Y/N)   |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 11 | <ol> <li>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.</li> </ol> |        |        |           |      |       |        |  |  |  |  |  |  |  |
|    | a. Sample no  | ot dr  | awn    | (Y/N)     |      |       |        |  |  |  |  |  |  |  |
|    | b. Partial sar  | mple   | dra    | wn (Y/N   | )    |       |        |  |  |  |  |  |  |  |
|    | c. Tournique  |        |        | , ,       |      |       |        |  |  |  |  |  |  |  |
|    | d. Fist clencl  | _      |        |           |      |       |        |  |  |  |  |  |  |  |
|    | e. Needle me  |        |        |           |      |       |        |  |  |  |  |  |  |  |
|    | f. Participan   |        |        |           |      |       |        |  |  |  |  |  |  |  |
|    | g. Sample re  | e-dra  | awn(`  | Y/N)      |      |       |        |  |  |  |  |  |  |  |
| 12 | . If any other b  | looc   | d dra  | wing pro  | bler | ns n  | ot lis | ted above (e.g., fasting status, etc.), describe incident or problem here: |  |  |  |  |  |  |
| 13 | . Phlebotomist  | i's co | ode r  | number:   |      |       |        |  |  |  |  |  |  |  |
| OF | RAL RINSE   |        |        |           |      |       |        |  |  |  |  |  |  |  |
| 14 | . Was the tong  | gue s  | scrap  | oing coll | ecte | d? (` | Y/N)   |  |  |  |  |  |  |  |
| 15 | . Collection tim  | ne:    |        |           |      |       |        | AM / PM h h : m m (Circle One)   |  |  |  |  |  |  |

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|---|--|--|--|--|--|--|--|--|--|--|--|--|
| 16. Was the oral rinse collected? (Y/N)   |  |  |  |  |  |  |  |  |  |  |  |  |
| 17. Collection time: AM / PM  h h : m m (Circle One)                              |  |  |  |  |  |  |  |  |  |  |  |  |
| 18a. Was the time between oral rinse and bronchoscopy more than 60 minutes? (Y/N) |  |  |  |  |  |  |  |  |  |  |  |  |
| 18b. If yes, was an additional tongue scraping collected? (Y/N)                   |  |  |  |  |  |  |  |  |  |  |  |  |
| PROCEDURES:   |  |  |  |  |  |  |  |  |  |  |  |  |
| BRONCHOSCOPY  |  |  |  |  |  |  |  |  |  |  |  |  |
| 19. Saline Control Samples  |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Sterile Saline Sample Collected? (Y/N)   |  |  |  |  |  |  |  |  |  |  |  |  |
| b. Scope Saline Sample Collected? (Y/N)   |  |  |  |  |  |  |  |  |  |  |  |  |
| 20. Protected Brush Specimen (X3 in lower lobe):                                  |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Lobe   |  |  |  |  |  |  |  |  |  |  |  |  |
| b. Number collected   |  |  |  |  |  |  |  |  |  |  |  |  |
| 21. Airway wash (Combined data for first and second wash)                         |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Lobe:  |  |  |  |  |  |  |  |  |  |  |  |  |
| b. Infused: mL c. Return: mL  |  |  |  |  |  |  |  |  |  |  |  |  |
| 22. Bronchial alveolar lavage (Combined data on both BALs)                        |  |  |  |  |  |  |  |  |  |  |  |  |
| a. Lobe:  |  |  |  |  |  |  |  |  |  |  |  |  |
| b. Infused:mLc. Return:mLmL   |  |  |  |  |  |  |  |  |  |  |  |  |
| d.Collection time:  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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.

| ID NUMBER:                                       |  |            |         |                      |         | FORM CODE: BCV<br>VERSION: <b>2.0</b> 6/10/1 |    |       | SEQ# |     |      |  |  |
|--|--|------------|---------|----------------------|---------|--|----|-------|------|-----|------|--|--|
| 23. Cytological b                                | rushings   | s (X3 in i | osilate | eral lowe            | r lobe) |  |    |       |      |     |      |  |  |
| a. Lobe:   |  |            |         |                      |         | -  |    |       |      |     |      |  |  |
| b. Numb  | er of br   | ushes co   | llected | d:t                  |         |  |    |       |      |     |      |  |  |
| 24. Small airway epithelial brushings (optional) |  |            |         |                      |         |  |    |       |      |     |      |  |  |
| a. Small airways brush samples collected? (Y/N)  |  |            |         |                      |         |  |    |       |      |     |      |  |  |
| b. Lobe:   |  |            |         |                      |         |  |    |       |      |     |      |  |  |
| c. Numb  | er of br   | ushes co   | llected | d::b                 |         |  |    |       |      |     |      |  |  |
| Endobronchial                                    | Endobronchial biopsy collected (X8 in contralateral lung, using all lobes if possible) |            |         |                      |         |  |    |       |      |     |      |  |  |
|  |  |            | ·       |                      |         |  |    | ]     |      |     |      |  |  |
| L  | _eft   |            |         |                      |         | 0<br>1                                       |    |       |      |     |      |  |  |
| 26. Biopsies:                                    |  |            |         |                      |         |  |    |       |      |     |      |  |  |
| a. Biops   | y 1: Sna   | p Freeze   | e (Y/N) | )                    |         |  |    |       |      |     |      |  |  |
| b. Biops   | -  |            |         |                      | F       |  |    |       |      |     |      |  |  |
| c. Biops   | y 3: For   | malin (Y/  | N)      |                      |         |  |    |       |      |     |      |  |  |
| d. Biops   | y 4: For   | malin (Y/  | N)      |                      |         |  |    |       |      |     |      |  |  |
| e. Biops   | y 5: For   | malin (Y/  | N)      |                      |         |  |    |       |      |     |      |  |  |
| f. Biops   | y 6: Sna   | p Freeze   | e (Y/N) | )                    |         |  |    |       |      |     |      |  |  |
| g. Biops   | y 7: For   | malin (Y/  | N)      |                      |         |  |    |       |      |     |      |  |  |
| h. Biops   | y 8: For   | malin (Y/  | N)      |                      |         |  |    |       |      |     |      |  |  |
| 27a. Lidocaine: 1                                | %  |            | mg      |                      | b. 2%   | % m  | g  | c. 4% |      | mg  |      |  |  |
| 28. Comments: _                                  |  |            |         |                      |         |  |    |       |      |     |      |  |  |
| PRE-BRONCHO                                      | SCOPY  | PULMO      | NARY    | r FUNC               | TION    |  |    |       |      |     |      |  |  |
| 29. Pre-bronchoo                                 | dilator F  | EV₁ (repo  | orted/b | oest):               |         |  |    |       |      | L-E | BTPS |  |  |
| 30. Did you admi                                 | nister a   | dditional  | albute  | erol? (Y/ľ           | N)      |  |    |       |      |     |      |  |  |
| 31. How many m                                   | icrograr   | ns?        |         |                      |         |  | ug |       |      |     |      |  |  |
| 32. Post-broncho                                 | dilator (  | 4 puffs a  | lbuter  | ol) FEV <sub>1</sub> | (repoi  | rted/best):                                  |    |       |      | L-E | BTPS |  |  |

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|--|--|--------|---------|------------|--------|-------|--------|------|---|-----------------|--|------|--|------|
| 33   | 33. Did you administer additional albuterol? (Y/N) |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 34   | 34. How many micrograms? ug                        |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 35. Additional FEV <sub>1</sub> values after additional albuterol (reported/best) :            |  |        |         |            |        |       |        |      |   |                 |  |      |  | BTPS |
| POST-BRONCHOSCOPY STATUS   |  |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 36. Did the participant experience any adverse events during the bronchoscopy? (Y/N)           |  |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 37. Did the participant need to be admitted for overnight observation post bronchoscopy? (Y/N) |  |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 38. CONDITION ON DISCHARGE:  |  |        |         |            |        |       |        |      |   |                 |  |      |  |      |
|  | a. No chest d                                      | liscor | nfort   | complai    | nts (` | Y/N). |        |      |   |                 |  |      |  |      |
|  | b. Alert / resp                                    | onsiv  | /e (Y   | ′/N)       |        |       |        |      |   |                 |  |      |  |      |
|  | c. Oriented to                                     | time   | e, per  | rson, pla  | ce (\  | ′/N)  |        |      |   |                 |  |      |  |      |
|  | d. Heart rate                                      | < 100  | 0/min   | 1 (Y/N).   |        |       |        |      |   |                 |  |      |  |      |
|  | e. Ambulate  | w/o d  | ifficul | Ity (Y/N)  |        |       |        |      |   |                 |  |      |  |      |
|  | f. Sips water                                      | w/o    | cougl   | h/difficul | ty (Y  | /N)   |        |      |   |                 |  |      |  |      |
|  | g. FEV1 > 90                                       | % of   | the p   | ore-BD b   | aseli  | ne FE | ₹V1 (Y | ′/N) |   |                 |  |      |  |      |
| 39   | . Comments: _                                      |        |         |            |        |       |        |      |   |                 |  |      |  |      |
| 40   | . Coordinator S                                    | Signa  | ature   | e and Da   | ate:   |       |        |      |   |                 |  |      |  |      |