


BRONCHOSCOPY SUB-STUDY SPECIMEN COLLECTION WORKSHEET, BCW QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Bronchoscopy Sub-study Specimen Collection Worksheet (BCW) is to be completed during the participant's Bronchoscopy Visit 2.

Please answer every question on this form. *NOTE: All response options in the paper form may not appear in CDART (e.g., 'Don't know', 'Declines to answer', etc.).* Beside each item input is a small double bracket icon which looks like this: . Clicking this icon displays a field dialogue box in which the "Field Status" selection menu allows you to choose from the following options: 'Refused', 'No response', 'Doesn't know', 'Not applicable', 'Maximum value', 'Minimum value', and 'Missing'. **See MOP 6 – Section 3.2 for additional instructions on how to select a Field Status option.**

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 (e.g., enter 0.25 rather than .25).

II. INSTRUCTIONS FOR INDIVIDUAL ITEMS

Header Information: Consists of key fields which uniquely identify each subject and recorded occurrence of a form. For the "ID NUMBER", record the 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at Pre-Bronchoscopy Visit 1 or Bronchoscopy Visit 2.

- Item 0a.** Record the date the data was collected or abstracted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 0b.** Record the SOURCE staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.

OXYGEN SATURATION (OF ROOM AIR) (PRE-BRONCHOSCOPY)

- Item 1.** Record the O₂ saturation of the room air in % in the space provided.

MEDICAL HISTORY AND PHYSICAL

- Item 2.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 3.
 - Item 2a.** Describe the lab work prior to bronchoscopy required by your center in the space provided.
 - Item 2b.** Select only one option among the two possible choices.
 - Item 2c.** Select only one option among the two possible choices. If 'Yes' is selected, **Go to End** of the form, and **Save and Close** the form.

- Item 3.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 4.
- Item 3a.** Select only one option among the two possible choices.
- If 'No' is selected, skip to Item 3b.
 - If 'Yes' is selected, complete Item 3a1; then, **Go to End** of the form, and **Save and Close** the form.
- Item 3a1.** Describe the other physical symptoms or conditions that make the participant ineligible for participation in the bronchoscopy sub-study in the opinion of the doctor in the space provided.
- Item 3b.** Select only one option among the two possible choices.
- If 'No' is selected, skip to Item 4.
 - If 'Yes' is selected, complete Item 3b1; then, **Go to End** of the form, and **Save and Close** the form.
- Item 3b1.** Describe the new physical symptoms or conditions reported by the participant that would make the participant ineligible for participation in the bronchoscopy sub-study in the space provided.
- Item 4.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 5.
- Item 4a.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 5.
- Item 4b.** Select only one option among the two possible choices.
- Item 5.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 6.
- Items 5a-5e.** Select only one option among the two possible choices.
- Item 6.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 7.
- Item 6a.** Record the date of onset of the acute exacerbation of COPD in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 7.** Select only one option among the two possible choices. If 'Yes' is selected, skip to Item 8.
- Item 7a.** Record the date of the participant's most recent completed spirometry in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 8.** Record the participant's pre-bronchodilator FEV₁ (reported/best; today or most recent) in L-BTPS in the space provided.
- Item 9.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 10.
- Item 9a.** Record the amount of albuterol administered to the participant in micrograms in the space provided.
- Item 10.** Record the participant's post-bronchodilator FEV₁ (reported/best; today or most recent) in L-BTPS in the space provided.

BLOOD COLLECTION

- Item 11.** Record the date the blood was collected in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.
- Item 12.** Record the time (i.e., hour/minute) the blood was collected in the HH:MM AM/PM format in the space provided.
- Item 13.** Record the number of times venipuncture was attempted for the blood collection, including the successful attempt, in the space provided.
- Item 14.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 16.

NOTE: Document problems with blood drawing in Items 14a-14g. If a problem other than those listed occurred, use Item 15.

Item 14a. Select only one option among the two possible choices. If 'No' is selected, skip to Item 14b.

Item 14a1. Specify which tube(s) were not drawn in the space provided.

Items 14b-14g1. Follow the instructions as in Item 14a and Item 14a1 as the question pattern is identical (if applicable).

- Item 15.** Describe any blood drawing incident or problem not listed in Items 14-14g in the space provided.
- Item 16.** Record the staff code of the phlebotomist who collected the blood. This person should have a SOURCE staff code that is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.

NASAL EPITHELIAL BRUSHINGS

- Item 17.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 19.
- Item 18.**

Item 18a. Record the number of brushings completed in the right naris in the space provided.

Item 18b. Record the number of brushings completed in the left naris in the space provided.

Item 18c. Record the time (i.e., hour/minute) the nasal brushings were collected in the HH:MM AM/PM format in the space provided.

ORAL RINSE

- Item 19.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 20.
- Item 19a.** Record the time (i.e., hour/minute) the tongue scrape was collected in the HH:MM AM/PM format in the space provided.

Item 20. Select only one option among the two possible choices. If 'No' is selected, skip to Item 21.

Item 20a. Record the time (i.e., hour/minute) the oral rinse was collected in the HH:MM AM/PM format in the space provided.

Item 20b. Select only one option among the two possible choices. If 'No' is selected, skip to Item 21.

Item 20b1. Select only one option among the two possible choices.

BRONCHOSCOPY PROCEDURES

Item 21. Select only one option among the two possible choices.

Item 22. Select only one option among the two possible choices. If 'No' is selected, skip to Item 23.

Item 22a. Record the lobe the protected brush specimens were collected from in the space provided.

Item 22b. Record the segment the protected brush specimens were collected from in the space provided.

Item 22c. Record the number of protected brush specimens collected in the space provided.

Item 22d. Record the time (i.e., hour/minute) the protected brush specimens were collected in the HH:MM AM/PM format in the space provided.

Item 23. Select only one option among the two possible choices. If 'No' is selected, skip to Item 24.

Item 23a. Record the lobe(s) the bronchial alveolar lavage (BAL) specimens were collected from in the space provided.

Item 23b. Record the segment the bronchial alveolar lavage (BAL) specimens were collected from in the space provided.

Item 23c. Record the amount infused from the bronchial alveolar lavage (BAL) specimens in mL in the space provided.

Item 23d. Record the amount returned from the bronchial alveolar lavage (BAL) specimens in mL in the space provided.

Item 23e. Record the time (i.e., hour/minute) the bronchial alveolar lavage (BAL) specimens were collected in the HH:MM AM/PM format in the space provided.

NOTE: If less than 15 cc of fluid is returned from the combined volume of the 20 cc wash and the 2 x 40 cc lavage, then the 1 x 50 cc lavage should not be performed.

Item 23f. Select only one option among the two possible choices.

Item 24. Select only one option among the two possible choices. If 'No' is selected, skip to Item 25.

Item 24a. Record the lobe the cytological brushings for RNA were collected from in the space provided.

- Item 24b.** Record the segment the cytological brushings for RNA were collected from in the space provided.
- Item 24c.** Record the number of cytological brushes for RNA collected in the space provided.
- Item 24d.** Record the time (i.e., hour/minute) the cytological brushings for RNA were collected in the HH:MM AM/PM format in the space provided.
- Item 25.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 26.
- Item 25a.** Record the lobe the cytological brushings for DNA were collected from in the space provided.
- Item 25b.** Record the segment the cytological brushings for DNA were collected from in the space provided.
- Item 25c.** Record the number of cytological brushes for DNA collected in the space provided.
- Item 25d.** Record the time (i.e., hour/minute) the cytological brushings for DNA were collected in the HH:MM AM/PM format in the space provided.
- Item 26.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 27.
- Item 26a.** Record the lobe the microcytological brushings for mucin were collected from in the space provided.
- Item 26b.** Record the segment the microcytological brushings for mucin were collected from in the space provided.
- Item 26c.** Record the number of microcytological brushes for mucin collected in the space provided.
- Item 26d.** Record the time (i.e., hour/minute) the microcytological brushings for mucin were collected in the HH:MM AM/PM format in the space provided.
- Item 27.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 28.
- Item 27a.** Record the lobe(s) the small airway epithelial brushings were collected from in the space provided.
- Item 27b.** Record the segment(s) the small airway epithelial brushings were collected from in the space provided.
- Item 27c.** Record the number of small airway epithelial brushes collected in the space provided.
- Item 27d.** Record the time (i.e., hour/minute) the small airway epithelial brushings were collected in the HH:MM AM/PM format in the space provided.
- Item 27e.** Select only one option among the two possible choices. If 'No' is selected, skip to Item 28.
- Item 27e1.** Record the time (i.e., hour/minute) the small airway epithelial brushings were put into basal cell culture in the HH:MM AM/PM format in the space provided.

Item 27e2. Record the time (i.e., hour/minute) the small airway epithelial brushings in basal cell culture were passaged and frozen in the HH:MM AM/PM format in the space provided.

Anesthesia with lidocaine should be performed using local protocols with the following limit on lidocaine dose: 600 mg or 9 mg/kg, whichever is less. Some institutions may have a more stringent cutoff, which should be observed (if applicable). Alert the bronchoscopist when 300 mg of lidocaine has been delivered.

Item 28. Record the total amount of 1% Lidocaine used in mg in the space provided.

Item 29. Record the total amount of 2% Lidocaine used in mg in the space provided.

Item 30. Record the total amount of 4% Lidocaine used in mg in the space provided.

Item 31. Select **Save and Reload** in CDART to automatically calculate the total amount of Lidocaine used in mg based on the values entered in Items 28, 29, and/or 30.

Item 32. Select only one option among the two possible choices. If 'No' is selected, skip to Item 33.

Item 32a. Provide detailed comments of any deviations from the planned bronchoscopy collection protocol in the space provided.

Item 33. Select only one option among the two possible choices. If 'No' is selected, skip to Item 39.

Item 34. Record the participant's pre-bronchodilator FEV₁ (reported/best; post-bronchoscopy) in L-BTPS in the space provided.

Item 35. Select only one option among the two possible choices. If 'No' is selected, skip to Item 36.

Item 35a. Record the amount of albuterol administered to the participant in micrograms in the space provided.

Item 36. Record the participant's post-bronchodilator FEV₁ (reported/best; post-bronchoscopy) in L-BTPS in the space provided.

Item 37. Select only one option among the two possible choices. If 'No' is selected, skip to Item 39.

Item 37a. Record the amount of additional albuterol administered to the participant in micrograms in the space provided.

Item 38. Record the participant's post-additional bronchodilator FEV₁ (reported/best; post-bronchoscopy) in L-BTPS in the space provided.

POST-BRONCHOSCOPY PROCEDURES STATUS

Item 39. Select only one option among the two possible choices. If 'No' is selected, skip to Item 40.

Item 39a. List relevant adverse events the participant experienced during the bronchoscopy in the space provided.

Item 40. Select only one option among the two possible choices. If 'No' is selected, skip to Item 43.

Item 41.

Items 41a-41g. Use the check boxes to answer all that apply to indicate which of the responses the participant had upon discharge.

Item 42. Enter any comments regarding the participant upon discharge in the space provided.

Item 43. Select only one option among the two possible choices. If 'No' is selected, skip to Item 44.

Item 43a. Record the SOURCE staff code of the person who contacted the participant. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.

Item 43b. Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 43c. Select only one option among the two possible choices. If 'No' is selected, skip to Item 44.

Item 43c1. Describe any problems the participant had the night of the bronchoscopy procedure in the space provided.

Item 44. Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.

Item 44a. Record the SOURCE staff code of the person who contacted the participant. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SOURCE data, please contact the GIC in order to receive your own individual staff code.

Item 44b. Record the date the participant was contacted in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 44c. Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.

Item 44c1. Describe any problems the participant had 24 hours after the bronchoscopy procedure in the space provided.

Select **Save and Close** at the bottom of the page/screen.