BRONCHOSCOPY SUB-STUDY SPECIMEN PROCESSING WORKSHEET, BPW
QUESTION BY QUESTION (QxQ), VERSION 5.0

I. GENERAL INSTRUCTIONS

The Bronchoscopy Sub-study Specimen Processing Worksheet (BPW) 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.

BLOOD

Item 1.

    Item 1a. Record the time (i.e., hour/minute) the purple top (EDTA) tube for local lab CBC was processed in the HH:MM AM/PM format in the space provided.

Item 2.

    Item 2a. Record the time (i.e., hour/minute) the purple top (EDTA) tubes for immunophenotyping were processed in the HH:MM AM/PM format in the space provided.

    Item 2b. Record the time (i.e., hour/minute) the purple top (EDTA) tubes for immunophenotyping were placed in the refrigerator in the HH:MM AM/PM format in the space provided.

Item 3.

    Item 3a. Record the time (i.e., hour/minute) the purple top (EDTA) tube for biomarkers was processed in the HH:MM AM/PM format in the space provided.

Item 3b.   Record the number of aliquots for biomarkers in the space provided.

Item 3c.   Record the volume of the last aliquot for biomarkers in microliters in the space provided.

Item 3d.   Record the time (i.e., hour/minute) the purple top (EDTA) tube for biomarkers was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 4.

Item 4a.   Record the time (i.e., hour/minute) the purple top (EDTA) tube for biomarkers was processed in the HH:MM AM/PM format in the space provided.

Item 4b.   Record the number of aliquots for biomarkers in the space provided.

Item 4c.   Record the volume of the last aliquot for biomarkers in microliters in the space provided.

Item 4d.   Record the time (i.e., hour/minute) the purple top (EDTA) tube for biomarkers was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 5.

Item 5a.   Record the time (i.e., hour/minute) the red top (for serum) tube for biomarkers was processed in the HH:MM AM/PM format in the space provided.

Item 5b.   Record the number of aliquots for biomarkers in the space provided.

Item 5c.   Record the volume of the last aliquot for biomarkers in microliters in the space provided.

Item 5d.   Record the time (i.e., hour/minute) the red top (for serum) tube for biomarkers was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 6.

Item 6a.   Record the time (i.e., hour/minute) the red top (for serum) tube for biomarkers was processed in the HH:MM AM/PM format in the space provided.

Item 6b.   Record the number of aliquots for biomarkers in the space provided.

Item 6c.   Record the volume of the last aliquot for biomarkers in microliters in the space provided.

Item 6d.   Record the time (i.e., hour/minute) the red top (for serum) tube for biomarkers was placed in the freezer in the HH:MM AM/PM format in the space provided.

NASAL SWAB

Item 7.

Item 7a.   Record the number of nasal swabs processed in the space provided.

Item 8.   Select only one option among the two possible choices. If 'No' is selected, skip to Item 9.

Items 8a-8b.   Use the check boxes to answer all that apply to specify the problem(s) processing the nasal swab.

Item 8b1. Specify other problem processing the nasal swab in the space provided.

Item 9. Record the time (i.e., hour/minute) the nasal swab was processed in the HH:MM AM/PM format in the space provided.

Item 10. Record the time (i.e., hour/minute) the nasal swab was placed in the freezer in the HH:MM AM/PM format in the space provided.

ORAL SPECIMEN

Item 11. Record the time (i.e., hour/minute) the oral specimen was processed in the HH:MM AM/PM format in the space provided.

Item 12. Record the number of 15 mL freezer jars in the space provided.

Item 13. Record the time (i.e., hour/minute) the 15 mL freezer jars were placed in the refrigerator in the HH:MM AM/PM format in the space provided.

Item 14. Record the date the 15 mL freezer jars were moved to the freezer in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 15. Record the time (i.e., hour/minute) the 15 mL freezer jars were moved to the freezer in the HH:MM AM/PM format in the space provided.

SALINE SPECIMEN

Item 16. Record the time (i.e., hour/minute) the <u>Scope Saline</u> specimen was placed in the freezer in the HH:MM AM/PM format in the space provided.

PROTECTED BRUSH SPECIMEN

Item 17. Record the time (i.e., hour/minute) the protected brush specimen was processed in the HH:MM AM/PM format in the space provided.

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

Items 18a-18b. Use the check boxes to answer all that apply to specify the problem(s) processing the protected brush specimen.

Item 18b1. Specify other problem processing the protected brush specimen in the space provided.

Item 19. Record the time (i.e., hour/minute) the protected brush specimen was placed in the refrigerator in the HH:MM AM/PM format in the space provided.

Item 20. Record the date the protected brush specimen was moved to the freezer in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 21. Record the time (i.e., hour/minute) the protected brush specimen was moved to the freezer in the HH:MM AM/PM format in the space provided.

BAL

Microbiome Sample with No Reagent:

Item 22. Record the time (i.e., hour/minute) the microbiome sample with no reagent was transferred to a 15 mL conical tube in the HH:MM AM/PM format in the space provided.

Item 23. Record the time (i.e., hour/minute) the microbiome sample with no reagent was placed in the freezer in the HH:MM AM/PM format in the space provided.

Microbiome Sample with RNA*later*™:

Item 24. Record the time (i.e., hour/minute) the microbiome sample with RNA*later*™ was processed in the HH:MM AM/PM format in the space provided.

Item 25. Record the time (i.e., hour/minute) the microbiome sample with RNA*later*™ was placed in the refrigerator in the HH:MM AM/PM format in the space provided.

Item 26. Record the date the microbiome sample with RNA*later*™ was moved to the freezer in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 27. Record the time (i.e., hour/minute) the microbiome sample with RNA*later*™ was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 28. Record the total volume of mixed pooled BAL fluid prior to centrifugation in mL in the space provided. *NOTE: This is the volume after both microbiome samples are completed.*

Supernatant Sample:

Item 29. Record the time (i.e., hour/minute) the supernatant sample was processed in the HH:MM AM/PM format in the space provided.

Item 30. Record the number of 1 mL aliquots made from the supernatant sample in the space provided.

Item 31. Record the number of 15 mL aliquots made from the supernatant sample in the space provided.

Item 32. Record the time (i.e., hour/minute) the supernatant sample was placed in the freezer in the HH:MM AM/PM format in the space provided.

Cell Counts:

Item 33. Record the time (i.e., hour/minute) the cell count was processed in the HH:MM AM/PM format in the space provided.

Item 34. Record the total volume returned of cell count in mL in the space provided.

Item 35. Record the <u>LIVE</u> cell count number in cells/mL in the space provided.

Item 36.   Record the <u>DEAD</u> cell count number in cells/mL in the space provided.

Item 37.   Record the <u>TOTAL</u> cell count number in cells in the space provided.

Item 38.   Select **Save and Reload** in CDART to automatically calculate the % cell viability based on the values entered and/or calculated in Items 35 and 36 [i.e., (35 / (35 + 36)) x 100]. *NOTE: If Items 35 and/or 36 is missing or not entered and/or calculated appropriately, Item 38 will not calculate.*

Item 39.   Record the cytospin suspension number in cells in the 10 mL tube in the space provided.

Item 40.   Record the volume to resuspend the pellet in with PBS in mL in the space provided.

Cytospin Slide Sample:

Item 41.   Record the time (i.e., hour/minute) the cytospin slide sample was processed in the HH:MM AM/PM format in the space provided.

Item 42.   Record the number of cytospin slides in the space provided.

Item 43.   Record the time (i.e., hour/minute) the cytospin slide sample(s) were fixed in the HH:MM AM/PM format in the space provided.

Alveolar Macrophage Isolation:

NOTE: The alveolar macrophage isolation <u>MUST</u> be processed <u>EXACTLY</u> 2 hours after collection.

Item 44.   Record the time (i.e., hour/minute) the alveolar macrophage isolation was processed in the HH:MM AM/PM format in the space provided.

Items 45-46.   Select only one option among the two possible choices.

Item 47.   Select only one option among the two possible choices. If 'No' is selected, skip to Item 48.

    Item 47a.   Record the number of minutes since alveolar macrophage isolation in the space provided.

    Item 47b.   Record the reason the alveolar macrophage isolation was processed sooner than 2 hours after collection in the space provided.

Item 48.   Select only one option among the two possible choices. If 'No' is selected, skip to Item 49.

    Item 48a.   Record the number of minutes since alveolar macrophage isolation in the space provided.

    Item 48b.   Record the reason the alveolar macrophage isolation was processed more than 2 hours after collection in the space provided.

Item 49.   Record the time (i.e., hour/minute) the alveolar macrophage isolation processing was completed in the HH:MM AM/PM format in the space provided.

Item 50.   Record the time (i.e., hour/minute) the alveolar macrophage isolation was placed in the freezer in the HH:MM AM/PM format in the space provided.

Immunophenotyping BAL:

Item 51.   Record the time (i.e., hour/minute) the immunophenotyping BAL was processed in the HH:MM AM/PM format in the space provided.

Item 52.   Record the time (i.e., hour/minute) the immunophenotyping BAL processing was completed in the HH:MM AM/PM format in the space provided.

Item 53.   Record the time (i.e., hour/minute) the immunophenotyping BAL was placed in the refrigerator in the HH:MM AM/PM format in the space provided.

CYTOLOGICAL BRUSHES FOR RNA (x 3)

Item 54.   Select only one option among the two possible choices. If 'No' is selected, skip to Item 55.

Items 54a-54b.   Use the check boxes to answer all that apply to specify the problem(s) processing the cytological brushes (RNA).

Item 54b1.   Specify other problem processing the cytological brushes (RNA) in the space provided.

Cytospin Slides:

Item 55.   Record the time (i.e., hour/minute) the cytospin slides were processed in the HH:MM AM/PM format in the space provided.

Item 56.   Record the cell count number in cells/mL in the space provided.

Item 57.   Record the number of cytospin slides in the space provided.

Epithelial RNA Extraction:

Item 58.   Record the time (i.e., hour/minute) the epithelial RNA extraction was processed in the HH:MM AM/PM format in the space provided.

Item 59.   Record the time (i.e., hour/minute) the epithelial RNA extraction was placed in the freezer in the HH:MM AM/PM format in the space provided.

CYTOLOGICAL BRUSHES FOR DNA (x 2)

Item 60.   Select only one option among the two possible choices. If 'No' is selected, skip to Item 61.

Items 60a-60b.   Use the check boxes to answer all that apply to specify the problem(s) processing the cytological brushes (DNA).

Item 60b1.   Specify other problem processing the cytological brushes (DNA) in the space provided.

Item 61.   Record the time (i.e., hour/minute) the cytological brushes (DNA) were processed in the HH:MM AM/PM format in the space provided.

Item 62. Record the time (i.e., hour/minute) the cytological brushes (DNA) were placed in the freezer in the HH:MM AM/PM format in the space provided.

MICROCYTOLOGICAL BRUSHES FOR MUCIN (x 2)

Item 63. Select only one option among the two possible choices. If 'No' is selected, skip to Item 64.

Items 63a-63b. Use the check boxes to answer all that apply to specify the problem(s) processing the microcytological brushes (Mucin).

Item 63b1. Specify other problem processing the microcytological brushes (Mucin) in the space provided.

Item 64. Record the time (i.e., hour/minute) the microcytological brushes (Mucin) were processed in the HH:MM AM/PM format in the space provided.

Item 65. Record the time (i.e., hour/minute) the PBS tube was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 66. Record the time (i.e., hour/minute) the Urea tube was placed in the refrigerator in the HH:MM AM/PM format in the space provided.

SMALL AIRWAY EPITHELIAL BRUSHES

Item 67. Select only one option among the two possible choices. If 'No' is selected, skip to Item 68.

Items 67a-67b. Use the check boxes to answer all that apply to specify the problem(s) processing the small airway epithelial brushes.

Item 67b1. Specify other problem processing the small airway epithelial brushes in the space provided.

Cytospin Slides:

Item 68. Record the time (i.e., hour/minute) the cytospin slides were processed in the HH:MM AM/PM format in the space provided.

Item 69. Record the cell count number in cells/mL in the space provided.

Item 70. Record the number of cytospin slides in the space provided.

Epithelial RNA Extraction:

Item 71. Record the time (i.e., hour/minute) the epithelial RNA extraction was processed in the HH:MM AM/PM format in the space provided.

Item 72. Record the time (i.e., hour/minute) the RNA tube was placed in the freezer in the HH:MM AM/PM format in the space provided.

Item 73. Record the time (i.e., hour/minute) the DNA tubes were placed in the freezer in the HH:MM AM/PM format in the space provided.

Basal Cells for Culture:

Item 74. Record the time (i.e., hour/minute) the basal cells were put into culture in the HH:MM AM/PM format in the space provided.

    Item 74a. Record the date the basal cells were put into culture in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 75. Record the time (i.e., hour/minute) the basal cells were put into passage in the HH:MM AM/PM format in the space provided.

    Item 75a. Record the date the basal cells were put into passage in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 76. Record the time (i.e., hour/minute) the basal cells were frozen in the HH:MM AM/PM format in the space provided.

    Item 76a. Record the date the basal cells were frozen in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 77. Record the number of basal cell stock aliquots in the space provided.

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