

INSTRUCTIONS FOR EXHALED BREATH CONDENSATE COLLECTION FORM EBC, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Exhaled Breath Condensate Collection Form (EBC) is to be completed during the participant's Clinic Visit 5 and/or during the Bronchoscopy Substudy Visit. It documents the exhaled breath condensate collection process.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected or abstracted. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS 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 SPIROMICS data please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Please answer every question on this form.

- Item 1. **Exhaled breath condensate sample collection:** Select only one option among the two possible choices.
 - Select No if the exhaled breath condensate sample was not collected. [Go to END]
 - Select Yes if the exhaled breath condensate sample was collected.
- Item 2. Start time of EBC collection: Record the time that the EBC collection began in hours: minutes.
- Item 3. End time of EBC collection: Record the time that the EBC collection stopped in hours: minutes.
- Item 4. **EBC collection early termination**: Select only one option among the two possible choices.
 - Select No if the EBC collection was not terminated early. [Go to Q5]
 - Select Yes if the EBC collection was terminated early.
- Item 4a. Specify reason for early termination: Specify why EBC collection was terminated early.
- Item 5. **Number of aliquots created:** Record the number of aliquots created from the processed EBC collected.

Note: If the answer to Q4 was Yes and no sample was created due to early termination enter zero for the number of aliquots collected. The number entered here will determine the number of aliquots presented for recording volume in Q6.

Item 6. **Volume of EBC aliquots collected:** Record the volume of each EBC aliquot collected in microliters.

Note: The number of aliquots entered in Q5 will determine the number of successive aliquots presented here (i.e. Item 6a., Item 6b, etc.) for recording volume.

Item 6a. Volume of Aliquot 1: Record the volume of aliquot 1 in microliters.

[If needed] Item 6b. Volume of Aliquot 2: Record the volume of aliquot 2 in microliters.

[If needed] Item 6c. Volume of Aliquot 3: Record the volume of aliquot 3 in microliters.

[If needed] Item 6d. Volume of Aliquot 4: Record the volume of aliquot 4 in microliters.

- Item 7. **EBC sample aliquots freezer storage:** Record the time that the EBC sample aliquots were placed in the -80°C freezer in hours: minutes.
- Item 8. **Incidents or problems during collection:** Select only one option among the two possible choices.
 - Select No if there were no incidents or problems during collection. [Go to End]
 - Select Yes if there were incidents or problems during collection.
- Item 8a. **Describe incidents or problems:** Describe incidents or problems that occurred during the exhaled breath condensate collection.

Save and close the form.