BRONCHOSCOPY SUB-STUDY INCLUSION/EXCLUSION CRITERIA FORM, BIE QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Bronchoscopy Sub-study Inclusion/Exclusion Criteria Form (BIE) is to be completed immediately after the participant signs the SOURCE Bronchoscopy Sub-study informed consent. This form, along with spirometry, determines the participant's eligibility for the SOURCE Bronchoscopy Sub-study.

NOTE: In order for a participant to be considered 'screened', the BIE form must be entered into CDART with all questions populated.

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

Each question should be read <u>exactly</u> as written to allow for consistency in screening data collection.

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.

Item 1.   CDART will automatically populate the participant's age based on the values entered in the PID and BIE forms (i.e., PID1 and BIE0a). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If PID1 and/or BIE0a is missing or not entered appropriately, Item 1 in the BIE form will not calculate and will not auto-populate accordingly.*

Item 2.   Select only one option among the two possible choices. If 'No' is selected, go to Item 3.

   Items 2a-2b.   Select only one option among the two possible choices.

Item 3.   Select only one option among the two possible choices. If 'No' is selected, go to Item 4.

Item 3a.   List any medication(s) that thin the blood the participant is currently taking in the space provided.

Item 3b.   Select only one option among the two possible choices.

Item 4.   Select only one option among the two possible choices. If 'No' is selected, go to Item 5.

Item 4a.   Describe any cardiac disease the participant has been diagnosed in the space provided.

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, go to Item 6.

Item 5a.   Describe any other significant illness the participant has in the space provided.

Item 5b.   Select only one option among the two possible choices.

Item 6.   Select only one option among the two possible choices. If 'No' is selected, go to Item 7.

Item 6a.   Describe any other physical symptoms or conditions that make this participant ineligible per your investigator's opinion in the space provided.

Item 7.   Select only one option among the two possible choices. If 'No' is selected, go to Item 8.

Item 7a.   Describe any additional lab tests prior to bronchoscopy the study physician ordered in the space provided.

Items 7b-7c.   Select only one option among the two possible choices.

Item 8.   Select only one option among the two possible choices.

Item 9.   Select only one option among the two possible choices. If 'No' is selected, go to Item 10.

Item 9a.   Record the PI's electronic signature in the space provided.

Item 9b.   Record the date of the PI signature in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 10.   Record any comments related to the participant's bronchoscopy sub-study eligibility status in the space provided.

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