



INSTRUCTIONS FOR BRONCHOSCOPY SUBSTUDY INCLUSION/EXCLUSION CRITERIA FORM BIE, VERSION 3.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

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

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 that has not already been auto-filled.

- Item 1. **Participant's age at time of visit:** Computer will auto-fill one option among the two possible choices.
- Computer auto-filled response 0= No the participant is eligible being younger than age 80 at the time of visit.
 - Computer auto-filled response 1=Yes the participant is ineligible being age 80 or older at the time of visit. [Go to Q9]
- Item 2. **Supplemental oxygen:** Select only one option among the two possible choices.
- Select No if the participant does not use supplemental oxygen while at rest (sitting or lying down). [go to Q3]
 - Select Yes if the participant does use supplemental oxygen while at rest (sitting or lying down).
- Item 2a. **Oxygen saturation:** Select only one option among the two possible choices.
- Select No if the participant's PaO₂ is greater than 60% or SaO₂ is greater than 88%.
 - Select Yes if the participant's PaO₂ is less than 60% or SaO₂ is less than 88%.
- Item 2b. **Supplement oxygen use at described in 2a:** Select only one option among the two possible choices.
- Select No if the participant's use of supplemental oxygen as described in 2a does not make the participant ineligible.
 - Select Yes if the participant's use of supplemental oxygen as described in 2a does make the participant ineligible. [go to Q9]

- Item 3. **Current blood-thinning medications:** Select only one option among the two possible choices.
- Select No if the participant is not currently taking any medications that thin the blood, such as anti-platelet medications such as Clopidogrel or Ticagrelor, or anticoagulants such as Warfarin, Apixaban, Rivaroxaban, Dabigatran, or other similar medications. [Go to Q4]
 - Select Yes if the participant is currently taking any medications that thin the blood, such as anti-platelet medications such as Clopidogrel or Ticagrelor, or anticoagulants such as Warfarin, Apixaban, Rivaroxaban, Dabigatran, or other similar medications.
- Item 3a. If yes, list the medication(s) in the space provided.
- Item 3b. **Medications listed in 3a:** Select only one option among the two possible choices.
- Select No if the participant's use of medications listed in 3a does not make the participant ineligible.
 - Select Yes if the participant's use of medications listed in 3a does make the participant ineligible. [go to Q9]
- Item 4. **Cardiac disease:** Select only one option among the two possible choices.
- Select No if the participant has never been diagnosed with cardiac disease. [Go to Q5]
 - Select Yes if the participant has been diagnosed with cardiac disease.
- Item 4a. If yes, describe the cardiac disease diagnosis.
- Item 4b. **Cardiac disease described in 4a:** Select only one option among the two possible choices.
- Select No if the participant's cardiac disease described in 4a does not make the participant ineligible.
 - Select Yes if the participant's cardiac disease described in 4a does make the participant ineligible. [go to Q9]
- Item 5. **Heart or lung disease:** Select only one option among the two possible choices.
- Select No if the participant has never been diagnosed with heart or lung disease. [Go to Q6]
 - Select Yes if the participant has been diagnosed with heart or lung disease.
- Item 5a. If yes, describe the heart or lung disease diagnosis.
- Item 5b. **Heart or lung disease described in 5a:** Select only one option among the two possible choices.
- Select No if the participant's heart or lung disease described in 5a does not make the participant ineligible.
 - Select Yes if the participant's heart or lung disease described in 5a does make the participant ineligible. [go to Q9]
- Item 6. **Post-bronchodilator FEV1:** Select only one option among the two possible choices.
- Select No if the participant's post-bronchodilator FEV1 is less than 30% predicted.
 - Select Yes if the participant's post-bronchodilator FEV1 is greater than 30% predicted.
- Item 7. **Other physical symptoms or conditions:** Select only one option among the two possible choices.
- Select No if the opinion of the investigator is that there are no other physical symptoms or conditions that would make this participant ineligible for participation in the bronchoscopy substudy. [Go to Q8]

- Select Yes if the opinion of the investigator is that there are other physical symptoms or conditions that would make this participant ineligible for participation in the bronchoscopy substudy. [Go to Q7a]

Item 7a. If yes, describe the other physical symptoms or conditions that would make this participant ineligible. [Go to Q9]

Item 8. **Additional lab tests:** Select only one option among the two possible choices.

- Select No if the study physician did not order any additional lab tests prior to bronchoscopy. [Go to Q9]
- Select Yes if the study physician did order any additional lab tests prior to bronchoscopy.

Item 8a. If yes, describe the additional lab tests.

Item 8b. **Lab work results:** Select only one option among the two possible choices.

- Select No if the additional lab work results were normal.
- Select Yes if the additional lab work results were abnormal.

Item 8c. **Lab results described in 8a and 8b:** Select only one option among the two possible choices.

- Select No if the results of blood work described in 8a and 8b do not make the participant ineligible.
- Select Yes if the results of blood work described in 8a and 8b make the participant ineligible.

Item 9. **Eligibility determination:** Computer will auto-fill one option among the two possible choices.

- Computer auto-filled response 0=No if the participant is not eligible for enrollment in the SPIROMICS Bronchoscopy Substudy.
- Computer auto-filled response 1=Yes if the participant is eligible for enrollment in the SPIROMICS Bronchoscopy Substudy.

Save and close the form.