SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

Temporary Inclusion/Exclusion Criteria, IEC
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Temporary Inclusion/Exclusion Criteria (IEC) should be completed immediately after the participant signs the informed consent before proceeding with the study visit. Some of the information collected on this form may determine if the participant is eligible for the study visit at this point in time or if the participant should be re-screened for completion of the study visit at a later date. Please read form notes carefully to determine whether the participant's response to a given item may affect their current eligibility.

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.**

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 2 or 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at the clinic visit (E1), a follow-up phone call, or "other."

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 SPIROMICS III 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 III data, please contact the GIC in order to receive your own individual staff code.

Item 1-7. These items have been removed.

NOTE TO INTERVIEWER: Questions 8-11 do *not* affect current eligibility. These data are being collected for analysis purposes only.

Item 8a-8d. Select only one option among the two possible choices to indicate if the statement applies to the participant.

Item 9a-9c. Select only one option among the two possible choices to indicate if the statement applies to the participant.

Item 10a-10g. Select only one option among the two possible choices to indicate if the statement applies to the participant.

Item 11. Select only one option among the two possible choices to indicate if the participant is currently taking any immunosuppressives. If 'No' is selected, go to item 13.

Item 11a. List immunosuppressives that the participant is currently taking.

Item 12. This item was removed.

NOTE TO INTERVIEWER: Questions 13-16 *do* affect current eligibility as indicated.

Item 13a-13d. Select only one option among the two possible choices to indicate if the statement applies to the participant.

Item 14a-14b. Select only one option among the two possible choices to indicate if the statement applies to the participant.

Item 15. Select only one option among the two possible choices to indicate if the participant has taken antibiotics in the last 30 days. If 'No' is selected, go to item 16.

Item 15a. Select only one option among the two possible choices to indicate if the participant is taking the antibiotics as part of a long-term or suppressive treatment.

Item 15b. Select only one option among the two possible choices to indicate if the participant has been taking these long-term antibiotics continuously for at least six weeks.

Item 16. **For female participants only. If the participant is male, go to item 17.** Select only one option among the two possible choices.

Instructions: If the participant answers Yes to any one of the questions 17-22, please consult the study physician regarding impact on eligibility for the study visit at this point in time, which is at their discretion/decision, or whether the participant should be re-screened at a later point in time.

Item 17. Select only one option among the two possible choices to indicate if the participant has ever been diagnosed with any other heart of lung disease. If 'No' is selected, go to item 18.

Item 17a. Describe other heart or lung disease with which the participant has been diagnosed.

Item 18. Select only one option among the two possible choices to indicate if the participant has ever had any other kind of lung surgery. If 'No' is selected, go to item 19.

Item 18a. Describe other kind of lung surgery that the participant had.

Item 19. Select only one option among the two possible choices to indicate if the participant has any other significant illness. If 'No' is selected, go to item 20.

Item 19a. Describe other significant illness that the participant has.

Item 20. Select only one option among the two possible choices to indicate if the participant has any metal implants in their chest. If 'No' is selected, go to item 21.

Item 20a. Describe metal implants that the participant has in their chest.

Item 21. Select only one option among the two possible choices to indicate if the participant has ever or is currently undergoing chemotherapy or radiation treatments.

Item 22. Select only one option among the two possible choices to indicate if the participant is currently enrolled in any other clinical trial or research study. If 'No' is selected, go to end of form.

Item 22a. Describe other clinical trial or research study in which the participant is currently enrolled.

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