SOURCE
SPIROMICS Study of Early COPD Progression

INCLUSION/EXCLUSION CRITERIA FORM, IEC
QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Inclusion/Exclusion Criteria Form (IEC) is to be completed immediately after the participant signs the informed consent. This form determines the participant's eligibility along with information in the following forms: ANT, DEM, CAA, PID, and SDF. After completing the IEC form and the others required, the study coordinator will run the *'Participant Eligibility Report'* to determine eligibility status and study group.

NOTE: In order for a participant to be considered 'screened', the IEC 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

Read the instructions as they are written to the participant. 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 Baseline or another event.

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.

NOTE: Read the script preceding Item 1 <u>exactly</u> as written to the participant.

Item 1.   CDART will automatically populate the participant's age based on the values entered in the PID and DEM forms (i.e., PID1 and DEM0a). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If PID1 and/or DEM0a is missing or not entered appropriately, Item 1 in the DEM form will not calculate, and Item 1 in the IEC form will not auto-populate accordingly.*

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

Item 2a.   Record the number of years the participant has or did smoke in the space provided.

Item 2b. Record the average number of packs of cigarettes the participant did or does smoke each day in the space provided.

Item 2c. Select **Save and Reload** in CDART to automatically calculate the participant's number of smoking pack-years based on the values entered in Items 2a and 2b. *NOTE: If Item 2a and/or 2b is missing or not entered appropriately, Item 2c will not calculate accordingly.*

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

Item 4. CDART will automatically populate the participant's assigned sex at birth based on the entry selected in the DEM form (i.e., DEM7). If not selected appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If DEM7 is missing or not selected appropriately, Item 4 in the IEC form will not auto-populate accordingly.* If 'Male' is populated, go to Item 5.

Items 4a-4c. Select only one option among the two possible choices.

Item 5. CDART will automatically populate the participant's BMI based on the values entered in the ANT form (i.e., ANT2 and ANT3). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If ANT2 and/or ANT3 is missing or not entered appropriately, Item 4 in the ANT form will not calculate, and Item 5 in the IEC form will not auto-populate accordingly.*

Item 6. CDART will automatically populate the participant's CAAT score based on the values entered in the CAA form (i.e., CAA1-8). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If one or more items (i.e., CAA Items 1-8) are missing or not entered appropriately, Item 9 will not calculate, and Item 6 in the IEC form will not auto-populate accordingly.*

Item 7.

Item 7a. CDART will automatically calculate the participant's FEV_1 % predicted based on the values entered in the ANT, DEM, PID, and SDF forms (i.e., ANT2, DEM0a, DEM5, DEM6a-6e, DEM7, PID0a, PID1, and SDF4a). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If one or more items (i.e., ANT2, DEM0a, DEM5, DEM6a-6e, DEM7, PID0a, PID1, and/or SDF4a) are missing or not entered appropriately, Item 7a in the IEC form will not auto-calculate accordingly.*

Item 7b. CDART will automatically populate the participant's FEV_1/FVC ratio based on the values entered in the SDF form (i.e., SDF4a and SDF4b). If not calculated appropriately, the autogenerated field will not populate and will remain a greyed-out box. *NOTE: If SDF4a and/or SDF4b is missing or not entered appropriately, Item 4c in the SDF form will not calculate, and Item 7b in the IEC form will not auto-populate accordingly.*

NOTE: Read the script preceding Item 8 <u>exactly</u> as written to the participant.

Item 8.

Items 8a-8d. Select only one option among the two possible choices.

NOTE: Read the script preceding Item 9 <u>exactly</u> as written to the participant.

Item 9.

    Items 9a-9c.   Select only one option among the two possible choices.

NOTE: Read the script preceding Item 10 <u>exactly</u> as written to the participant.

Item 10.

    Items 10a-10g.   Select only one option among the two possible choices.

Item 11.   Select only one option among the two possible choices. If 'No' is selected, go to Item 12.

    Item 11a.   List any immunosuppressives the participant is currently taking in the space provided.

    Item 11b.   Select only one option among the two possible choices.

NOTE: Read the script preceding Item 12 <u>exactly</u> as written to the participant.

Item 12.

    Items 12a-12c.   Select only one option among the two possible choices.

NOTE: Read the script preceding Item 13 <u>exactly</u> as written to the participant.

<mark>**If 'Yes' to one or more of Items 13a-13d, the participant will need to be rescreened after 6 weeks.**</mark>

Item 13.

    Items 13a-13d.   Select only one option among the two possible choices.

NOTE: Read the script preceding Item 14 <u>exactly</u> as written to the participant.

<mark>**If 'Yes' to one or both of Items 14a-14b and/or Item 15, the participant will need to be rescreened after 30 days.**</mark>

Item 14.

    Items 14a-14b.   Select only one option among the two possible choices.

Item 15.   Select only one option among the two possible choices. If 'No' is selected, go to Item 16.

    Items 15a-15c.   Select only one option among the two possible choices.

<mark style="background-color: #00FF00">**If Item 4 is 'Female' or 'Declines to answer', go to Item 16. If Item 4 is 'Male', go to Item 17.**</mark>

NOTE: Read the script preceding Item 16 <u>exactly</u> as written to the participant.

<mark>**If 'Yes' to Item 16, the participant will need to be rescreened after 3 months.**</mark>

Item 16.   Select only one option among the two possible choices.

NOTE: Read the script preceding Item 17 <u>exactly</u> as written to the participant.

If 'Yes' to one or more of Items 17-22, the study coordinator should consult the PI regarding the participant's eligibility.

Item 17. Select only one option among the two possible choices. If 'No' is selected, go to Item 18.

    Item 17a. Describe any other heart or lung disease the participant has been diagnosed in the space provided.

    Item 17b. Select only one option among the two possible choices.

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

    Item 18a. Describe any other kind of lung surgery the participant has ever had in the space provided.

    Item 18b. Select only one option among the two possible choices.

Item 19. Select only one option among the two possible choices. If 'No' is selected, go to Item 20.

    Item 19a. Describe any other significant illness the participant has in the space provided.

    Item 19b. Select only one option among the two possible choices.

Item 20. Select only one option among the two possible choices. If 'No' is selected, go to Item 21.

    Item 20a. Describe any metal implants the participant has in their chest in the space provided.

    Item 20b. Select only one option among the two possible choices.

Item 21. Select only one option among the two possible choices. If 'No' is selected, go to Item 22.

    Item 21a. Describe the chemotherapy or radiation treatments the participant has ever or is currently undergoing in the space provided.

    Item 21b. Select only one option among the two possible choices.

Item 22. Select only one option among the two possible choices. If 'No' is selected, go to Item 23.

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

    Items 22b-22c. Select only one option among the two possible choices.

Item 23. Select only one option among the two possible choices. If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.

    Item 23a. Select only one option among the four possible choices.

NOTE: To determine the participant's eligibility status and stratum assignment, select the link at the bottom of the last page to run the "Participant Eligibility Report" as circled in red below:

Save form then CLICK HERE to run the Eligibility Report.

Once the "Participant Eligibility Report" is generated, review for the following:

- If "Eligibility Status" is highlighted **green**, please confirm the "Stratum" the participant has been assigned and proceed with SOURCE study procedures.

- If "Eligibility Status" is highlighted **red**, please inform the participant they are ineligible for SOURCE.

- If "Eligibility Status" is highlighted **yellow**, please review the "Comments" section and consult your PI to determine eligibility status.

- If "Eligibility Status" is **blank**, please review the "Comments" section and correct any errors and/or complete any missing items to determine eligibility status.

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