SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

WAIVER OF DOCUMENTATION OF CONSENT TRACKING – PHONE CALL FOLLOW-UP, WPC QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Waiver of Documentation of Consent Tracking – Phone Call Follow-Up (WPC) is to be completed after obtaining the participant's informed agreement from the phone conversation using the Waiver of Documentation of Consent Script.

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. DETAILED 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) 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 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. 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.

<u>Items 2a – 2d refer to the research team member collecting and documenting the waiver</u>

Item 2a. Record the initials of the study personnel who obtained the waiver of documentation of consent.

Item 2b. Record the SPIROMICS III staff code of the study personnel who obtained the waiver of documentation of consent. 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 2c. Record the signature of the study personnel who obtained the waiver of documentation of consent.

Item 2d. Record the date of the signature of the study personnel who obtained the waiver of documentation of consent.

Items 2e – 2h refer to the study personnel who witnessed the collection and documentation of the waiver, if applicable

NOTE: If your site **does not** require a witness (i.e., there is no place for a witness signature on your current approved waivers or consent documents), please set the witness signature field status to "Not applicable" in CDART.

If your local IRB **requires** a witness (i.e., there is a place for a witness signature on your current approved waivers or informed consent documents), use the following guidance:

- If the witness IS a certified CDART user, complete the fields as instructed.
- If the witness IS NOT a certified CDART user, ADD a notelog to the witness signature field noting "[Name of Witness] witnessed the informed consent process but does not have CDART access nor a study staff code".

Item 2e. Record the initials of the study personnel who witnessed the waiver of documentation of consent.

Item 2f. Record the SPIROMICS III staff code of the study personnel who witnessed the waiver of documentation of consent. 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 2g. Record the signature of the study personnel who witnessed the waiver of documentation of consent.

Item 2h. Record the date of the signature of the study personnel who witnessed the waiver of documentation of consent.

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