SPIROMICS
SubPopulations and InteRmediate Outcome Measures In COPD Study

INFORMED CONSENT TRACKING, ITF
QUESTION BY QUESTION (QxQ), VERSION 3.0

I. GENERAL INSTRUCTIONS

The Informed Consent Tracking Form (ITF) is to be completed after obtaining the participant's witnessed signature on the informed consent document during the clinic visit, or verbal consent if participant is doing a comprehensive phone contact, key the responses on this form to document their consent responses, and upload a copy of the signature pages.

Please answer every question on this form. *NOTE: 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.

IMPORTANT: *Please confirm your site has IRB approval to conduct comprehensive phone visits before consenting for any comprehensive phone visits.*

Item 0c. Select only one option among the five possible choices.

- If 'In-person visit (E1)', 'In-person visit (SOURCE Visit 3)', or 'In-person visit (MAPCOPD Visit 3)' is selected, go to Item 1.
- If 'Comprehensive phone visit' is selected, go to Item 0d. Skip items 3, 4, and 6 if consenting to a comprehensive phone visit
- If 'Other' is selected, go to Item 0c1.

Item 0c1. Specify other contact type in the space provided.

Item 0d. Select only one option among the four possible choices.

- If 'Other' is selected, go to Item 0d1.

Item 0d1. Specify other contact type in the space provided.

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. If participant is completing a comprehensive phone visit, skip items 3, 4, and 6.

Items 2-7. Select only one option among the two possible choices. Skip items 3, 4, and 6 if consenting to a comprehensive phone visit

Item 8a. Record the initials of the study personnel who obtained the signed informed consent.

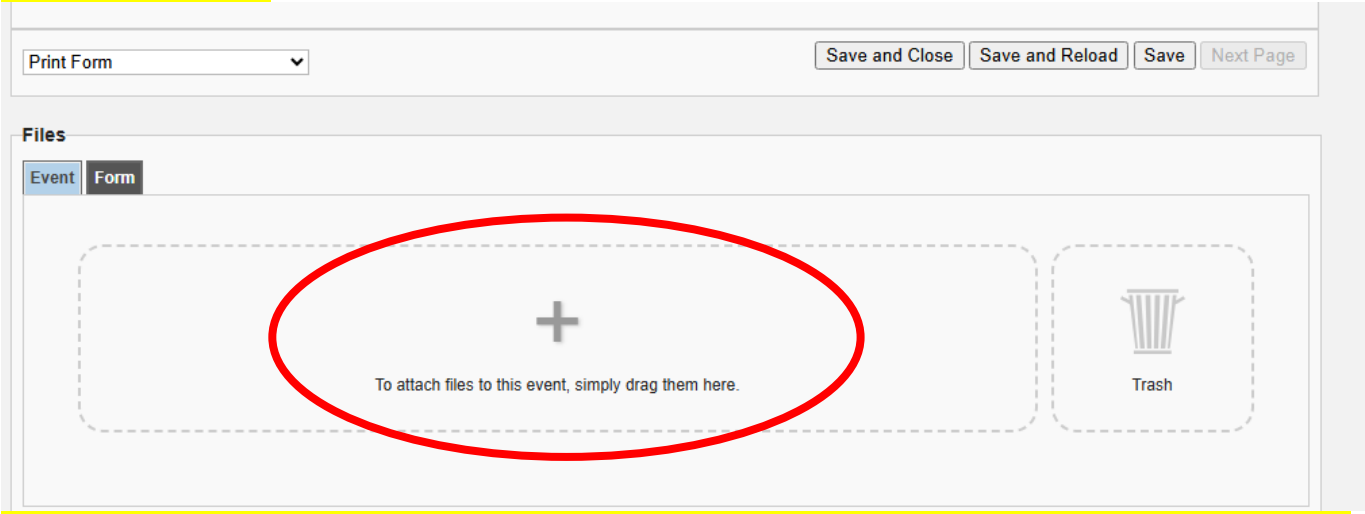
Item 8b. Record the SPIROMICS III staff code of the study personnel who obtained the signed informed consent. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS III data, please contact the GIC in order to receive your own individual staff code.

Item 8b1. Select only one option among the two possible choices indicating whether a witness required for this consent. If 'Yes', go to Item 8c. If 'No", go to Item 9.

Item 8c. Record the initials of the study personnel who witnessed the informed consent.

Item 8d. Record the SPIROMICS III staff code of the study personnel who witnessed the informed 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.

Please upload images of the signature pages (pages 14, 15, and 16 for most sites) of the informed consent document.



Upload images by dragging and dropping them into this box at the bottom of the form in CDART.

Item 9. Select only one option among the two possible choices to indicate whether the images of the signature pages have been uploaded to CDART. If **'No'**, please upload the images and return to this item.

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