

## BRONCHOSCOPY SUB-STUDY INFORMED CONSENT TRACKING FORM, BCT QUESTION BY QUESTION (QxQ), VERSION 2.0

### I. GENERAL INSTRUCTIONS

The Bronchoscopy Sub-study Informed Consent Tracking Form (BCT) is to be completed (1) to confirm the participant's interest or not in participating in the SOURCE Bronchoscopy Sub-study, then, (2) to obtain consent if interested. After obtaining the participant's witnessed signature on the informed consent document during the baseline visit for healthy controls or during Pre-Bronchoscopy Visit 1 for all other participants. Key the responses on this form to document their consent responses. If any aspect of consent is modified by the participant at a later date, such as a new restriction, please enter a new BCT form occurrence.

**NOTE:** If a participant indicated in their SOURCE main study consent that they do not agree to allow SOURCE study staff and investigators to contact them about participating in additional assessments, procedures, and studies in addition to the SOURCE study (see Item 5 in the ITF), they should NOT be contacted regarding the SOURCE Bronchoscopy Sub-study.

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 3-character, 6-digit number assigned to the specific participant. For the "Event", record if this is happening at Pre-Bronchoscopy Visit 1 or Bronchoscopy Visit 2.

- 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.
- Item 0c.** Select only one option among the two possible choices.
- If 'In-person visit' is selected, go to Item 1.
  - 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 three possible choices.
- If 'No' is selected, **Go to End** of the form, and **Save and Close** the form.
  - If 'Yes' is selected, go to Item 1.
  - If 'Yes, but not at this time' is selected, go to Item 0d1.

**Item 0d1.** Specify the best time to contact the participant again regarding their interest in participating in the SOURCE Bronchoscopy Sub-study in the space provided. Then, **Go to End** of the form, and **Save and Close** the form.

**NOTE:** *If a participant prefers to be contacted at a later date regarding their interest in the SOURCE Bronchoscopy Sub-study, a new occurrence of the BCT should be completed and entered into CDART at the time the participant is re-contacted.*

**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.

**Items 2-6.** Select only one option among the two possible choices.

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