

Informed Consent Changes, ICC QUESTION BY QUESTION (QxQ), VERSION 1.0

I. GENERAL INSTRUCTIONS

The Informed Consent Changes (ICC) should be completed when a participant indicates a change, at any point, in their initial response to specific items collected during initial informed consent via the Informed Consent Tracking (ITF) form.

Note: This form does not apply to a change in response to ITF item 1. If there is a change in response to ITF item 1, please enter the Reason for Study Withdrawal (RSW) form according to protocol.

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.** Select only one option among the two possible choices to indicate whether the participant is requesting a change to ITF item 2.
- Item 1a.** Select only one option among the two possible choices to indicate the participant's new response to ITF item 2.
- Item 2.** Select only one option among the two possible choices to indicate whether the participant is requesting a change to ITF item 3.
- Item 2a.** Select only one option among the two possible choices to indicate the participant's new response to ITF item 3.
- Item 3.** Select only one option among the two possible choices to indicate whether the participant is requesting a change to ITF item 4.

Item 3a. Select only one option among the two possible choices to indicate the participant's new response to ITF item 4.

Item 3b. Select only one option among the two possible choices to confirm that changes were put in place to reflect the participant's current wishes. If 'No' is selected, appropriate changes should be put in place at this time.

Item 4. Select only one option among the two possible choices to indicate whether the participant is requesting a change to ITF item 5.

Item 4a. Select only one option among the two possible choices to indicate the participant's new response to ITF item 5..

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