


INFORMED CONSENT TRACKING FORM, ITF QUESTION BY QUESTION (QxQ), VERSION 1.0

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 baseline visit. 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 ITF form occurrence.

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 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.
- 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 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 2-8.** Select only one option among the two possible choices.

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