

PARTICIPANT ELIGIBILITY STATUS AND STRATUM FORM, PSS QUESTION BY QUESTION (QxQ), VERSION 2.0

I. GENERAL INSTRUCTIONS

The Participant Eligibility Status and Stratum Form (PSS) is to be completed after generating the *'Participant Eligibility Report'* from the link at the bottom of the last page of the Inclusion/Exclusion Criteria Form (IEC). Refer to the "Eligibility Status" and "Stratum" columns of the report to help complete this form.

NOTE: In cases that the *'Participant Eligibility Report'* determines the participant's eligibility status to be "PI decision required", ensure the PI's decision is entered in Item 1 and their review and sign off is entered in Items 2-2b.

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 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.** Record the Screening ID (i.e., SCR ID) in the space provided. Capitalize all characters when entering the SCR ID. *NOTE: The Screening ID, which should begin with "SCR" and follow with a 6-digit number in CDART, is the ID assigned to a potential participant during phone screening for the purpose of entering the Recruitment Tracking Form (RTF). Please complete Item 0c in order to link the Screening ID to the primary Subject ID.*
- Item 1.** Select only one option among the two possible choices. If 'No' is selected, go to Item 2.
- Item 1a.** Select only one option among the four possible choices.
- Item 2.** Select only one option among the two possible choices. If 'No' is selected, go to Item 3.
- Item 2a.** Record the PI's electronic signature in the space provided.
- Item 2b.** Record the date of the PI signature in the MM/DD/YYYY format either by selecting the pop-up calendar in CDART or entering the date in the space provided.

Item 3. Record any comments related to the participant's eligibility status and/or stratum assignment in the space provided.

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