



# HCHS/SOL V3 - Participant Safety Screening (PSE)

QxQ

3/15/2022

## General Instructions

The Participant Safety Screening (Bilingual) Form (PSE) is completed prior to or at the time of the Visit 3 examination, during the informed consent process. It is recommended that staff with some clinical knowledge administer this form so that questions can be answered appropriately and that probes to positive responses which would exclude someone can be fully documented.

Following an explanation of the HCHS/SOL study and the procedures involved, the interviewer requests an opportunity to verify the individual's eligibility for all procedures. The conditions reviewed during this interview (and listed on the form) include pregnancy, the participant's use of a pacemaker or defibrillator, and diabetes. Study participants who are pregnant are asked to schedule an examination visit at three months after delivery, and to provide a date by which the HCHS/SOL can re-contact them for this purpose. The presence of a pacemaker or defibrillator is recorded on the PSE form and the participant is told of the procedures to avoid and that a sticker will be placed on his/her name tag to make the study technicians aware of this during the field center examination.

Each participant safety screening form should then be entered into the HCHS/SOL study data management system within 48 hours after collection. Note that failure to exclude a participant correctly from portions of the examination when indicated is a protocol violation.

**Please NOTE:** To make sure the pre-fills on Q0c (sex assigned at birth) and 0d (age at V3) function properly, enter the PSE completion date (Q0a) and the staff ID (Q0b). Then Save/Reload the form. Q0c (sex assigned at birth) is editable in case the pre-filled information for sex assigned at birth is incorrect. If you edit Q0c, remember to SAVE and RELOAD the form afterwards.

## Question by Question Instructions

**Please be sure to use the appropriate clinic scheduling script when completing this form.**

### Safety and Access Questions

Q1 FEMALES ONLY: This field will be enabled if Q0c=2 (Sex assigned at birth is female). The question asks female participants of childbearing age if they are currently pregnant. Pregnancy is a temporary exclusion from the examination, which requires that the full visit be rescheduled for 3 months after expected delivery date. Read the closing script and end call/visit with respondent.

Q2 This question is designed to uncover any special needs of the participant in order to undergo the examination, such as assistance reading, or in moving to and from exam stations. If Yes, complete Q2a and note any special needs on the exam checklist form.

Q3 This question about implanted/internal electronic pacemakers or defibrillators is critical to answer because it is an exclusion trigger for the bio-impedance measurements taken with the Tanita scale.

If someone says that they do have a pacemaker or defibrillator, be sure to **update PSE3 to 1=Yes**. The technician who performs the anthropometry measurement must turn off the bioimpedance function on the scale when weighing the participant (use Weight-only mode). Note this exclusion from BIA on the exam checklist form (CHK).

Internal/implanted electronic devices that are NOT a heart pacemaker or defibrillator do not require exclusion from BIA.

Q4 This question asks if the respondent has ever been told by a doctor that they have diabetes (high sugar in the blood or urine). This question must be answered for use in other forms.

- Q5 This question seeks to ascertain if the participant can safely walk 1 block without help. This pertains to their safety during the field center visit.

### **COVID-19 Vaccine**

A new section has been added to the PSE form for COVID data collection, to confirm COVID screening at the Field Center and documentation of conditions and procedure/tests exclusions to the V3 visit.

- Q6 This is a vaccination status question.
- Q7 If participant has received a COVID vaccination, record the brand received.
- Q8-8a Record how many doses of the COVID vaccine the participant has received so far, and the most recent month/year a vaccination was received. A new answer choice of Three or more vaccinations has now been added to record additional COVID-19 vaccinations, including booster shots.
- Q9 Confirmation that the participant has successfully passed the field center COVID screening prior to participating in V3 activities.
- Q10-10c are enabled if the participant is eligible for V3 activities (male, non-pregnant female), and are used to note any special conditions that will affect participation or to note exclusions from study activities. Completing Q10 items is not required if the participant does not have a special condition or exclusion, but IS required in any of Q2, Q3, or Q4=Yes, or if Q5=No.
- Q10 List conditions or circumstances that will exclude the participant from participating in all V3 activities and tests.
- Q10a List the procedures or tests that will be excluded from the V3 visit.
- 10b Enter the name of the staff member making the safety/exclusion determination.
- 10c Enter the Staff ID of the staff member making the safety/exclusion determination.