General Instructions
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, defibrillator or other implanted electronic device, and screening questions for 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 implanted devices 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 and 0d function properly, enter the PSE completion date, the staff ID and then Save/Reload the form.

Question by Question Instructions

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

Q1 FEMALES ONLY: This question asks female participants of child-bearing age if they are currently pregnant. Pregnancy is a temporary exclusion from the examination and the full visit would need to be re-scheduled for 3 months after expected delivery date. Read the closing script and end call/visit with respondent.

Q2 The 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 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 then the technician who performs the anthropometry measurement must turn off that function on the scale when weighing the participant. Note this exclusion from BIA on the exam checklist form.

Q4 The 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.

Q6 Specify condition or circumstance that excludes the participant from participation in all or part of the field center visit, noting if specific procedures are excluded and having the clinic manager authorize by entering their ID in Q6b.