

SECTION 6

RELIABILITY SUBSAMPLE

6.0 Overview of NBS Reliability Subsample

- For a subset of about 110 women (a 20% reliability sample), the NBS protocol is repeated in conjunction with a woman's WHI Close-out visit, an average of six months after her NBS Visit 2. The 110 women in the NBS Reliability Subsample are identified at the end of the NBS Visit 2 when they sign the *Consent for Future Contact and Continued Participation in this Study* indicating that they are willing to participate in a repeat of the procedures in the WHI Nutritional Biomarkers Study. For additional information about the NBS Reliability Subsample, refer to the *NBS Manual, Section 5.2.3.9 – Invite Repeat of NBS – (Reliability Subsample)*.
- Whenever possible participants repeat the procedures for the NBS Study in conjunction with their WHI Close-out visit. Below are two examples of how this can be accomplished:
 - Option 1: Schedule NBS Visit 3 on the same day as the WHI Close-out visit and schedule NBS Visit 4 to occur 14 to 16 days later.
 - Option 2: Schedule NBS Visit 3 to occur 14-16 days before the WHI Close-out visit so that NBS Visit 4 occurs on the same day as the WHI Close-out visit.

6.1 Sample Size

- Each CC strives to have **10** participants repeat the procedures for the NBS Reliability Subsample (Tucson and Memphis – 5 participants).
 - To ensure that CCs have the required number of participants available to repeat the procedures, each CC recruited approximately 13 participants for the NBS Reliability Subsample (Tucson and Memphis – approximately 7 participants).
 - Not all participants recruited for the NBS Reliability Subsample repeat the procedures. The reasons a participant does not repeat the procedures include:
 - The participant is no longer available or interested.
 - The participant is no longer eligible (e.g., now using insulin or hypoglycemic agents).
 - The CC has already enrolled all the women needed for the NBS Reliability Subsample.

6.2 Approaching Participants for the NBS Reliability Subsample

- When approaching participants for the NBS Reliability Subsample, keep the following in mind:
 - Approach and schedule participants for NBS Visit 3 in the order they will be seen for their WHI Close-out visit.
 - Limit the number of participants who complete NBS Visit 3 and Visit 4 to **10** participants (Tucson and Memphis – 5 participants). To accomplish this, consider the following:
 - Schedule all recruited participants, but let participants with the latest NBS Visit 3 dates know that they are on a waiting list and may not be needed.
 - Schedule participants on the waiting list so that their NBS Visit 3 date is at least 5 weeks after the last NBS Visit 4 has occurred for the first **10** participants (Tucson and Memphis – 5 participants). This ensures that participants on the waiting list will not begin repeating the procedures until the CC is sure the participant is needed.
- After **10** participants (Tucson and Memphis – 5 participants) have completed NBS Visit 3 and Visit 4, contact the participants on the waiting list. Thank these participants for their interest and willingness to participate and let them know that your CC has enrolled all the women needed for the NBS Reliability Subsample.

6.3 Pre-NBS Visit 3 Activities

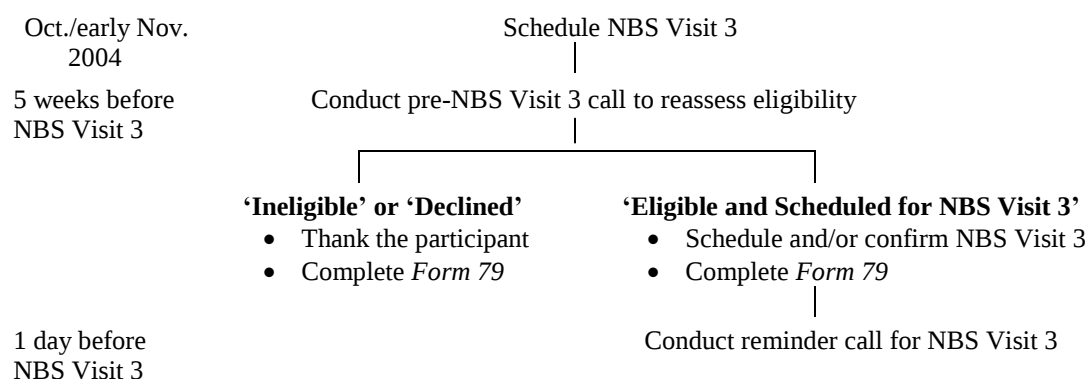
6.3.1 Pre-NBS Visit 3 Call to Reassess Eligibility (exactly 5 weeks prior to NBS Visit 3)

- Call the participant exactly 5 weeks before her NBS Visit 3 to reassess eligibility (refer to *Figure 6.1 – Reassessing Eligibility*). Rationale for 5 weeks: a) if a participant is called more than 5 weeks before NBS Visit 3, her eligibility may change before she arrives for her visit and; b) if a participant is called less than 5 weeks before her NBS Visit 3, there may be insufficient time to conduct the 24-hour recall before she arrives for her visit. During the call:
 - Briefly summarize NBS Visit 3 and NBS Visit 4 activities and confirm that the participant is still interested in participating in the NBS Reliability Subsample.
 - Use the NBS Screening Eligibility Checklist (Qx. 1-7) in the *NBS Telephone Screening Questionnaire/Script* (copy available in *NBS Manual, Appendix D – NBS Staff Materials*) to reassess the following NBS eligibility requirements:
 - Use of insulin or oral hypoglycemic agents for diabetes.
 - Use of supplemental oxygen.
 - Receipt of blood transfusions or IV fluids (i.e., hospitalizations or tests with IV meds, such as a colonoscopy) in the 2 weeks before the upcoming NBS Visit 3.*
 - Bladder control problems that would make it difficult to collect urine.
 - Intentional or unintentional weight loss or gain (greater than 15 pounds) during the past 4 weeks.
 - Traveling 200 miles or more away from home in the 2 weeks before the upcoming NBS Visit 3.*

* Note: Travel of 200 miles or more away from home or receipt of blood transfusions or IV fluids in the two weeks prior to NBS Visit 3 makes a participant temporarily ineligible. Ask the participant if she is willing to reschedule her NBS Visit 3 and her WHI Close-out visit to accommodate the 2-week waiting period.

- If a participant is ineligible or unwilling to reschedule (if ‘temporarily ineligible’), thank her for her time and interest in repeating the NBS Study. Complete *Form 79 – Pre NBS Visit 3 Eligibility Reassessment Result*. Refer to the *NBS Manual, Section 6.3.2 – Complete and Data Enter Pre NBS Visit 3 Eligibility Reassessment Result (Form 79)*.
- If a participant is eligible or willing to reschedule (if ‘temporarily ineligible’), schedule and/or confirm her NBS Visit 3 appointment. Complete *Form 79 – Pre NBS Visit 3 Eligibility Reassessment Result*. Refer to the *NBS Manual, Section 6.3.2 – Complete and Data Enter Pre NBS Visit 3 Eligibility Reassessment Result (Form 79)*.
 - Ask the participant to refrain from traveling more than 200 miles away from home or receiving blood transfusions or IV fluids in the 2 weeks prior to her NBS Visit 3 appointment.

Figure 6.1 - Reassessing Eligibility



6.3.2 Complete and Data Enter *Pre NBS Visit 3 Eligibility Reassessment Result (Form 79)*

- The NBS staff completes a *Form 79* for all participants receiving a pre-NBS Visit 3 call to reassess eligibility.
- Record the participant's 'Final Eligibility Reassessment Disposition' on *Form 79 – Pre NBS Visit 3 Eligibility Reassessment Result (Qx. 5 - Final Eligibility Reassessment Disposition)*. The 'final disposition' represents the participant's status at the end of the eligibility reassessment call:
 - 'Eligible and Scheduled for NBS Visit 3': Participant was eligible and interested in participating in a repeat of the NBS Study and is scheduled for NBS Visit 3.
 - 'Ineligible': Participant was not eligible to participate in a repeat of the NBS Study.
 - 'Declined': Participant was not interested in participating in a repeat of the NBS Study.
- Key-enter *Form 79* only after the final result of the eligibility reassessment call is known. For example, if a participant is unable to schedule her NBS Visit 3 appointment until she checks her family schedule, then *Form 79, Qx. 5 – Final Eligibility Reassessment Disposition* would not be marked until the participant has been scheduled for NBS Visit 3.
- Key-enter the *Form 79 – Pre NBS Visit 3 Eligibility Reassessment Result* within 1 day of completing the form. Timely key-entry is critical because the CCC will use information from *Form 79* to schedule the second 24-hour dietary recall (3 weeks prior to the participant's NBS Visit 3).
- File the completed and key-entered *Form 79* in the participant's chart (or special NBS notebook).

Note: After *Form 79* has been key-entered into WHILMA, if a participant's NBS Visit 3 date changes by more than 4 weeks, immediately notify the CCC (hpenor@whi.org). Notification allows time for the CCC to modify the 24-hour dietary recall schedule.

6.3.3 Pre-Visit 3 Reminder (one day prior to NBS Visit 3)

- NBS staff calls each participant one day prior to her NBS Visit 3. If a participant is scheduled for Monday, the call may be made on the preceding Friday. During the call, provide the same reminder information described in the *NBS Manual, Section 5.1.3.2 – Pre-Visit 1 Reminder Call*.

6.3.4 Supplies and Forms

Supplies:

- NBS staff confirms that all supplies and forms needed for NBS Visit 3 are available for the participant's visit. Refer to the *NBS Manual, Section 5.1.3.1 – Supplies and Forms*, for a list of the supplies to have available for NBS Visit 3.

Forms:

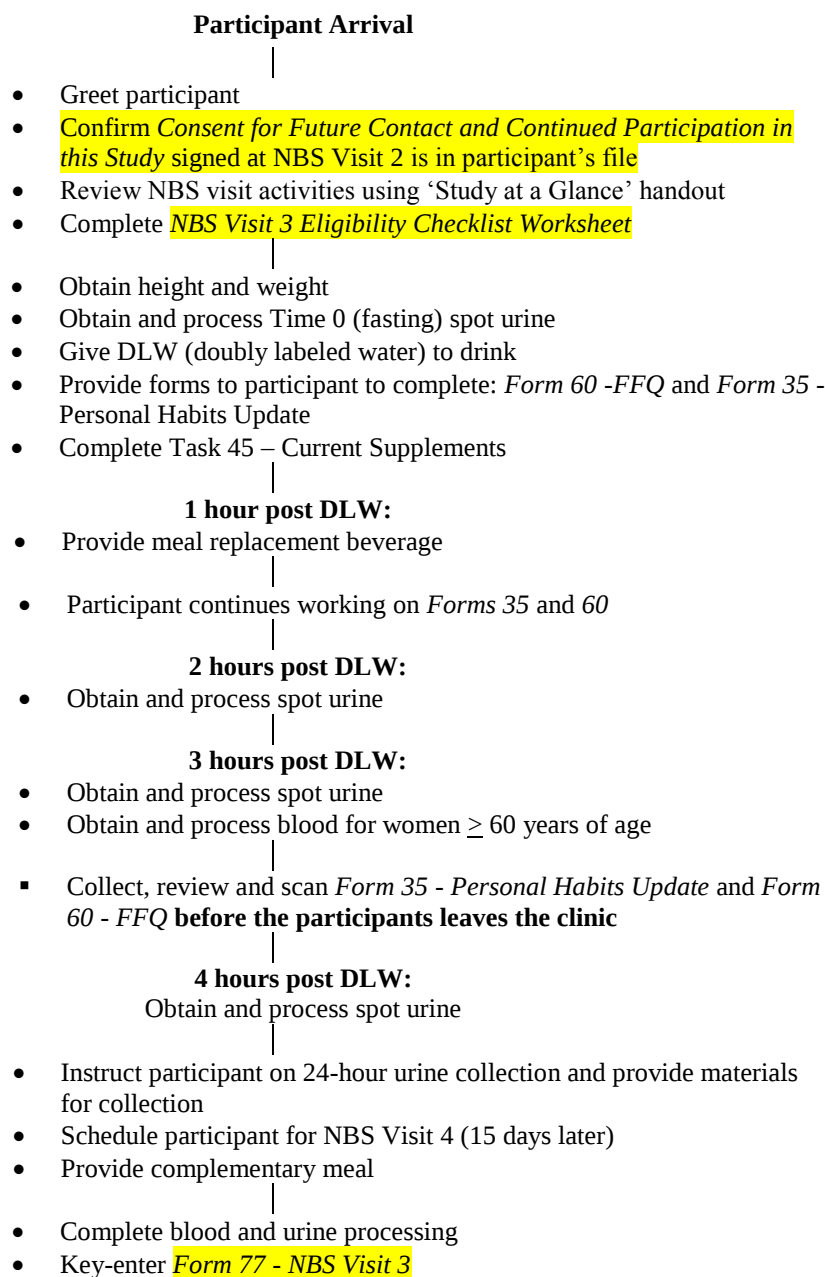
- *NBS Visit 3 Eligibility Checklist Worksheet*
- *Consent for Future Contact and Continued Participation in this Study* (confirm that consent signed at NBS Visit 2 is in participant's chart)
- *Form 77 – NBS Visit 3*
- *Form 60 – Food Frequency Questionnaire*
- *Form 35 – Personal Habits Update*
- *Form 45 – Current Supplements (Backup)* – (have available if not directly key-entering supplement information into WHILMA using Task 45)
- *NBS Visit 2 (or Visit 4) PABA Worksheet for Staff*

6.4 NBS Visit 3 (Day 1)

6.4.1 Overview of NBS Visit 3 Activities

- *Figure 6.2 – Overview of NBS Visit 3* provides an overview of NBS Visit 3. The highlighted areas indicate activities that are different from NBS Visit 1 activities.

Figure 6.2
Overview of NBS Visit 3 (Day 1)



6.4.2 NBS Visit 3 Activities

- NBS Visit 3 activities are very similar to those described in the *NBS Manual, Section 5.1 – NBS Visit 1 (Day 1)*, with the exception of the following:
 - Informed consent is not needed. Staff confirms that the participant has a signed *Consent for Future Contact and Continued Participation in this Study* in her chart.
- For a detailed description of NBS Visit 3 activities, refer to the *NBS Manual, Section 5.1.4 – NBS Visit 1 Activities*.
- Staff uses *Form 77 – NBS Visit 3* to record information collected at NBS Visit 3.

6.4.3 Post-NBS Visit 3 Activities

- For a detailed description of post-NBS Visit 3 activities, refer to the *NBS Manual, Section 5.1.5 – Post-NBS Visit 1 Activities*.

6.5 NBS Visit 4 (Day 15)

6.5.1 Pre-NBS Visit 4 Activities

6.5.1.1 Pre-Visit 4 Reminder Call

- NBS staff calls each participant two days prior to her NBS Visit 4. During the call, provide the same reminder information described in the *NBS Manual, Section 5.2.2.2 – Pre-Visit 2 Reminder Call*.

6.5.1.2. Supplies and Forms

Supplies:

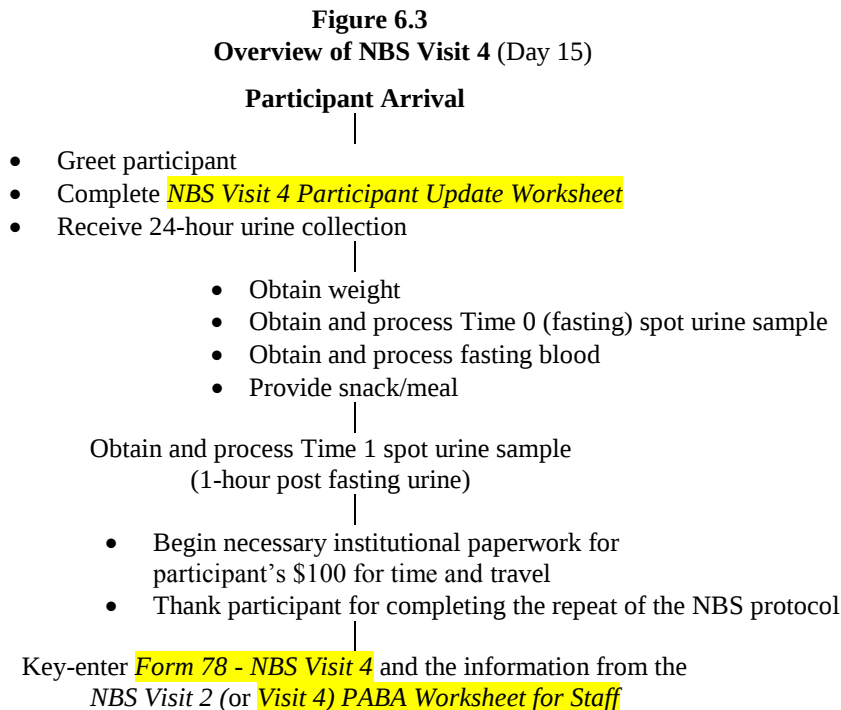
- NBS staff confirms that all supplies and forms needed for NBS Visit 4 are available for the participant's visit. Refer to the *NBS Manual, Section 5.2.2.1 – Supplies and Forms*, for a list of the supplies to have available for NBS Visit 4.

Forms:

- NBS Visit 4 Eligibility Checklist Worksheet*
- Form 78 - NBS Visit 4*
- NBS Visit 2 (or Visit 4) PABA Worksheet for Staff* (should be in participant's file from NBS Visit 3)

6.5.2 Overview of Activities

- Figure 6.3 – Overview of NBS Visit 4* provides an overview of NBS Visit 4. The highlighted areas indicate activities that are different from NBS Visit 2 activities.



6.5.3 NBS Visit 4 Activities

- NBS Visit 4 activities are very similar to those described in the *NBS Manual, Section 5.2 – NBS Visit 2 (Day 15)*, with the exception of the following:
 - Staff do not invite the participant to return and do not collect the *Consent for Future Contact and Continued Participation in this Study* at the end of the visit.
- For detailed descriptions of NBS Visit 4 activities, refer to the *NBS Manual, Section 5.2.3 – NBS Visit 2 Activities* (omitting the invitation to repeat NBS).
- Staff uses *Form 78 – NBS Visit 4* and the *NBS Visit 2 (or Visit 4) PABA Worksheet for Staff* to record information collected at NBS Visit 4.

6.5.4 Post-NBS Visit 4 Activities

- For a detailed description of post-NBS Visit 4 activities, refer to the *NBS Manual, Section 5.2.4 – Post-NBS Visit 2 Activities*.