WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
FORM NP01: BASELINE NEUROPATHY SIGNS AND SYMPTOMS

General Instructions:

1. All dates should be recorded in the MM/DD/YY format.
2. Times should be recorded in HH:MM format.
3. Remember to use leading zeros for the time and severity questions, e.g., 08:00 or 06.
4. Participants should remove shoes and socks.

PARTICIPANT INFORMATION

This form should be completed before beginning the physical exam. Remember to verify with the participant the date of her birth. Record the actual time you began **NP01** in **Question A6** "Time Module Began" and the actual time you ended the questionnaire in **Question C5** "Time Module Ended."

PROMPT: DO NOT ADMINISTER IF PARTICIPANT DOES NOT HAVE TWO LEGS AND TWO FEET.

READ THE INTRODUCTION TO THE PARTICIPANT.

Our goal is to identify pain associated with distal sensory polyneuropathy (DSPN). This kind of pain is bilateral and affects at least the toes. It is described as burning, gnawing, aching, and shooting. Some pain should be present in the toes and/or feet to conclude that DSPN is present. Pain present in the calves or knees that is not also present in the toes and feet is unlikely to be due to DSPN.

Radicular pain – usually due to a herniated disc in the lumbosacral spine or to bony overgrowth from osteoarthritis in this region (although many other disorders can cause this syndrome) – may be the most difficult to separate from pain due to neuropathy. Radicular pain typically starts in the back and radiates down the leg but we are not interested in this type of pain. Herniated discs usually cause unilateral pain and the pain is located in the back or at least buttocks.

We are also not interested in leg pain due to venous thromboses (blood clots); arthritis in the knee, ankle, or foot; or foot problems due to podiatric causes such as corns and bunions. Neuropathic pain of distal sensory polyneuropathy (the kind of pain we are interested in) starts in both toes and feet and may eventually extend into the leg.

HAND PARTICIPANT RESPONSE CARD NP01 TO RATE SEVERITY.

B1. Indicate if the participant has ever had pain, aching or burning in both feet, or both feet and both legs, at around the same time. If the participant responds in the negative, then circle "2" and skip to **Question B3**.

In **Questions B1** through **B6**, we are looking to characterize a specific type of pain that starts in the toes and may spread upward to the legs, and always occurs on both sides of the body simultaneously. The severity of pain on each side may differ; however, the pain must happen at the same time, bilaterally. If pain has fluctuated or disappeared at times, the participant should rate the pain when it was at its worst. Other types of pain may be only in one side of the body, or spread from the back down the legs. These questions should specifically exclude these sorts of pain. This is to ensure that we are eliciting an appropriate response with regard to pain from DSPN and not other kinds of pain.

a. Have the participant use the scale on the *NP01* response card. Ask her to rate the severity of the pain in her right foot and leg where 1 is mild and 10 is severe.

b. Have the participant use the scale on the *NP01* response card. Ask her to rate the severity of the pain in her left foot and leg where 1 is mild and 10 is severe.

B2. Indicate if the participant has had, in the last 6 months, pain, aching or burning in both feet, or both feet and both legs, at around the same time. If the participant responds in the negative, then circle "2" and skip to **Question B3**.

a. Ask the participant to rate the severity of the pain in her right foot and leg.

b. Ask the participant to rate the severity of the pain in her left foot and leg.

B3. Indicate if the participant has ever had "pins and needles" in both feet, or both feet and both legs, at around the same time. If the participant responds in the negative, then circle "2" and skip to **Question B5**. **PROBE**: ***"This is called paresthesias, the sensation you have when sitting too long in one place on a hard surface or sleeping on your arm."***

a. Ask the participant to rate the severity of the paresthesias in her right foot and leg.

b. Ask the participant to rate the severity of the paresthesias in her left foot and leg.

B4. Indicate if the participant has had, in the last 6 months, "pins and needles" in both feet, or both feet and both legs, at around the same time. If the participant responds in the negative, then circle "2" and skip to **Question B5**.

a. Ask the participant to rate the severity of the paresthesias in her right foot and leg.

b. Ask the participant to rate the severity of the paresthesias in her left foot and leg.

B5. Indicate if the participant has ever had numbness in both feet, or both feet and both legs, at around the same time. **PROBE**: ***"This feeling is similar to when a dentist injects medicine into your gum before filling a cavity."*** If the participant responds in the negative, then circle "2" and skip to **Section C**.

a. Ask the participant to rate the severity of the numbness in her right foot and leg.

b. Ask the participant to rate the severity of the numbness in her left foot and leg.

B6. Indicate if the participant has had, in the last 6 months, numbness in both feet, or both feet and both legs, at around the same time. If the participant responds in the negative, then circle "2" and skip to **Section C**.

a. Ask the participant to rate the severity of the numbness in her right foot and leg.

b. Ask the participant to rate the severity of the numbness in her left foot and leg.

SECTION C: NEUROPATHY SIGNS

Questions in **Section C** do not need to be read aloud to the participant. Please use a 128-Hz tuning fork to conduct the perception of vibration testing. Refer to **Figure 1** for the correct placement of the tuning fork. Many participants will have neuropathy. For some of these participants, any manipulation of their feet will be painful. As the tuning fork testing and reflex testing is absolutely painless in participants without neuropathy and in some participants with neuropathy, the examiner should not forget that for some participants it will be painful.

The participant will usually be seated on the side of the examining table. Some examiners prefer to bend over for the testing, some prefer to use a stool, and a select few prefer to get on the floor on their knees. Please use the method that works best for you. The examiner may or may not use gloves. It will not affect the results of the testing.

The tuning fork should be held on the stem, just below the point where the two blades of the tuning fork meet. One should strike the tuning fork hard enough that the sound of the impact of the two blades of the tuning fork are audible. Striking the part of the palm near the little finger and not near the thumb is less painful to some examiners. Others prefer striking the tuning fork against a hard object such as a table.

First place the tuning fork on the participant's wrist and ask her what she feels. The sensation we are interested in is the vibration, not simply the pressure. Almost all participants will tell you that they feel "vibration or buzzing or 'zzzing'"at the wrist. You want the participant to tell you when the vibration stops. There is a little art to this as some participants will "tune out" and forget to tell you. This may lead you to infer that they still feel the buzzing. One should test this at the wrist by purposely withdrawing the tuning fork after a few seconds. If the participant correctly stated that the buzzing stopped, repeat the test at the wrist and time how long she feels the vibration. You should use your watch or a stopwatch to time this duration. With a little practice, one can master viewing the watch and placing the tuning fork in the correct position at the top (dorsal) side of the last digit of the big toe. Some examiners may prefer to do this with an assistant.

Participants who do have neuropathy may not feel the vibration at all. Participants with mild neuropathy will feel the vibration for less than ten seconds; they will be aware that the vibration is less strong on their toes than it was on the wrist. The examiner can use this information if there is any ambiguity about the participants' responses.

Once again, be aware that some participants "tune out" and this may yield a false negative result. If you have concerns that they are not paying attention, purposely stop the tuning fork and be sure they tell you the vibration stopped.

Figure 1. Testing of vibration. Press the 128 Hz tuning fork firmly (but not too hard) against the last joint of the big toe. A normal response is for the participant to feel vibration (not just pressure) for more than 10 seconds.

C1a. Indicate the length of time that the participant felt the vibration in her right great toe distal interphalangeal joint. Please use a stop watch or timer to accurately measure the length of time. Circle the correct value for the length of time that the participant felt the vibration:

0	Greater than 10 seconds	Normal perception of vibration
1	6-10 seconds	Mild loss
2	5 seconds or less	Moderate loss
3	No feeling	
-9	Unable to evaluate	

C1b. Indicate the length of time that the participant felt the vibration in her left great toe distal interphalangeal joint.

Please use a large Queen's Square hammer to conduct the deep tendon reflex testing. Refer to **Figure 2** for correct placement of the hammer and the appropriate way to the hold the participant's foot. Once again, the participant is usually sitting on the side of the examining table. Gloves are optional and their use will not affect results.

The examiner should practice until a "swinging" movement of the hammer is mastered. Use your wrist to start the motion and then loosen your grip slightly so that the weight of the hammer leads the motion. If you loosen too much, you may lose control of the hammer. The movement of the hammer is stopped when the hammer strokes the participant's tendon; the examiner does not provide the braking of the hammer.

The biggest problem is when no or very little reflex is elicited. Sometimes this is due to poor technique and sometimes because the reflex is not there. The examiner should check her technique by eliciting a knee reflex or by establishing a baseline with a normal control subject. Most of the time with DSPN, the ankle reflex is lost, but other reflexes are present. So by eliciting a knee reflex and not eliciting an ankle reflex, one gains confidence that bad technique is not the cause of the absent reflex. Furthermore, the Jendrassik maneuver (see below) may help elicit the reflex; reassuring the examiner that her technique was acceptable.

Most of the time, if one is not sure whether or not a reflex is present, the reflex is not present. A normal response is for the ankle to plantar flex downward after a short delay. If there is not a delay, then this may only be a mechanical response, i.e., simply striking the ankle may cause some movement that has nothing to do with a reflex. Please refer to notes from the in-person training. A true reflex occurs when the muscle (in this case the gastrocnemius in the posterior of the calf) contracts. If you are not sure whether you are getting a reflex, you can put your hand over the muscle when you strike the reflex (you may need someone to dorsiflex the participant's ankle) and feel for the contraction. If you don't find a reflex, it could be because the reflex was absent or decreased or because the technique used to conduct the reflex testing is inadequate.

Figure 2. You should be able to elicit ankle reflexes in most patients when they are sitting on a chair in the normal way (on their posterior). The examiner dorisflexes the ankle from its passive position to a ninety degree angle between the foot and ankle.

C2a. Indicate the results of the ankle reflex test in the right foot. Circle the correct value for results of the evaluation:

0	Absent reflex
1	Hypoactive reflex
2	Normal, Increased, or Clonus reflex
-9	Unable to evaluate

C2b. Indicate the results of the ankle reflex test in the left foot.

C3. Based on the results in **Questions C2a** and **C2b**, indicate if both the right and left ankle reflexes are equal to 2, i.e., normal, increased or clonus. If yes, then circle "1" and skip to question C5. If no, meaning that the participant had at least one ankle reflex measured as absent ("0"), hypoactive ("1"), or the clinician could not assess an ankle reflex ("-9"), then circle "2" and go to **Question C4**.

C4a. Demonstrate the Jendrassik method to the participant and ask her to hold this pose while performing the next ankle reflex measurements. Refer to **Figure 3** to demonstrate the Jendrassik method. Indicate the results of the ankle reflex test in the right foot.

Figure 3. If no reflex is elicited, use this technique. Have the participant interlace her fingers as shown, and tell the participant that on the count of 3, she should pull outwards. Strike the reflex when she is pulling outwards.

C4b. Indicate the results of the ankle reflex test in the left foot using the Jendrassik method.

C5. Record the time that the neuropathy questions and measurements in *NP01* were completed.