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

A1.	PARTICIPANT ID:	- - -
A2.	WIHS STUDY VISIT #:	
A3.	FORM VERSION:	10/01/07
A4.	DATE OF INTERVIEW:	/ / Y
A5.	CLINICIAN'S INITIALS:	
A6.	TIME MODULE BEGAN:	: AM1 PM2

SECTION B: NEUROPATHY SYMPTOMS

INTRODUCTION: In some patients, the HIV virus can affect the nerves in their feet. We want to see how often this might happen to the women in our study. We are interested in problems with the nerves that start in the toes of both feet and may go up into the legs. This kind of pain occurs at the same time in both the right and the left feet and legs. Please do not include pain that is the result of an injury or pain that starts in the back and goes down the leg.

I am going to ask you some questions about how well the nerves in your feet work. Then, I am going to see how well you can feel a tuning fork on your big toe and test your ankle reflexes. Do you have any questions?

HAND PARTICIPANT RESPONSE CARD NP01 TO RATE SEVERITY.

B1. Have you <u>ever had pain</u>, aching, or burning in <u>both</u> your feet and legs <u>at around the same time</u>?

On a scale of 1 to 10, where 1 is mild and 10 is severe, please rate to what extent this bothered you in the...

a. \underline{right} foot and $leg: |__| |__|$

b.	<u>left</u> foot and leg:	
----	---------------------------	--

B2. In the last 6 months, have you had pain, aching, or burning in <u>both</u> your feet and legs <u>at around the same</u> <u>time</u>?

On a scale of 1 to 10, where 1 is mild and 10 is severe, please rate to what extent this bothered you in the...

a. \underline{right} foot and leg: $|_|$

b. <u>left foot and leg:</u> $|__|$

WIHSID#

B3.	Sometimes people feel a sensation after they have been sitting for too long in one place on a hard surface.
	This is what I mean by "pins and needles."

Have you <u>ever</u> had "pins and needles" in <u>both</u> your feet and legs <u>at around the same time</u>? (**PROBE**: I am not asking about "pins and needles" caused by sitting for too long.)

	C I			
On a scale of 1 to 10, where 1 is mild and 10 is severe, please rate to what extent this bothe you in the				
	<i>y</i> • <i>a</i> • <i>a</i> • <i>a</i> • • • • • • • • • •	a.	right foot and leg:	
		b.	<u>left</u> foot and leg:	
B4.	In the last 6 months, have yo	u had "p	nins and needles" in both your feet and legs at around the same time?	
	On a scale of 1 to 10 you in the	, where	1 is mild and 10 is severe, please rate to what extent this bothered	
	y	a.	<u>right</u> foot and leg:	
		b.	<u>left</u> foot and leg:	
B5. Sometimes people have Novocaine or Orajel administered to the their lips and mouth, they cannot feel the tap. This is what I may be a set of the tap.			r Orajel administered to their gums by a dentist. Even if you tap the tap. This is what I mean by numbness.	
	Have you <u>ever</u> had numbness asking about numbness cause		your feet and legs <u>at around the same time</u> ? (PROBE : I am not ovocaine or Oragel.)	
	On a scale of 1 to 10 you in the	, where	1 is mild and 10 is severe, please rate to what extent this bothered	
	you in them	a.	<u>right</u> foot and leg:	
		b.	<u>left</u> foot and leg:	
B6.	In the last 6 months, have yo	u had nu	umbness in both your feet and legs at around the same time?	
	On a scale of 1 to 10, where 1 is mild and 10 is severe, please rate to what extent this you in the			
	ý	a.	<u>right</u> foot and leg:	
		b.	<u>left</u> foot and leg:	
Nor				
NOTE			CURRENT PAIN AS "8" OR ABOVE, THEN REFER RIMARY CARE PROVIDER OR A NEUROLOGIST	

SECTION C: NEUROPATHY SIGNS

INSTRUCTIONS FOR EVALUATING PERCEPTION OF VIBRATION:

Have the participant sit on the edge of the exam table with her legs hanging over the side. Strike the end of a 128 Hz tuning fork hard enough that the disks audibly touch. First, establish a vibration control on the participant's wrist. Next, watch the timer as you place the stem gently but firmly on the top of the distal interphalangeal (DIP) joint of the great toe. Stop measuring the seconds when the participant indicates that no vibration is felt or after 12 seconds. The participant should say that the vibration stops when it is removed. Otherwise, re-do the test. Repeat these steps for the left toe.

C1. I am going to put the tuning fork on your toe. I want you to tell me if you feel the vibration and as soon as it stops.

	> 10	6-10	5 SECONDS OR	NO FEELING	UNABLE TO
	SECONDS	SECONDS	LESS (MODERATE	OF	EVALUATE OR
	(NORMAL)	(MILD LOSS)	LOSS)	VIBRATION	DID NOT ASSESS
a. RIGHT	0	1	2	3	-9
b. LEFT	0	1	2	3	-9

INSTRUCTIONS FOR EVALUATING DEEP TENDON REFLEXES:

With the participant seated, use one hand to press upward on the ball of the foot, dorsiflexing the participant's ankle to 90 degrees. Use a Queen's Square hammer to strike the Achilles tendon. The tendon reflex is felt by the examiner's hand as a plantar flexion of the foot, appearing after a slight delay from the time the Achilles tendon was struck. If the reflex cannot be elicited, try again with the Jendrassik maneuver (C3).

C2. Please close your eyes and relax.

	ABSENT	HYPOACTIVE	NORMAL, INCREASED, OR CLONUS	UNABLE TO EVALUATE OR DID NOT ASSESS
a. RIGHT	0	1	2	-9
b. LEFT	0	1	2	-9

C3. ARE <u>BOTH</u> THE RIGHT AND LEFT NORMAL, INCREASED, OR CLONUS (i.e., "2" is circled for both C2a and C2b)?

YES1	(C5)
NO2	(C4)

INSTRUCTIONS FOR EVALUATING DEEP TENDON REFLEXES USING THE JENDRASSIK MANEUVER:

The participant should clasp her hands with one thumb up, the other thumb down, and then interlace the fingers. Instruct the participant that, on the count of three, she should pull outwards while keeping her fingers intertwined. Once she starts pulling, try to elicit the reflex again.

C4. Please close your eyes and relax. On the count of three, tightly pull your hands.

	ABSENT	HYPOACTIVE	NORMAL, INCREASED, OR CLONUS
a. RIGHT	0	1	2
b. LEFT	0	1	2

NOTE: IF A PARTICIPANT ASKS HOW SHE DID, PLEASE TELL HER THAT MANY DIFFERENT PROCESSES CAN AFFECT NERVE FUNCTION. THESE INCLUDE DIABETES, HEPATITIS C, NORMAL AGING, THE MEDICATIONS USED TO TREAT HIV, AND SOMETIMES THE HIV VIRUS ITSELF. IF SHE HAS FURTHER CONCERNS, THEN SHE SHOULD BE DIRECTED TO HER HIV DOCTOR OR TO A LOCAL HIV-NEUROLOGIST.

C5. TIME MODULE ENDED:

|____:

AM1 PM2