# Standard Operating Procedures for

 **Brief Peripheral Neuropathy Screening**

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# Standard Operating Procedures for:

# Brief Peripheral Neuropathy Screening

## PURPOSE

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| This standard operating procedure (SOP) describes the procedures for brief peripheral neuropathy screening (BPNS) in the endTB observational study and clinical trial for participant safety monitoring. |

## SCOPE

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| This SOP is developed for health care professionals conducting brief peripheral neuropathy screening (BPNS) among participants of the endTB observational study and clinical trial. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| Clinical staff | * Prepares BPNS materials and test environment,
* Instructs patients on the screening procedures,
* Conducts subjective symptom screening, evaluates vibration perception and deep tendon reflexes,
* Completes BPNS scoring sheet,
* Reviews patients’ medical history to detect abnormal changes from baseline.
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| Research staff | * Prepares BPNS materials and test environment,
* Instructs patients on the screening procedures,
* Completes BPNS scoring sheet.
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## DEFINITIONS and ABBREVIATIONS

**ACTG brief peripheral neuropathy screening tool:** A validated screening tool developed by the AIDS Clinical Trials Group (ACTG) funded by the National Institute of Health of USA. This tool assesses both clinical signs and subjective symptoms suggestive of peripheral neuropathy. It can be administered by non-neurologists following minimal training.

**BPNS:** Brief peripheral neuropathy screening.

## PROCEDURE:

### 5.1. Materials Needed for BPNS

* BPNS scoring sheet (Appendix 1)
* 128 Hz tuning fork
* Reflex hammer

### 5.2. Preparation

**Clinical staff** should be trained on administering the ACTG BPNS tool and the scoring/grading system.

**Clinical staff** should locate a quiet work environment with minimal interruption to seat the participant comfortably. The participant should be informed of the purpose and procedures of BPNS.

### Subjective Symptoms Screening

**Clinic staff** is recommended to follow the procedural details below:

1. Introduce one’s self and verify the subject’s name and date of birth. Subject identifier must match the clinical chart.
2. Ask the participant “Are you currently suffering from pain or burning in your right foot or leg?” When asking the question to the participant, assess whether his/her symptom is suggestive of neuropathic pain. Although difficult to define and variable for each individual, neuropathic pain is often described as "burning", "electric", "tingling", and "shooting" in nature. It can vary from a constant pain to intermittent sharp shooting pains. As described, the pain is most often present without associated stimulation, but can be exacerbated by stimuli.
	* Record “00- Currently absent” as the subjective symptom score if the participant does not have the symptom.
	* If the patient has a symptom which is suggestive of neuropathic pain, instruct the participant to rate his/her symptom on a scale of 1 (mild) to 10 (most severe). Record the score.
3. Ask the participant “Are you currently suffering from ‘pins and needles’ in your right foot or leg?”
	* Record “00- Currently absent” as the subjective symptom score if the participant does not have the symptom.
	* Instruct the participant to rate his/her symptom on a scale of 1 (mild) to 10 (most severe) if the participant is currently having such symptom. Record the score.
4. Ask the participant “Are you currently suffering from ‘numbness’ in your right foot or leg?”
	* Record “00- Currently absent” as the subjective symptom score if the participant does not have the symptom.
	* Instruct the participant to rate his/her symptom on a scale of 1 (mild) to 10 (most severe) if the participant is currently having such symptom. Record the score.
5. Repeat steps 1 to 3 for the left foot or leg.

**Clinical staff** should record all subjective sensory neuropathy scores on the BPNS Scoring Sheet and obtain the subjective sensory neuropathy grade of the participant.

### Evaluation of Vibration Perception in the Great Toes

**Clinical staff** is recommended to follow the procedural details below:

* 1. Compress the ends of a 128 Hz tuning fork just hard enough that the sides touch, then release the ends to make the fork vibrate.
	2. Place the vibrating tuning fork on a bony prominence on the participant’s wrist or hand to be sure that he/she can recognize the vibration or “buzzing” quality of the fork.
	3. Compress the ends of the tuning fork again just hard enough so that the sides touch.
	4. Immediately place the vibrating tuning fork gently but firmly on the top of the distal interphalangeal joint of the right great toe and begin counting the seconds.
	5. Instruct the participant to tell you when the “buzzing” stops and note the perception time.
	6. Repeat steps 1 to 5 for the left great toe.

**Clinical staff** should record all vibration perception time on the BPNS Scoring Sheet and obtain the vibration perception grade of the participant.

### Evaluation of the Achilles Tendon Reflexes

**Clinical staff** is recommended to follow the procedural details below:

1. Have the participant seated.
2. Use one hand to press upward on the ball of the right foot, dorsiflexing the participant’s ankle to 90 degrees.
3. Use a reflex hammer to strike the Achilles tendon.

1. Feel the tendon reflex by hand as a plantar flexion of the foot, appearing after a slight delay from the time the tendon was struck.
2. Have the subject clench his/her fists while testing the tendon reflex before classifying the reflex as absent.
3. Repeat steps 2 to 5 for the left foot.

**Clinical or research staff** should complete the BPNS Scoring Sheet to obtain the ankle reflexes score of the participant.

### Overall BPNS Assessment

**Clinical staff** should refer to participant’s medical history to check for any changes of peripheral neuropathy findings from baseline.

### Reporting BPNS Results

* BPNS is a validated procedures for a non-specialist (i.e. TB doctors) to screen for peripheral neuropathy; however it is not a diagnostic tool for neuro-sensory disorders. The BPNS assessment described in this SOP only allows a non-specialist to detect and report event of paresthesia. TB Doctors and Specialists should follow the MSF Severity Grading Scale to grade the paresthesia according to subjective symptom score of the BPNS, and use only paresthesia to guide the management of the AE
* BPNS is not a good diagnostic tool to detect other neuro-sensory disorder. Thus, a non-specialist should not use the BPNS result to guide any AE management other than paresthesia. The vibration and reflexes components may help informing a non-specialist’s screening of neurological disorders. Nonetheless, the TB doctor should refer patients to a specialist if s/he detects reduced reflexes or vibration perception on the BPNS.

## REFERENCES

* ACTG Brief Peripheral Neuropathy Screening Tool. NIAID Adult AIDS Clinical Trial Group. 2009. <http://www.hiv.va.gov/provider/manual-primary-care/peripheral-neuropathy-tool1.asp>
* Generic Screening Tools for Peripheral Neuropathy, Mood and AIDS Dementia Complex in HIV Positive Individuals. Neurology Working Group of the National Centre in HIV Epidemiology and Clinical Research. 2004. <http://kirby.unsw.edu.au/sites/default/files/hiv/attachment/GenScreenTools0904.pdf>

## APPENDIX

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| **Appendices & Forms for completion** |
| **Number** | **Title** |
| A1 | Brief Peripheral Neuropathy Screening Scoring Sheet |
| A2 | Brief Peripheral Neuropathy Screening Guide (from endTB Clinical Guide) |