PNRR-2 SOP for Nerve Conduction Study (NCS) form

NERVE CONDUCTION STUDY FORM

Requested electrophysiological testing information includes Nerve Conduction Study (NCS) evaluations of the peroneal motor and the sural sensory nerves in the distal legs.

The **Minimum Data Set (MDS)** for electrophysical testing includes the sural sensory nerve (either conduction velocity plus amplitude or latency plus amplitude) of one leg. If no electrophysiological testing was performed, then the participant must have skin biopsy pathology report on record to be eligible for PNRR enrollment.

Note: Only electrophysiological testing results from NCS testing performed at one of the consortia sites or at a trusted outside facility should be entered into PNRR.

GENERAL INFORMATION:

1. **Subject ID:** study ID assigned to participant at the time of enrollment into PNRR
2. **Sex (check one):** genetic sex of PNRR participant
3. **Year of visit:** year of clinic visit the NCS testing results are associated with
4. **Year of birth:** year the PNRR participant was born
5. **Year of Nerve Conduction Study:** calendar year the electrophysiological testing was conducted (must be within 36 months of study visit)

ELECTROPHYSIOLOGICAL TESTING RESULTS:

For each evaluated parameter, both the absolute value should be entered into REDcap database and the entered value should be evaluated if it is considered normal or abnormal at the consortia site, as normative values vary slightly for each site.

I. PERONEAL MOTOR NERVE:

The distal peroneal motor nerve should be evaluated with receiver located above the Extensor Digitorum Brevis (EDB) muscle in the foot. Peroneal motor nerve evaluations with receiver located above Tibialis Anterior (TA) muscle should NOT be recorded in PNRR.

1. **Motor Nerve Conduction Velocity (MNCV) for peroneal nerve:**
   - I. **MNCV (m/s) ankle to knee:** motor nerve conduction velocity calculated for the distal peroneal nerve (below knee) in meters per second (m/s).
   - II. **MNCV (m/s) around knee:** motor nerve conduction velocity calculated for the peroneal nerve around the knee, in meters per second (m/s).

Normative values for peroneal MNCV for each Consortia Site:

Consortia Site	Normative values for Peroneal MNCV
Johns Hopkins	>39 m/s
Mount Sinai	≥44 m/s
Northwestern	>41 m/s for participants <30, >40 m/s for participants ≥30
University of Utah	>41 m/s
Kansas University	>41 m/s
Washington University	>41 m/s
University of Michigan	>41 m/s
University of North Carolina	≥38 m/s

Evaluation of peroneal MNCV:

- Normal – conduction velocity faster than normative value
- Abnormal – recorded conduction velocity slower normative value
- NR – No Response. Value field should be left blank
- ND – Not Done. Value field should be left blank

2. **Distal Onset Latency (Latency) for Peroneal Nerve:**

Measured time it takes an electrical impulse to travel from the stimulation point to the recording site in milliseconds (msec). The onset latency should be recorded in this data entry field, reflecting the conduction along the fastest fibers in the peroneal nerve.

Normative values for peroneal onset latency for each Consortia Site:

Consortia Site	Normative value for Peroneal Latency
Johns Hopkins	<5.6 msec
Mount Sinai	≤6.5 msec
Northwestern	<5.5 msec for participants <50, <6.0 msec for participants ≥50
University of Utah	<6.1 msec
Kansas University	<6.6 msec
Washington University	<6.1 msec
University of Michigan	<6.1 msec
University of North Carolina	≤5.6 msec

Evaluation of peroneal Onset Latency:

- Normal – onset latency faster than normative value (shorter time)
- Abnormal – onset latency slower than normative value (longer time)
- NR – No Response. Value field should be left blank
- ND – Not Done. Value field should be left blank

3. **Distal Compound Muscle Action Potential (CMAP) for Peroneal Nerve:**

   Highest measured action potential evoked in the distal peroneal nerve, in milli-Volts (mV).

   Normative values for peroneal CMAP for each Consortia Site:

Consortia Site	Normative values for Peroneal CMAP
Johns Hopkins	>2.0 mV
Mount Sinai	≥2.0 mV
Northwestern	>3.0 mV for participants <50, >2.5 mV for participants ≥50
University of Utah	≥2.0 mV
Kansas University	>2.0 mV
Washington University	>2.0 mV
University of Michigan	>2.0 mV
University of North Carolina	≥2.0 mV

   Evaluation of peroneal CMAP:
   - Normal – CMAP higher than normative value
   - Abnormal – CMAP lower than normative value
   - NR - Not Recordable. "0" should be entered as value for CMAP.
   - ND – Not Done. Value field should be left blank

4. **F-wave Latency for Peroneal Nerve:**

   Time elapsed until the onset of the second voltage change after supramaximal nerve stimulation of the peroneal nerve, recorded in milliseconds (msec).

   Normative values for peroneal F-wave for each Consortia Site:

Consortia Site	Normative values for Peroneal F-wave
Johns Hopkins	<56 msec
Mount Sinai	Dependent on height, range from ≤48 to ≤58 msec
Northwestern	<56 msec
University of Utah	<55 msec
Kansas University	<57 msec
Washington University	<56 msec
University of Michigan	<55 msec
University of North Carolina	≤56 msec

   Evaluation of peroneal F-wave:
   - Normal – F-wave faster than normative value (shorter time)
   - Abnormal – F-wave slower than normative value (longer time)
   - NR – No Response. Value field should be left blank
   - ND – Not Done. Value field should be left blank

II. SURAL SENSORY NERVE

1. Sensory Nerve Conduction Velocity (SNCV):

Calculated nerve conduction velocity for Sural Sensory Nerve in meters per second (m/s) for distal sural nerve between calf and ankle.

Normative values for sural SNCV for each Consortia Site:

Consortia Site	Normative value for Sural SNCV
Johns Hopkins	>39 m/s
Mount Sinai	≥40 m/s
Northwestern	Not applicable
University of Utah	>41 m/s
Kansas University	>41 m/s
Washington University	>38 m/s
University of Michigan	>41 m/s
University of North Carolina	Not applicable

Evaluation of sural SNCV:

- Normal – conduction velocity faster than normative value (higher value)
- Abnormal – conduction velocity slower than normative value (lower value)
- NR – No Response. Value field should be left blank
- ND – Not Done. Value field should be left blank

2. Peak Latency for Sural Sensory Nerve:

Peak latency for distal sural sensory nerve, measured in milliseconds (msec).

Normative values for peak latency for each Consortia Site:

Consortia Site	Normative values for Sural Onset Latency	Distance
Johns Hopkins	No normative value defined	11 cm
Mount Sinai	Peak latency not measured	
Northwestern		
University of Utah	≤4.2 msec	14 cm
Kansas University	≤4.5 msec	14 cm
Washington University		
University of Michigan		
University of North Carolina	≤4.2 msec	14 cm

Evaluation of sural onset latency:

- Normal – onset latency faster than normative value (lower value)
- Abnormal – onset latency slower than normative value (higher value)
- NR – No Response. Value field should be left blank
- ND – Not Done. Value field should be left blank

3. **Sensory Nerve Action Potential (SNAP) for Sural Nerve:**

Action potential (amplitude) measured for Distal Sural Sensory Nerve in microVolts (μV).

Normative values for sural SNCV for each Consortia Site:

Consortia Site	Normative values for Sural SNAP
Johns Hopkins	>9.0 μV <60 years; >5.0 μV ≥60 years
Mount Sinai	≥6.0 μV
Northwestern	>6 μV <30 years; >5 μV 30-49 years; >4 μV 50-59; >3 μV ≥60
University of Utah	≥6.0 μV
Kansas University	>6.0 μV <60 years; >3.0 μV ≥60 years
Washington University	>5.0 μV
University of Michigan	>6.0 μV
University of North Carolina	≥5.0 μV

Evaluation of sural SNAP:

- Normal – onset latency faster than normative value (lower value)
- Abnormal – onset latency slower than normative value (higher value)
- NR – Not Recordable. "0" should be entered as value for measured SNAP.
- ND – Not Done. Value field should be left blank

III. NCS Interpretation

Information from the NCS/EMG report generated by the consortia site should be referenced to complete the NCS Interpretation section for PNRR. If the information is not included in the NCS/EMG report, the enrolling physician should be consulted to provide interpretation.

Nerve Conduction Study Interpretation

- **Normal:** nerve function of all tested nerves was within the normal range, or electrodiagnostic findings do not confirm peripheral polyneuropathy.
- **Abnormal:** electrophysiological testing of one or more nerves was abnormal and confirms presence of peripheral neuropathy
- **ND/NA:** no NCS/EMG testing was conducted with this participant

If abnormal, mark one:

- **Sensory:** sensory nerves are more affected than motor nerves by degenerative process
- **Motor:** motor nerves are more affected than sensory nerves by degenerative process
- **Sensorimotor:** both sensory and motor nerves are affected by degenerative process

And mark one:

- **Axonal:** axons are predominantly affected by degenerative process
- **Demyelinating:** Schwann cells (myelin sheath) are predominantly affected by degenerative process
- **Mixed:** both axons and Schwann cells are both affected by degenerative process

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IV. Skin Biopsy

Nerve Conduction Study (NCS) are not conducted at some consortia sites when participants have Small Fiber Neuropathy (SFN). SFN is confirmed through skin biopsy, and participants without NCS on record are only eligible for PNRR enrollment when they have skin biopsy performed.

Skin Biopsy Interpretation:

- **Normal:** small fiber density in normal range.
- **Abnormal:** small fiber density below normal range or absent
- **ND/NA:** no skin biopsy performed

If abnormal, mark one:

- **Length-dependent:** skin biopsy confirms length-dependent process (nerve fiber density distally reduced in comparison to proximal testing sites)
- **Non-Length-dependent:** nerve fiber densities are equally reduced at all testing sites or are more reduced proximal compared to distal testing site

Distal Nerve Fiber density:
Information should be obtained from skin biopsy pathology report as the normative values vary between skin laboratories. The following information should be obtained in reference to the normative value of the skin biopsy which performed the analysis. The testing results from the distal testing site (ankle) should be referenced:

- **Normal:** small fiber density in normal range at distal testing site
- **Slightly reduced:** small fiber density reduced, but >50% of normative value
- **Significantly reduced:** small fiber density <50%, but fibers were still found
- **Absent:** no small nerve fibers were detected in samples

Date Data Entry Completed:
Date should be entered when data entry was **completed** (= assumed final).

Nerve Conduction Study (NCS) Form Status:

- **Incomplete:** not all data is entered yet
- **Unverified:** all data is entered, but pending verification, e.g. confirmation from physician
- **Complete:** all information is verified, no additional edits are anticipated