

Exhibit F
PNRR-SOP for NCS Form 2019

NERVE CONDUCTION STUDY FORM

The Nerve Conduction Study Form (NCS) should be submitted every time a Nerve Conduction Study (NCS) is performed with a PNRR participant. **It is required that a NCS data entry form is completed in the PNRR data base for the initial (enrollment) visit.** For follow-up visits, a NCS form should only be filled out when a nerve conduction evaluation was performed.

It is highly desired that NCS/EMG information is available for each PNRR participant. However, for patients with predominantly small fiber neuropathy, NCS/EMG testing information may be waived at the physician's discretion if clinically not required. If no NCS/EMG information is available, the reason for not performing the testing should be reflected in the NOTES of the NCS data entry form.

GENERAL INFORMATION:

Physician: last name of examining physician

Sex (circle one): genetic sex of the PNRR participant

Year of visit: year of the visit this NCS form is associated with

Year of birth: year the PNRR participant was born

Year of NCS Testing: year the NCS test was performed (should be within 12 months of visit)

MEDIAN MOTOR NERVE:

Median Motor Nerve Conduction Velocity (MNCV):

Calculated motor nerve conduction velocity (MNCV) for median nerve in meter per second (m/s). The median nerve is stimulated at two locations: (1) just above the wrist and (2) just below the elbow. For both stimulation sites, the evoked potential is measured above the Abductor Pollicis Brevis (APB) muscle.

Data Entry:

- The calculated numeric value (m/s) shall be entered into the data entry fields labeled "Right" or "Left" pending if the test was conducted with the median nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median MNCV:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥49 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <50, >50 m/s for patients ≥50
 - University of Utah: >49 m/s
 - Kansas University: >49 m/s
 - Washington University: >49 m/s
- NR – Not Recordable. "NR" should be entered as value and "NR" should be chosen as evaluation.
- ND – Not Done

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Median Distal Motor Latency:

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

Data Entry:

- The measured onset latency shall be entered into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the median nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median Distal Motor Latency:
 - Johns Hopkins: <4.3 msec
 - Mount Sinai: ≤4.4 msec
 - Beth Israel: ≤4.0 msec
 - Northwestern: <3.9 msec for patients <50, <4.0 msec for patients ≥50
 - University of Utah: <4.4 msec
 - Kansas University: <4.5 msec
 - Washington University: <4.4 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Median Distal Compound Muscle Action Potential (CMAP):

Highest measured action potential evoked for the median nerve during NCS testing, in millivolts (mV).

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the median nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median CMAP:
 - Johns Hopkins: >4 mV
 - Mount Sinai: ≥4 mV
 - Beth Israel: ≥4.0 mV
 - Northwestern: >6 mV for patients <60, >5 mV for patients ≥60
 - University of Utah: >4 mV
 - Kansas University: >4.5 mV
 - Washington University: >4 mV
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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Median F-wave latency:

Time elapse until the second voltage change after supramaximal nerve stimulation in milliseconds (msec). The F-wave onset is usually 25-32 msec in the upper extremities, including the median nerve.

Data Entry:

- The measured time elapse in milliseconds (msec) shall be entered as a numeric value, using the data entry field labeled “Right” or “Left” pending if the test was conducted with the median nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median F-wave:
 - Johns Hopkins: <32 msec
 - Mount Sinai: ≤31 msec
 - Beth Israel: ≤31 msec
 - Northwestern: <31 msec
 - University of Utah: <31 msec
 - Kansas University: <32 msec
 - Washington University: <31 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done.

ULNAR MOTOR NERVE:

Ulnar Motor Nerve Conduction Velocity (MNCV) for distal ulnar nerve:

Nerve Conduction velocity calculated for the distal ulnar nerve in meter per second (m/s). The ulnar nerve is stimulated at two locations: (1) just above the wrist and (2) just below the elbow. For both stimulation sites, the evoked potential is measured at the Abductor Digiti Minimi (ADM) muscle.

Data Entry:

- The calculated numeric value shall be entered into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar MNCV between wrist and elbow:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥49 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <30, >50 m/s for patients ≥30
 - University of Utah: >49 m/s
 - Kansas University: >50 m/s
 - Washington University: >49 m/s
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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Ulnar Motor Nerve Conduction Velocity (MNCV) around elbow:

Nerve conduction velocity calculated for the ulnar nerve around the elbow in meter per second (m/s) from two stimulation sites: (1) an action potential is evoked just below the elbow and (2) just above the elbow, to evaluate for cubital tunnel syndrome. For both stimulations, the evoked potential is recorded above the Abductor Digiti Minimi (ADM) muscle.

Data Entry:

- The calculated numeric value in meters/second shall be entered into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar MNCV around elbow:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥49 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <30, >50 m/s for patients ≥30
 - University of Utah: >49 m/s
 - Kansas University: >49 m/s
 - Washington University: >49 m/s
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Ulnar Distal Motor Latency:

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

Data Entry:

- The calculated onset latency shall be entered into the data entry fields labeled “Right” or “Left” pending if the testing was conducted with the ulnar nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar onset latency:
 - Johns Hopkins: <3.5 msec
 - Mount Sinai: ≤3.3 msec
 - Beth Israel: ≤3.3 msec
 - Northwestern: <3.0 msec for patients <30, <3.1 msec for patients ≥30
 - University of Utah: <3.5 msec
 - Kansas University: <3.6 msec
 - Washington University: <3.5 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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Ulnar Distal Compound Muscle Action Potential (CMAP):

Highest measured action potential evoked for the ulnar nerve during the NCS testing, in millivolts (mV).

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar CMAP:
 - Johns Hopkins: >4 mV
 - Mount Sinai: ≥6 mV
 - Beth Israel: ≥6 mV
 - Northwestern: >8 mV for patients <30, >7 mV for patients ≥30
 - University of Utah: >6 mV
 - Kansas University: >5 mV
 - Washington University: >6 mV
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Ulnar F-wave latency (msec):

Recorded time elapse until the second voltage change after supramaximal nerve stimulation of distal ulnar nerve, in milliseconds (msec).

Data Entry:

- The measured time elapse in milliseconds (msec) shall be entered as a numeric value, using the data entry field labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar F-wave latency:
 - Johns Hopkins: <33 msec
 - Mount Sinai: ≤33 msec
 - Beth Israel: ≤32 msec
 - Northwestern: <32 msec
 - University of Utah: <31 msec
 - Kansas University: <33 msec
 - Washington University: <32 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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PERONEAL MOTOR NERVE:

Motor Nerve Conduction Velocity (MNCV) for Distal Peroneal Nerve:

Nerve conduction velocity calculated for the peroneal nerve in meter per second (m/s). Value is calculated from two stimulations: (1) an action potential is evoked at the ankle and (2) just below the knee (fibular head). For both stimulations, the evoked potential is recorded above the Extensor Digitorum Brevis (EDB) muscles.

Data Entry:

- The calculated numeric value (meter per second) shall be entered into the data entry field labeled “Right” or “Left” pending if the peroneal nerve in the right or left leg was evaluated.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Peroneal MNCV:
 - Johns Hopkins: >39 m/s
 - Mount Sinai: ≥44 m/s
 - Beth Israel: ≥40 m/s
 - Northwestern: >41 m/s for patients <30, 40 m/s for patients ≥30
 - University of Utah: >41 m/s
 - Kansas University: >41 m/s
 - Washington University: >41 m/s
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Motor Nerve Conduction Velocity (MNCV) for Peroneal Nerve Around Knee:

Nerve conduction velocity calculated for the peroneal nerve around knee, in meter per second (m/s). Value calculated from two stimulations: (1) an action potential is evoked just below the knee (fibular head) and (2) a second potential is evoked “behind” (above) the knee to evaluate for potential nerve entrapment at the knee. For both stimulations, the evoked potential is recorded above the Extensor Digitorum Brevis (EDB) muscles.

Data Entry:

- The calculated numeric value (meter per second) shall be entered into the data entry fields labeled “Right” or “Left” pending if the peroneal nerve in the right or left leg was evaluated.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for peroneal MNCV:
 - Johns Hopkins: >39 m/s
 - Mount Sinai: ≥44 m/s
 - Beth Israel: ≥40 m/s
 - Northwestern: >41 m/s for patients <30, 40 m/s for patients ≥30
 - University of Utah: >41 m/s
 - Kansas University: >41 m/s
 - Washington University: >41 m/s
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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Distal Motor 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.

Data Entry:

- The calculated onset latency shall be entered into the data entry fields labelled “Right” or “Left” pending if the peroneal nerve in the right or left leg was evaluated.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for peroneal distal motor latency:
 - Johns Hopkins: <5.6 msec
 - Mount Sinai: ≤6.5 msec
 - Beth Israel: ≤6.5 msec
 - Northwestern: <5.5 msec for patients <50, <6.0 msec for patients ≥50
 - University of Utah: <6.1 msec
 - Kansas University: <6.6 msec
 - Washington University: <6.1 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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

Highest measured action potential evoked in the peroneal nerve, in milliVolts (mV).

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the peroneal nerve in the right or left leg was evaluated.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Peroneal CMAP:
 - Johns Hopkins: >2 mV
 - Mount Sinai: ≥2 mV
 - Beth Israel: ≥2 mV
 - Northwestern: >3 mV for patients <50, >2.5 mV for patients ≥50
 - University of Utah: ≥2 mV
 - Kansas University: >2 mV
 - Washington University: >2 mV
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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F-wave Latency for Peroneal Nerve:

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

Data Entry:

- The measured time elapse in milliseconds (msec) shall be entered as a numeric value, using the data entry field labeled “Right” or “Left” pending if the peroneal nerve in the right or left leg was evaluated.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for peroneal F-wave latency:
 - Johns Hopkins: <56 msec
 - Mount Sinai: Dependent on height, range from ≤48 to ≤58
 - Beth Israel: ≤56 msec
 - Northwestern: <56 msec
 - University of Utah: <55 msec
 - Kansas University: <57 msec
 - Washington University: <56 msec
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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SENSORY NERVES

SURAL NERVE

Sensory Nerve Conduction Velocity (SNCV) for Sural Nerve:

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

Data Entry:

- The calculated nerve conduction velocity for the Sural Sensory Nerve in meters per second (m/s) shall be entered as a numeric value into the data entry field labeled “Right” or “Left” pending if the test was conducted with the sural nerve on the right or left leg.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Sural SNCV as normal or abnormal:
 - Johns Hopkins: >39 m/s
 - Mount Sinai: ≥40 m/s
 - Beth Israel: ≥40 m/s
 - Northwestern: >41 m/s for patients <30 y, >40 m/s for patients ≥30 y
 - University of Utah: >41 m/s
 - Kansas University: >41 m/s
 - Washington University: >38 m/s
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Sensory Nerve Action Potential (SNAP) for Sural Nerve:

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

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left”, pending if the test was conducted with the sural nerve on the right or left leg.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Sural SNAP as normal or abnormal:
 - Johns Hopkins: dependent on age, range from >5 to >9 μV
 - Mount Sinai: ≥6 μV
 - Beth Israel: dependent on age, range from ≥3 to ≥14 μV
 - Northwestern: >6 μV for patients <30, >5 μV for patients 30-49, >4 μV for patients 50-59 and >3 μV for patients ≥60
 - University of Utah: ≥6 μV
 - Kansas University: >6 μV for patients <60 years, >3 μV for patients >60 years
 - Washington University: >5 μV
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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MEDIAN NERVE

Sensory Nerve Conduction Velocity (SNCV) for Median Nerve:

Calculated Nerve Conduction Velocity for Distal Median Sensory Nerve, in meter per second (m/s). Preferably, the entered value should reflect the SNCV between Digit II and above the wrist.

Data Entry:

- The measured time elapse in meters per second (m/s) shall be entered as a numeric value into the data entry field labeled “Right” or “Left” pending if the test was conducted with the median nerve on the right or left hand.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median SNCV as normal or abnormal:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥50 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <50, >50 m/s for patients ≥50
 - University of Utah: >50 m/s
 - Kansas University: >48 m/s
 - Washington University: >44 m/s
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Sensory Nerve Action Potential (SNAP) for Median Nerve:

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

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the median nerve on the right or left hand.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Median SNAP as normal or abnormal:
 - Johns Hopkins: >9 μV
 - Mount Sinai: ≥20 μV
 - Beth Israel: ≥20 μV
 - Northwestern: >20 μV for patients <50, >15 μV patients 50-59, >10 μV patients ≥ 60
 - University of Utah: ≥20 μV
 - Kansas University: >15 μV
 - Washington University: >7 μV
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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ULNAR NERVE

Sensory Nerve Conduction Velocity (SNCV) for Ulnar Nerve:

Calculated Nerve Conduction Velocity for Distal Ulnar Sensory Nerve, in meter per second (m/s). Preferably, the entered value should reflect the SNCV between Digit V and above the wrist.

Data Entry:

- The measured conduction velocity shall be entered as a numeric value into the data entry field labeled “Right” or “Left” pending if the test was conducted with the sensory ulnar nerve on the right or left hand.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar SNCV as normal or abnormal:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥50 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <50, >50 m/s for patients ≥50
 - University of Utah: >50 m/s
 - Kansas University: >48 m/s
 - Washington University: >44 m/s
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Sensory Nerve Action Potential (SNAP) for Ulnar Nerve:

Action potential (amplitude) measured for distal sensory ulnar nerve in microVolts (μV).

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left hand.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Ulnar SNAP as normal or abnormal:
 - Johns Hopkins: >9 μV
 - Mount Sinai: ≥17 μV
 - Beth Israel: depending on age ≥20.8 to ≥11 μV
 - Northwestern: >18 μV for patients <30, >12 μV for patients 30-49, >10 μV for patients 50-59 and >10 μV for patients ≥60
 - University of Utah: ≥10 μV
 - Kansas University: >10 μV for patients <60 years, >5 μV for patients >60 years
 - Washington University: >5 μV
- NR – Not Recordable: “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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RADIAL NERVE

Sensory Nerve Conduction Velocity (SNCV) for Radial Nerve:

Calculated Nerve Conduction Velocity for Distal Radial Sensory Nerve, in meter per second (m/s). Preferably, the entered value should reflect the SNCV between wrist and mid forearm, using the superficial branch of the radial nerve.

Data Entry:

- The measured conduction velocity shall be entered as a numeric value into the data entry field labeled “Right” or “Left” pending if the test was conducted with the radial nerve on the right or left arm.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Radial SNCV as normal or abnormal:
 - Johns Hopkins: >49 m/s
 - Mount Sinai: ≥50 m/s
 - Beth Israel: ≥50 m/s
 - Northwestern: >51 m/s for patients <50, >50 m/s for patients ≥50
 - University of Utah: >50 m/s
 - Kansas University: >48 m/s
 - Washington University: >50 m/s
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

Sensory Nerve Action Potential (SNAP) for Radial nerve:

Action potential (amplitude) measured for distal radial nerve in microVolts (μV).

Data Entry:

- The calculated value of the amplitude of evoked response shall be entered as a numeric value into the data entry fields labeled “Right” or “Left” pending if the test was conducted with the ulnar nerve on the right or left hand.
- The entered value shall be evaluated in accordance with the normative value established by the enrollment center for Radial SNAP as normal or abnormal:
 - Johns Hopkins: >9 μV
 - Mount Sinai: ≥15 μV
 - Beth Israel: Dependent on age, range from ≥12 to ≥25.5
 - Northwestern: >18 μV for patients <50, >14 μV for patients 50-59 and >10 μV for patient ≥60
 - University of Utah: ≥20 μV
 - Kansas University: >15 μV for patients <60 years, >10 μV for patients >60 years
 - Washington University: ≥10 μV
- NR - Not Recordable. “NR” should be entered as value and “NR” should be chosen as evaluation.
- ND – Not Done

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NOTES

The following information should be provided at the bottom of the form if applicable:

- If NCS testing was not performed at the enrollment center, the location of the test should be reported. Only NCS data from other trusted NCS-sites should be entered into PNRR.
- Other conditions contributing to the neuropathy and diagnosed during NCS/EMG should be listed in the NOTES together with the vertebrae / disc location where the damage is present; e.g. spinal stenosis L3-L5
- Any technical difficulties encountered during the NCS test that might have influenced / altered the results should be reported here, e.g. severe obesity of the patient preventing sural evaluation.
- If NCS/EMG testing was waived as a requirement because the patient has predominantly small fiber neuropathy, “patient has small fiber neuropathy” should be added to the NOTES.

Date Data Entry Completed:

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

Physician Examination Form (PEF) Status:

- **Incomplete:** not all data is entered yet
- **Unverified:** all data is entered, but waiting for confirmation for some data (for example, when waiting for confirmation about primary diagnosis pending lab results, the form should be considered unverified)
- **Complete:** all information is verified, no additional edits are anticipated