Definition of Spinal Cord Injury

For the purposes of the Model Systems’ program, a case of spinal cord injury is defined as the occurrence of an acute traumatic lesion of neural elements in the spinal canal (spinal cord and cauda equina), resulting in temporary or permanent sensory and/or motor deficit. The clinical definition of spinal cord injury excludes intervertebral disc disease, vertebral injuries in the absence of spinal cord injury, nerve root avulsions and injuries to nerve roots and peripheral nerves outside the spinal canal, cancer, spinal cord vascular disease, and other non-traumatic spinal cord diseases.

Essentially, traumatic cases would involve an external event to trigger the injury rather than disease or degeneration.

COMMENT: This definition is a slightly modified version of the CDC’s case definition. The CDC includes “temporary or permanent sensory or motor deficit, bladder dysfunction, or bowel dysfunction” and also excludes birth trauma. However, for the model systems, an ASIA E (normal sensory and motor function) on admission would not be eligible even if bowel or bladder dysfunction existed.
Eligibility

The following criterion applies to participants who are admitted to the model system on or after January 1, 2005.

**Inclusion Criteria for Form I and Registry:**

1. Presence of an external traumatic event that results in a spinal cord injury, including surgical procedures, radiation, and medical complications.
2. Temporary or permanent loss of sensory and/or motor function as a result of the traumatic event.
3. Admission to the system within one year of injury.
4. If patient is discharged from System Acute as Minimal Deficit or Recovered, they must be hospitalized in the system for at least one week before discharge.\(^1\)
5. Discharge from the system as:
   a. Having completed inpatient acute rehabilitation\(^2\),
   b. Achieving a neurologic status of normal or minimal deficit.
   c. Deceased
6. Signed informed consent and HIPAA authorization forms\(^3\).
   ◊ HIPAA Authorization is not required for research on deceased persons

**Additional Criteria for Form I Inclusion:**

1. Reside in the geographic catchment area of the system at the time of the injury. Patients may be injured outside of the catchment area.
2. A US citizen or non-US citizen who is expected to stay in the catchment area.

The above criteria do not apply to patients who 1) are discharged as deceased or 2) achieved a neurologic status of normal or minimal deficit.

**Exclusion Criteria\(^4\) for Registry and Form I:**

1. Must not have previously been treated at another model system for the injury.
   ◊ Ensures that patients are enrolled into the database by only one model system.
2. Must not have completed an organized rehabilitation program prior to the admission to the system.

**NOTES:**

\(^1\) This ensures their condition is significant and requires at least one week’s hospital care. One week hospitalization is not required if patient dies in acute medical unit.

\(^2\) Completion of rehabilitation is defined as finishing the prescribed course of inpatient rehab which may lead to a less intensive course of rehab (such as outpatient rehab), but does not include being transferred to another rehab facility for continued care. Discharges against medical advice are not considered ‘completed’.

\(^3\) Some systems IRB may not require these forms for the Registry patients, data obtained from the deceased, or both.

\(^4\) A prior history of spinal cord injury or other medical conditions (i.e. spinal stenosis, stroke, traumatic brain injury...etc) does not preclude individuals from being included in the database as long as an external/traumatic event could be identified as a cause of the NEW injury and further neurologic deficit.
NSCISC Eligibility Criteria Flow Chart

1. Did the patient have a traumatic event resulting in sensory and/or motor deficits?
   - YES
     - Patient not eligible for SCI Database
   - NO
     - Was the patient admitted to your System facility within 1 year of injury?
       - YES
         - Patient not eligible for SCI Database
       - NO
         - Was the patient previously treated at a Model System facility other than yours for SCI?
           - NO
             - Did the patient complete an organized rehab program for SCI before System admit?
               - YES
                 - Patient not eligible for SCI Database
               - NO
                 - What type of treatment did the patient receive while in your System?
                   - Acute Care
                     - Acute Care Only
                       - Was the patient discharged as deceased?
                         - YES
                           - Does your IRB allow Registry submission without a signed Informed Consent?
                             - YES
                               - Submit a Registry form for patient
                             - NO
                               - Has the patient signed an Informed Consent and HIPAA Authorization?
                                 - YES
                                   - Submit a Form I for Patient
                                 - NO
                                   - Does your IRB allow Registry submission without a signed Informed Consent?
                                     - YES
                                       - Submit a Registry form for patient
                                     - NO
                                       - Has the patient signed an Informed Consent and HIPAA Authorization?
                                         - YES
                                           - Submit a Form I for Patient
                                         - NO
                                           - Does your IRB allow Registry submission without a signed Informed Consent?
                                             - YES
                                               - Submit a Registry form for patient
                                             - NO
                                               - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                 - YES
                                                   - Submit a Form I for Patient
                                                 - NO
                                                   - Does your IRB allow Registry submission without a signed Informed Consent?
                                                     - YES
                                                       - Submit a Registry form for patient
                                                     - NO
                                                       - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                         - YES
                                                           - Submit a Form I for Patient
                                                         - NO
                                                           - Does your IRB allow Registry submission without a signed Informed Consent?
                                                             - YES
                                                               - Submit a Registry form for patient
                                                             - NO
                                                               - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                 - YES
                                                                   - Submit a Form I for Patient
                                                                 - NO
                                                                   - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                     - YES
                                                                       - Submit a Registry form for patient
                                                                     - NO
                                                                       - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                         - YES
                                                                           - Submit a Form I for Patient
                                                                         - NO
                                                                           - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                             - YES
                                                                               - Submit a Registry form for patient
                                                                             - NO
                                                                               - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                 - YES
                                                                                     - Submit a Form I for Patient
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                                                                                     - Does your IRB allow Registry submission without a signed Informed Consent?
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                                                                                         - Submit a Registry form for patient
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                                                                                         - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                           - YES
                                                                                             - Submit a Form I for Patient
                                                                                             - NO
                                                                                             - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                               - YES
                                                                                                 - Submit a Registry form for patient
                                                                                                 - NO
                                                                                                 - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                   - YES
                                                                                                    - Submit a Form I for Patient
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                                                                                                    - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                      - YES
                                                                                                        - Submit a Registry form for patient
                                                                                                        - NO
                                                                                                        - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                          - YES
                                                                                                            - Submit a Form I for Patient
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                                                                                                            - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                              - YES
                                                                                                                - Submit a Registry form for patient
                                                                                                                - NO
                                                                                                                - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                  - YES
                                                                                                                    - Submit a Form I for Patient
                                                                                                                    - NO
                                                                                                                    - Does your IRB allow Registry submission without a signed Informed Consent?
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                                                                                                                        - Submit a Registry form for patient
                                                                                                                        - NO
                                                                                                                        - Has the patient signed an Informed Consent and HIPAA Authorization?
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                                                                                                                            - Submit a Form I for Patient
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                                                                                                                            - Does your IRB allow Registry submission without a signed Informed Consent?
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                                                                                                                                - Submit a Registry form for patient
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                                                                                                                                - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                  - YES
                                                                                                                                    - Submit a Form I for Patient
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                                                                                                                                    - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                                                      - YES
                                                                                                                                        - Submit a Registry form for patient
                                                                                                                                        - NO
                                                                                                                                        - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                          - YES
                                                                                                                                            - Submit a Form I for Patient
                                                                                                                                            - NO
                                                                                                                                            - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                                                             - YES
                                                                                                                                                - Submit a Registry form for patient
                                                                                                                                                - NO
                                                                                                                                                - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                                 - YES
                                                                                                                                                    - Submit a Form I for Patient
                                                                                                                                                    - NO
                                                                                                                                                    - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                                                                          - YES
                                                                                                                                                           - Submit a Registry form for patient
                                                                                                                                                           - NO
                                                                                                                                                           - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                                            - YES
                                                                                                                                                               - Submit a Form I for Patient
                                                                                                                                                               - NO
                                                                                                                                                               - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                                                                                - YES
                                                                                                                                                                    - Submit a Registry form for patient
                                                                                                                                                                    - NO
                                                                                                                                                                    - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                                                      - YES
                                                                                                                                                                          - Submit a Form I for Patient
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                                                                                                                                                                          - Does your IRB allow Registry submission without a signed Informed Consent?
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                                                                                                                                                                                - Submit a Registry form for patient
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                                                                                                                                                                                - Has the patient signed an Informed Consent and HIPAA Authorization?
                                                                                                                                                                                  - YES
                                                                                                                                                                                    - Submit a Form I for Patient
                                                                                                                                                                                    - NO
                                                                                                                                                                                    - Does your IRB allow Registry submission without a signed Informed Consent?
                                                                                                                                                                                    - NO
                                                                                                                                   - Does the patient reside in your designated catchment area?
                                                                                                                                     - YES
                                                                                                                                       - Is the patient a US citizen?
                                                                                                                                         - YES
                                                                                                                                             - Is the patient expected to stay in the catchment area?
                                                                                                                                             - YES
                                                                                                                                                - Submit a Registry form for patient
                                                                                                                                                - NO
                                                                                                                                                - Does the patient reside in your designated catchment area?
                                                                                                                                                  - NO
                                                                                                                                                    - Did the patient have at least a 1 week stay in your System?
                                                                                                                                                          - YES
                                                                                                                                                                         - Submit a Registry form for patient
                                                                                                                                                                         - NO
                                                                                                                                                                         - Did the patient have at least a 1 week stay in your System?
                                                                                                                                                                          - NO
                                                                                                                                                                           - Was the patient discharged Normal or Minimal Deficit?
                                                                                                                                                                              - YES
                                                                                                                                                                                            - Submits a Form I for Patient
                                                                                                                                                                                            - NO
                                                                                                                                                                                            - Was the patient discharged Normal or Minimal Deficit?
                                                                                                                                                                                              - NO
                                                                                                                                                                                                             - Patient not eligible for SCI Database
                                                                                                                                                                                                                                                                 1

2. If the patient dies during his/her Acute System stay, a signed Informed Consent is not required (if the System’s IRB exempts data obtained solely from chart review).
3. HIPAA Authorization is not required for research on deceased persons.
4. Patients may be injured outside of catchment area.
5. Form II follow-up is not required for patients discharged as deceased, Normal, or Minimal Deficit.