Enter all significant surgical or procedural items.

For specific surgeries or interventions for the spine, genitourinary (urinary tract), gastrointestinal system, skin or upper extremity, please see the Supplemental questions that are from the relevant ISCoS International SCI Data Sets as identified in the Instructions, which may be applicable.

Table 1 Surgical Procedures Example

| Surgical or Therapeutic Procedure | Inpatient or Outpatient? | Start Date | End Date |
| --- | --- | --- | --- |
| Example: Appendectomy | [x]  Inpatient[ ]  Outpatient | 11/09/2008 | 11/09/2008 |

Table 1 Surgical Procedures

| Surgical or Therapeutic Procedure | Inpatient or Outpatient? | Start Date | End Date |
| --- | --- | --- | --- |
| TBD | [ ]  Inpatient[ ]  Outpatient |  |  |
| TBD | [ ]  Inpatient[ ]  Outpatient |  |  |
| TBD | [ ]  Inpatient[ ]  Outpatient |  |  |
| TBD | [ ]  Inpatient[ ]  Outpatient |  |  |
| TBD | [ ]  Inpatient[ ]  Outpatient |  |  |

Add additional rows as neededSupplemental Questions (primarily from the ISCoS International SCI Data Sets).

**Spinal Surgical and Procedural Interventions:**

1. Was a spinal intervention or a surgical procedure performed at a non-participating facility (other facility not affiliated with the study)?

[ ]  Yes (please complete the questions below)

[ ]  No (Using available documentation, able to reliably determine intervention was NOT performed)

[ ]  Unknown (Documentation not available or not complete, therefore unable to reliably determine if intervention was performed)

1. Was a spinal intervention or a surgical procedure performed at the study facility?

[ ]  Yes (please complete the questions below)

[ ]  No

[ ]  Unknown

1. Intervention/procedure date and start time:1

[ ]  Unknown

1. Non-surgical bed rest and external immobilization:1

[ ]  No

[ ]  Enforced bed-rest

[ ]  External immobilizing device

[ ] Both enforced bed-rest and external immobilizing device

[ ]  Unknown

1. Spinal intervention - closed manipulation and/or reduction of spinal elements:1

[ ] No

[ ]  Yes

[ ]  Unknown

1. Surgical procedure - approach:1

[ ] No

[ ]  Anterior open surgical procedure

[ ] Posterior open surgical procedure

[ ] Both anterior and posterior open surgical procedures

[ ] Unknown

1. Date and time of the intervention, completion or surgical closure**:**1

[ ]  Unknown

If an open surgical approach was performed (anterior, posterior, or both anterior and posterior), fill in the data elements below.

1. Surgical procedure – open reduction:1

[ ]  No

[ ]  Yes

[ ] Unknown

1. Surgical procedure – direct decompression of neural elements:1

[ ]  No

[ ]  Yes

[ ]  Unknown

1. Surgical procedure – stabilization and fusion: (one to be filled in for each level of injury, starting with the most cephalic injury):1

Stabilization and Fusion – Segment Number

Stabilization and Fusion – Segment Level

vC00-vC07-Cervical (C0-C07)

vT01-vT12-Thoracic (T1-T12)

vL01-vL05-Lumbar (L1-L5)

vS01-vS05-Sacral (S1-S5)

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vC99-Unknown Cervical (C0-C07)

vT99-Unknown Thoracic (T1-T12)

vL99-Unknown Lumbar (L1-L5)

vS99-Unknown Sacral (S1-S5)

vX99-Unknown Level

During the surgical procedure, did the patient/participant experience the following during the surgical procedure:

1. Did participant/subject experience hypotensive episode (systolic BP <90 mm Hg for longer than 5 minutes)? (choose one)

**[ ]** Yes

**[ ]** No

**[ ]** Suspected

**[ ]** Unknown

1. Did participant/subject experience hypoxic episode [oxygen saturation (SpO2) less than 90% for >5 min]? (choose one)

**[ ]** Yes

**[ ]** No

**[ ]** Suspected

**[ ]** Unknown

## **Urinary Tract Surgical and Procedural Interventions:**

1. Surgical procedures on the urinary tract:2

[ ]  No

 [ ]  Yes, supra-pubic catheter insertion, date last performed

[ ]  Yes, bladder stone removal, date last performed

[ ]  Yes, upper urinary tract stone removal, date last performed

[ ]  Yes, bladder augmentation, date last performed

[ ]  Yes, sphincterotomy/urethral stent, date last performed

[ ]  Yes, botulinum toxin injection, date last performed

[ ]  Yes, artificial sphincter, date last performed

[ ]  Yes, ileovesicostomy, date last performed

[ ]  Yes, ileoureterostomy, date last performed

[ ]  Yes, continent catheterizable valves, date last performed

[ ]  Yes, sacral anterior root stimulator, date performed

[ ]  Yes, other, specify, date performed

[ ]  Unknown

## **Gastrointestinal Tract Surgical and Procedural Interventions:**

1. Surgical procedures on the gastrointestinal tract3:

[ ]  No

[ ]  Yes, appendicectomy, date performed

[ ]  Yes, cholecystectomy, date performed

[ ]  Yes, colostomy, date last performed

[ ]  Yes, ileostomy, date last performed

[ ]  Yes, other, specify, date last performed

[ ]  Unknown

## **Pressure Ulcer Surgical and Procedural Interventions:**

1. Has the present pressure ulcer been surgically treated4: [ ]  Yes [ ]  No [ ]  Unknown

If yes, date of last surgical intervention:

1. Has any other pressure ulcer been surgically treated during the last 12 months4 [ ]  Yes [ ]  No [ ]  Unknown

If yes, date of last surgical intervention:

**Musculoskeletal Sugical and Procedural Interventions - Scoliosis:**

1. Surgical treatment of scoliosis:5 [ ]  Yes [ ]  No [ ]  Unknown

If yes: date of surgery [ ]  Unknown

## **Upper Extremity Surgical and Procedural Interventions:**

1. Upper Extremity/Hand Reconstructive Surgery6

[ ]  Yes [ ]  No [ ]  Unknown

If Yes, fill in below:

Performed Upper Extremity/Hand Reconstructive Surgery6

Check all that apply

Table 2 Surgical Procedures

| Surgery Type | Surgery Location | Right | Left | Date of Surgery | Date of Surgery Unknown |
| --- | --- | --- | --- | --- | --- |
| Soft Tissue Reconstruction  | Tendon transfer for elbow extension  | TBD | TBD | TBD | TBD |
| Soft Tissue Reconstruction  | Tendon transfer for wrist extension | TBD | TBD | TBD | TBD |
| Soft Tissue Reconstruction  | Restoration of pinch and or grasp | TBD | TBD | TBD | TBD |
| Soft Tissue Reconstruction  | Tendon/muscle releases or lengthenings  | TBD | TBD | TBD | TBD |
| Soft Tissue Reconstruction | Other | TBD | TBD | TBD | TBD |
| Osteotomy with or without rotation and or Arthrodesis | Humerus | TBD | TBD | TBD | TBD |
| Osteotomy with or without rotation and or Arthrodesis | Radius | TBD | TBD | TBD | TBD |
| Osteotomy with or without rotation and or Arthrodesis | Ulnar | TBD | TBD | TBD | TBD |
| Osteotomy with or without rotation and or Arthrodesis | Wrist | TBD | TBD | TBD | TBD |
| Osteotomy with or without rotation and or Arthrodesis | Fingers/Thumb | TBD | TBD | TBD | TBD |
| Implantable FES | - | TBD | TBD | TBD | TBD |
| Other | - | TBD | TBD | TBD | TBD |

## **General Instructions**

This case report form (CRF) contains data elements related to surgical and other procedure interventions the patient/participant is treated in the hospital or after initial discharge from the hospital for spinal cord injury.

Important note: None of the data elements included on this CRF Module is considered Core (i.e., strongly recommended for all spinal cord injury clinical studies to collect). Rather, all of the data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

## **Specific Instructions**

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Surgical or therapeutic procedure (Table 1) – Choose all that apply. Recommend collection during acute hospital care. In previous trials and studies, information on surgical procedures has typically been documented in free text format, thus often precluding any meaningful analysis. We therefore propose the use of ICD-9 coding.
* Inpatient or outpatient status (Table 1) - Choose one.
* Surgical or therapeutic procedure start date and time – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([International Organization for Standardization (ISO)](http://www.iso.org/iso/home.html). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* Surgical or therapeutic procedure end date and time - Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([International Organization for Standardization (ISO)](http://www.iso.org/iso/home/about.htm). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* Special Note: These data elements are from the ISCoS International SCI Data Sets:

[1International SCI Spinal Intervention and Spinal Procedures Basic Data Set](http://www.iscos.org.uk/international-sci-spinal-interventions-and-surgical-procedures-data-sets) (Version 1.0

[2International SCI Lower Urinary Tract Function Basic Data Set](http://www.iscos.org.uk/international-sci-lower-urinary-tract-function-data-sets) (Version 1.0)

[3International SCI Bowel Function Basic Data Set](http://www.iscos.org.uk/international-sci-bowel-data-sets) (Version 1.0)

[4International SCI Skin and Thermoregulation Function Basic Data Set](http://www.iscos.org.uk/international-sci-skin-and-thermoregulation-function-data-sets) (Version 1.0)

[5International SCI Musculoskeletal Basic Data Set](http://www.iscos.org.uk/international-sci-musculoskeletal-data-sets) (Version 1.0)

[6International SCI Upper Extremity Basic Data Set](http://www.iscos.org.uk/international-sci-upper-extremity-data-sets) (Version 1.1)