1. Date (and time) Medical History Taken:
2. Does the participant have a history of any medical problems/conditions in the following body systems?

No (leave #3 of form blank)  Yes

1. Enter all significant medical history items, including surgeries, EXCEPT the problem/condition that is the focus of this study. Use only one line per description.

Table 1 Example Medical History

| Body System§ | Medical History Term\*  (one item per line) | Start Date  (mm/dd/yyyy) | Ongoing? | End Date  (mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
| Example: Cardiovascular | Example: Hypertension | Example: 03/11/2009 | Yes  No | Example:  03/12/2009 |

Table 2 Medical History

| Body System§ | Medical History Term\*  (one item per line)  or SNOMED CT Code\* | Start Date  (mm/dd/yyyy) | Ongoing? | End Date  (mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
| TBD | TBD | TBD | Yes  No | (mm/dd/yyyy) |
| TBD | TBD | TBD | Yes  No | (mm/dd/yyyy) |

Use BODY SYSTEM categories for medical history:

* Constitutional symptoms (e.g., fever, weight loss)
* Eyes
* Ears, Nose, Mouth, Throat
* Cardiovascular§
* Respiratory§
* Gastrointestinal§
* Genitourinary§
* Musculoskeletal§
* Integumentary(skin and/or breast)
* Neurological§
* Psychiatric
* Endocrine§
* Hematologic/Lymphatic
* Allergic/Immunologic

§For specific questions related to cardiovascular, respiratory, gastrointestinal, genitourinary, musculoskeletal, neurological and endocrine systems, please see the Exploratory elements which may be applicable.

1. Does the participant have any other serious co-morbid or concomitant medical condition that, in the opinion of the investigator, would compromise the safety of the partient/participant or compromise the participant’s ability to participate in the study?

Yes

No

Unknown

Please specify condition:

1. Date of Death (and time):

Unknown

Not Applicable

1. Primary Cause of Death:
2. Secondary Cause(s) of Death:

## Additional Exploratory Elements (as applicable)\*\*\*:

1. Cardiovascular history before the spinal cord lesion1\*\*\***:**

None

Unknown (any cardiovascular disorder)

Cardiac pacemaker, date last inserted  Unknown

Cardiac surgery, specify  Unknown, date last performed

Other cardiac disorders, specify  Unknown

Hypertension  Unknown

Hypotension  Unknown

Orthostatic hypotension  Unknown

Deep vein thrombosis  Unknown

Neuropathy (alcoholic, diabetic, and others)  Unknown

Myocardial infarction  Unknown

Stroke  Unknown

Family history of cardiovascular disease,specify  Unknown

Other, specify

1. Pulmonary conditions present before the spinal cord lesion2\*\*\*:

None

Asthma

Chronic obstructive pulmonary disease (includes emphysema and chronic bronchitis)

Sleep apnea

Other, specify

Unknown

1. Endocrine & metabolic conditions diagnosed beforethe spinal cord lesion3\*\*\*:

None

Unknown (any endocrine disorder)

Diabetes mellitus  Type 1 Type 2  Unknown

Lipid values, if available, provide the most recent values prior to injury: Date

Unknown

Total cholesterol (TC) mg/dL:

Triglycerides (TG) mg/dL:

HDL cholesterol mg/dL:

LDL cholesterol mg/dL:

(TC, HDL or LDL cholesterol: mmol/L x 39 = mg/dL; TG: mmol/L x 89 = mg/dL)

Lipid disorder Specify diagnosis:  Unknown

Osteoporosis Method: DXA  Other (e.g. CT, radiograph)  Unknown

Thyroid disease Specify diagnosis:  Unknown

Other, specify:

1. Neuro-Musculoskeletal history before the spinal cord lesion4\*\*\*:

None

Pre-existing congenital deformities of the spine and spinal cord

If yes, specify Diagnosis and Location

If previous surgery due to this, description

Date of surgery Unknown

Pre-existing degenerative spine disorders

If yes, specify Diagnosis and Location

If previous surgery due to this, description

Date of surgery  Unknown

Pre-existing systemic neuro-degenerative disorders

If yes, specify Diagnosis and Location

If previous surgery due to this, description

Date of surgery  Unknown

1. Urinary tract impairment unrelated (before) the spinal cord lesion5\*\*\*:

Yes (specify below)

No

Unknown

If yes, specify:

1. Gastrointestinal or anal sphincter dysfunction unrelated (before) the spinal cord lesion6\*\*\*:

Yes (specify below)

No

Unknown

If yes, specify

## General Instructions

Medical History data are collected to verify the inclusion and exclusion criteria (e.g., no history of cognitive disabilities) and to describe the study population. Typically, the Medical History Form captures conditions that have occurred at some point in time within a protocol-defined period (e.g., the last 12 months).

The form should focus on significant medical history of all problems or conditions other than those related to the focus of the study and are presented in the order typically used during a patient visit. If the participant reports more than one medical condition per system, record each condition on a separate line.

Important note: The two Medical History CDEs (either use Medical Condition SNOMED CT Code OR Medical History Term) are considered Core (i.e., strongly recommended for all studies to collect). The remaining data elements are either Supplemental or Exploratory. Supplemental elements should be collected in clinical research only if the research team considers them appropriate for their study. The Exploratory elements, indicated by “\*\*\*”, were selected from the ISCoS International SCI Data Sets as cited below.

## Specific Instructions

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

* Date Medical History Taken -- Record the date (and time) the medical history was taken. 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.) and in the format acceptable to the study database.
* Does this participant have…? – Choose one. If this question is answered NO then the rest of the form is blank. If the question is answered YES then the medical history for at least one body system should be recorded.
* Body System – Record the appropriate body system for each line of medical history.
* Condition/Disease - Record one Medical History term per line. See the data dictionary for additional information on coding the condition using SNOMED CT. Future revision will include adding ICD-10 or 11 codes. This is considered a Core CDE.
* Start Date –Record the date the medical condition/disease started. 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.) and in the format acceptable to the study database.
* Ongoing? – Check Yes or No to indicate if the medical condition/disease is still present.
* End Date – If the condition is not ongoing, record the date (and time) the medical condition/disease stopped. 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.) and in the format acceptable to the study database.
* Special Note: Questions from the following ISCoS International SCI Data Sets have been included as Exploratory elements on this template CRF:

1 [International SCI Cardiovascular Function Basic Data Set](http://www.iscos.org.uk/international-sci-cardiovascular-function-data-sets) (Version 1.1)

2 [International SCI Pulmonary Function Basic Data Set](http://www.iscos.org.uk/international-sci-pulmonary-function-data-sets) (Version 1.0)

3 [International SCI Endocrine and Metabolic Function Basic Data Set](http://www.iscos.org.uk/international-sci-endocrine-and-metabolic-function-data-sets) (Version 2.0)

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

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

6 [International SCI Bowel Function Basic Data Set](http://www.iscos.org.uk/international-sci-bowel-data-sets) (Version 1.1)

\* Element is classified as Core.

\*\*\*Element is classified as Exploratory.