## Date of data collection:

## Pain Indicator:

1. Have you had any pain during the last seven days including today?

[ ]  No [ ]  Yes

1. If yes how many different pain problems did you have?

[ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 or more

## Pain Interference:

1. In general how much has pain interfered with your day to day activities in the last week?

(No interference) [ ]  0 [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 [ ]  10 (Extreme interference)

1. In general how much has pain interfered with your overall mood in the past week?

(No interference) [ ]  0 [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 [ ]  10 (Extreme interference)

1. In general, how much has pain interefered with your ability to get a good night’s sleep?

(No interference) [ ]  0 [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 [ ]  10 (Extreme interference)

**Please describe separately up to three of your worst pain problems (worst pain problem, 2nd worst pain problem, and 3rd worst pain problem). Complete the following sections separately for each pain problem described above.**

## Pain Location:

Table 1 Pain Location/Sites

| Pain locations /sites (can be more than one, so check all that apply):Right (R), Midline (M), or Left (L) | R | M | L |
| --- | --- | --- | --- |
| **Head** | TBD | TBD | TBD |
| **Neck/shoulders** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| throat | TBD | TBD | TBD |
| neck | TBD | TBD | TBD |
| shoulder | TBD | Intentionally Left Blank | TBD |
| **Arms/hands** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| upper arm | TBD | Intentionally Left Blank | TBD |
| elbow | TBD | Intentionally Left Blank | TBD |
| forearm | TBD | Intentionally Left Blank | TBD |
| wrist | TBD | Intentionally Left Blank | TBD |
| hand/fingers | TBD | Intentionally Left Blank | TBD |
| **Frontal torso/genitals** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| chest | TBD | TBD | TBD |
| abdomen | TBD | TBD | TBD |
| pelvis/genitalia | TBD | TBD | TBD |
| **Back** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| upper back | TBD | TBD | TBD |
| lower back | TBD | TBD | TBD |
| **Buttocks/hips** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| buttocks | TBD | Intentionally Left Blank | TBD |
| hip | TBD | Intentionally Left Blank | TBD |
| anus | Intentionally Left Blank | TBD | Intentionally Left Blank |
| **Upper legs /thighs**  | TBD | Intentionally Left Blank | TBD |
| **Lower legs/feet** | Intentionally Left Blank | Intentionally Left Blank | Intentionally Left Blank |
| knee | TBD | Intentionally Left Blank | TBD |
| shin | TBD | Intentionally Left Blank | TBD |
| calf | TBD | Intentionally Left Blank | TBD |
| ankle | TBD | Intentionally Left Blank | TBD |
| foot/toes | TBD | Intentionally Left Blank | TBD |

## Pain Type (see specific instructions for definitions):

1. Nociceptive

[ ] Musculoskeletal

[ ] Visceral

[ ] Other

1. Neuropathic

[ ] At-level SCI

[ ] Below-level SCI

[ ] Other

[ ] Unknown

## Pain Intensity:

1. Average pain intensity in the last week:

No pain [ ]  0 [ ]  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 [ ]  10 pain as bad as you can imagine

## Date of Onset:

## Pain Treatment:

1. Are you using or receiving any treatment for your pain problems?

[ ]  Yes [ ]  No

## General Instructions

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are Supplemental and should be collected on clinical trials and only 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 which are Supplemental.

* Pain Indicator – Choose one alternative for each question. Pain is defined by the International Association for the Study of Pain (IASP) as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey & Bogduk, 1994). The seven day interval was chosen in order to capture both constant and intermittent chronic pain and for purposes of consistency, e.g., the same time frame in all data sets.
* Pain Interference – Choose one alternative for each question. Please note that all interference items apply to overall pain during the last week, rather than to each of the different pain problems. Please note that "last week" specifically refers to the last seven days including today.
* For each of the 3 worst pain problems please indicate (on separate forms):
* Pain location – Check all that apply for pain location (e.g., Head, throat, neck, shoulder, etc.) and indicate right (R), midline (M), or left (L).
* Pain Type – Check all that apply:

Please note that the pain diagnosis has to be determined by a medical professional using the criteria below:

Musculoskeletal (nociceptive) pain refers to: (1) pain in a region with preserved sensation above, at or below the neurological level of injury (NLI) and (2) pain believed to be originating in musculoskeletal structures. This pain type is indicated by pain with a dull or aching quality, pain initiated or aggravated by movement, tenderness of musculoskeletal structures on palpation, relief in response to anti-inflammatory or opioid medications, or evidence of skeletal pathology on imaging consistent with the pain presentation. Examples include: mechanical pain, spinal fractures, muscular injury, shoulder overuse syndromes and muscle spasm.

Visceral (nociceptive) pain refers to: (1) pain located in the thorax, abdomen or pelvis; and (2) pain believed to originate in visceral structures. This pain type is indicated by dull, tender or cramping pain and related to visceral pathology or dysfunction, such as infection or obstruction, for example, urinary tract infection, ureteric calculus and constipation.

Other (nociceptive) pain refers to nociceptive pains that do not fall into the musculoskeletal or visceral categories directly related or unrelated to SCI, for example, pain associated with ulceration of the skin and headache.

At-level SCI (neuropathic) pain refers to neuropathic pain distributed segmentally due to spinal cord or nerve root damage. At-level neuropathic pain is located unilaterally or bilaterally anywhere within the dermatome of the NLI and three dermatomes below this level. This pain is often perceived as hotburning, tingling, pricking, pins and needles, squeezing, cold, electric or shooting and often associated with allodynia, hypoalgesia or hyperalgesia within the painful area.

Below-level SCI (neuropathic) pain refers to neuropathic pain that is located more than three dermatomes below the NLI and may be perceived up to the NLI. This pain is often perceived as hot-burning, tingling, pricking, pins and needles, squeezing, cold, electric or shooting and often associated with allodynia, hypoalgesia or hyperalgesia within the painful area.

Other (neuropathic) pain refers to neuropathic pains that are located above, at, or below the NLI but are not directly related to the SCI (for example, post-herpetic neuralgia, painful diabetic neuropathy, central post-stroke pain, and compressive mononeuropathies).

Other pain refers to: (1) pain that is unrelated to the SCI and (2) pain without any identifiable noxious stimulus, inflammation or damage to the nervous system, for example, Complex Regional Pain Syndrome type I, interstitial cystitis pain, irritable bowel syndrome pain and fibromyalgia.

Unknown pain refers to pain of unknown etiology.

* Pain Intensity – Choose one alternative.
* Date of pain onset – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times (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.).
* Pain Treatment – Choose one alternative.

Treatment: any prescribed or non-prescribed medical, surgical, psychological, or physical treatment that the patient is using or receiving for pain that has been present the last seven days to alleviate his/her pain/pains. This variable may include chronic and intermittent drug treatment, physical therapy, relaxation training, nerve blocks etc.

* Special Note: Questions from the **ISCoS International SCI Data Sets - International SCI Pain Basic Data Set (Version 2.0)** have been included on this template CRF.

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