## Data Collection

1. \*Date of assessment:  Unknown
2. \*Date of data collection:  Unknown
3. \*If patient/participant enrolled in any previous interventional clinical research studies/trials, enter trial name:
4. \*Data source:

Participant/subject

Spouse

Mother

Father

Sister

Brother

Son

Daughter

\*\*Family, specify relation:

Friend

Physician

Chart/Medical record

\*\*Other, specify

Unknown

## Demographics

1. \*Sex assigned at birth:

Male

Female

Intersex

Unknown

Other, specify

1. \*Gender identity:

Male

Female

Unknown

Other, specify

1. \*Date of birth:  Unknown

## Adverse Events

1. \*\*Has the participant/subject had any adverse events during the study? Yes  No  Unknown
2. \*\*Investigator Assessment of Causality:

Unrelated  Unlikely  Reasonable Possibility  Definite  Unknown

1. \*\*Adverse event(s):  Unknown
2. \*\*Describe event or problem:  Unknown
3. \*\*Serious Adverse Event?  Yes  No  Unknown

## Medical History

1. \*Neurological disorder: Yes No  Unknown
   1. \*Medical history condition start date and time:  Unknown
2. \*\*Hypertension: Yes No Unknown Suspected
3. \*\*Diabetes:  Yes  No  Unknown
4. \*\*Sleep problem diagnosis:
5. \*\*Arthritis: Yes No  Unknown

## Ambulation and Falls

1. \*Ambulatory status:

Able to ambulate independently (no help from another person) w/ or w/o device

With assistance (from person)

Unable to ambulate

Unknown

1. **\*\***Falls:  Daily  Weekly  Occasionally  Rarely  Unknown

## Pain

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 |
| Unknown | TBD | Intentionally Left Blank | TBD |

1. \*\*0-10 Numeric Pain Rating Scale:

0  1  2  3  4  5  6  7  8  9  10  Unknown

## Therapy or Rehabilitation

1. \*Type of Therapy or Rehabilitation

Behavior support plan

Developmental Instruction

None

Occupational therapy

Physical therapy

Psychological

Recreational

Respiratory

Social skills training

Speech therapy

Vision

\*\*Other, specify

Unknown

## General Instructions

This case report form (CRF) contains data elements collected to help verify the inclusion and exclusion criteria, ensure the participant receives the appropriate care and describe the study population. This exam is generally administered at screening and/or baseline to determine study eligibility. It may also be administered at follow- up visits to track a participant’s status.

Important note: Data elements included on this CRF Module are considered NeuroRehab Core (i.e., strongly recommended for all NeuroRehab clinical studies to collect) or NeuroRehab Supplemental – Highly Recommended, as indicated by asterisks below. Some of the data elements on this form are known as General Core CDEs and will be collected for every study population.

\*Element is classified as NeuroRehab Core

\*\*Element is classified as NeuroRehab Supplemental – Highly Recommended

## Specific Instructions

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

* Study protocol name – No additional instructions.
* Site name – Enter the name of the study site.
* Subject ID – The participant or subject identifiers or IDs should be assigned by the study.
* Assessment performed date; Data collected date and time – 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.).
* Clinical trial name – No additional instructions.
* Data source – Choose all that apply.
* Sex at birth – Choose one. Response is obtained by report of the participant/subject or caretaker. The assemblage of physical properties or qualities by which male is distinguished from female. Male is a person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. Female is a person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. Intersex is a person (one of unisexual specimens) who is born with genitalia and/or secondary sexual characteristics of indeterminate sex, or which combine features of both sexes. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm)).
* Gender identity – Choose one. Response is obtained by report of the participant/subject or caretaker. Internally held sense of the participant/subject gender which may or may not correspond to the individual’s genotypic or phenotypic sex.
* Date and Time of Birth – 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.) and in the format acceptable to the study database. Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded.
* Adverse Event (AE) During Study – NeuroRehab Supplemental – Highly Recommended for studies where adverse events are a potential concern.
* Investigator Assessment of Causality – NeuroRehab Supplemental – Highly Recommended for studies where adverse events are a potential concern. Choose one. Record the investigator’s assessment as to whether there is at least a reasonable possibility that the AE is related to (or caused by) use of the study intervention. Definitions for each of the relatedness response should be supplied in the protocol.
* Definition of AE – NeuroRehab Supplemental – Highly Recommended for studies where adverse events are a potential concern.
  + Any untoward medical occurrence in a study participant/subject that does not necessarily have a causal relationship with the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study intervention or study procedure, whether related, or not related to the study intervention or procedure. Each AE should be listed on a separate row. Any worsening of a baseline condition or reoccurrence of a baseline condition that had previously ended for a time should be listed as an AE. Events, such as nausea and vomiting are considered two events, and therefore should be listed on separate lines. A participant/subject may experience an unexpected AE (UAE). An unexpected adverse reaction has a nature or severity of which is not consistent with the study intervention description (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). The unexpected AE must be reported, whether related to the study intervention or not, with as much detail as is available. See the Data Dictionary for additional information on coding the adverse events using either the Common Terminology Criteria for Adverse Events (CTCAE) or the Medical Dictionary for Regulatory Activities (MedDRA).
* Event description text – NeuroRehab Supplemental – Highly Recommended for studies where adverse events are a potential concern.
* Serious Adverse Event (SAE) – NeuroRehab Supplemental – Highly Recommended for studies where adverse events are a potential concern.
  + This question should only be answered YES if the outcome of the AE results in at least one of the following: death; a life-threatening adverse drug experience; results in inpatient hospitalization or prolongation of existing hospitalization; a persistent or significant disability/incapacity; or a congenital anomaly/birth defect. If an AE is serious, this provides a trigger that additional information must be provided by the site investigator. The site investigator then completes a SAE form. Additionally, the site institution and/or IRB may also have an SAE form and procedures for reporting SAEs.
  + Serious Adverse Event: An adverse event is defined by the investigator or sponsor as "serious" when it is life-threatening, results in death, requires in-patient hospitalization, prolongs existing hospitalization, results in persistent or significant disability, or is a congenital anomaly/birth defect.
* Neurological disorder indicator – No additional instructions.
* Medical History Condition Start Date and Time – NeuroRehab Specific: Refers to the neurological disorder being studied. 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.).
* Hypertension indicator – In adults, hypertension is defined as a systolic pressure ≥ 140 and a diastolic pressure ≥ 90.
* Diabetes mellitus medical history indicator – No additional instructions.
* Sleep problem diagnosis type – NeuroRehab Supplemental – Highly Recommended for studies where sleep may be relevant to the outcome.
* Arthritis indicator – NeuroRehab Supplemental – Highly Recommended for motor rehabilitation studies.
* Ambulatory status – No additional instructions.
* Balance falls frequency – NeuroRehab Supplemental – Highly Recommended for studies where balance, falls, and ambulation are a focus.
* Pain location anatomic site – NeuroRehab Supplemental – Highly Recommended for studies where pain may be relevant to the outcome. Can be more than one, so check all that apply.
* Pain location laterality – NeuroRehab Supplemental – Highly Recommended for studies where pain may be relevant to the outcome. Can be more than one, so check all that apply.
* Pain present eleven-point intensity scale – NeuroRehab Supplemental – Highly Recommended for studies where pain may be relevant to the outcome.
  + On a scale from 0 to 10, with 0 being no pain and 10 being the worst pain imaginable, how bad is your pain right now?
  + 0 = no pain; 10 = the most intense pain imaginable
  + Please note that if there is more than one pain, this section should be consistent with the International Spinal Cord Injury Pain Basic Data Set and apply to Worst, 2nd Worst and 3rd Worst pains.
* Therapy or rehabilitation type – Choose all that the participant/ subject receives. Response is obtained from report by the participant/subject, a reliable proxy or medical records. Add date stamp for when assessed. Recommend collection at end of initial medical care.
* Data unknown text – Check box for Unknown.