1. \*Gender (Choose one):

[ ]  Male

[ ]  Female

[ ]  Unknown

[ ]  Unspecified

[ ]  Not Reported

1. \*Birth date:

[ ]  Not Available

1. Age (derived value):XX (years)

[ ]  Not Available

1. \*Race category (Choose all that apply):

[ ]  American Indian or Alaska Native

[ ]  Asian

[ ]  Black or African-American

[ ]  Native Hawaiian or Other Pacific Islander

[ ]  White

[ ]  Unknown

[ ]  Not reported

1. \*Ethnicity (“X” ONLY one with which you MOST CLOSELY identify):

[ ]  Hispanic or Latino

[ ]  Not Hispanic or Latino

[ ]  Unknown

[ ]  Not Reported

1. Marital status:

[ ]  Never married

[ ]  Married

[ ]  Domestic partnership

[ ]  Divorced

[ ]  Separated

[ ]  Widowed

[ ]  Unknown

1. How many members are there in your household[[1]](#footnote-1) (including yourself): <enter value here, if known>

[ ] Unknown

1. Area of residence:

[ ]  A big city (population>250,000)

[ ]  A town/small city (population 10,000-250,000)

[ ]  A small town/village (500-10,000)

[ ]  Rural area (population<500)

[ ]  Unknown

1. \*\*Number of years of education:

[ ] Unknown

1. Primary occupation *(Choose one)*:

[ ]  Paid work (employed/self-employed, including military)

[ ]  Homemaker

[ ]  Student (including on the job training)

[ ]  Retired (disability pension)

[ ]  Retired (non-disability)

[ ]  Unpaid work (volunteer)

[ ]  Unemployed (none of the above)

[ ]  Other, Specify

[ ]  Unknown

1. Secondary occupation (Choose all that apply):

[ ]  N/A

[ ]  Paid work (employed/self-employed, including military)

[ ]  Homemaker

[ ]  Student (including on the job training)

[ ]  Retired (disability pension)

[ ]  Retired (non-disability)

[ ]  Unpaid work (volunteer)

[ ]  Unemployed (none of the above)

[ ]  Other, Specify

[ ]  Unknown

1. Type of occupation (Paid employment):

[ ]  N/A

[ ]  Managers and officials

[ ]  Professionals

[ ]  Technicians and associate professionals (typically requiring a Bachelor degree or equivalent)

[ ]  Clerical support workers (secretary, clerk, office manager, book keeper)

[ ]  Service and sales workers (waiters, caretaker, shop assistants, insurance agents, sales manager)

[ ]  Skilled agricultural, forestry and fishery workers

[ ]  Craft and related trades workers (e.g. motor mechanic, printer, tool and die maker, electrician)

[ ]  Plant and machine operators and assemblers

[ ]  Elementary occupations (labourer, porter, unskilled workers)

[ ]  Armed forces occupation (officers, service personnel)

[ ]  Other, specify

[ ]  Unknown

1. \*\*\*Are you a citizen of (country)?

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Birth country name through corresponding [ISO 3166 1 alpha 2 code](http://www.iso.org/iso/country_codes)

[ ]  Unknown

1. \*\*\*Household income range (applicable for participants in the USA)

[ ]  Under $15,000

[ ]  $15,000 to $24,999

[ ]  $25,000 to $34,999

[ ]  $35,000 to $49,999

[ ]  $50,000 to $74,999

[ ]  $75,000 to $99,999

[ ]  $100,000 and over

[ ]  Refused to answer

[ ]  Unknown

1. \*\*\*How well do you manage with your current household income?

[ ]  Very well

[ ]  Rather well

[ ]  Adequately (neither well nor poorly)

[ ]  Rather poorly

[ ]  Very poorly

[ ]  Refused to answer

[ ]  Unknown

[ ]  Not Applicable

**Additional Pediatric-specific Elements**

These elements are recommended for pediatric studies.

1. Genotypic sex (Choose one):

[ ]  XX

[ ]  XY

[ ]  XXX

[ ]  XXY

[ ]  XYY

[ ]  Unspecified

[ ]  Unknown

[ ]  Other, specify

1. \*Age (years):

If less than 3 years of age (in months):

1. \*\*Level of education

What is the highest grade or level of school the participant/subject has completed or the highest degree obtained? (Choose one):

[ ]  Never attended/ Kindergarten only

[ ]  1st Grade

[ ]  2nd Grade

[ ]  3rd Grade

[ ]  4th Grade

[ ]  5th Grade

[ ]  6th Grade

[ ]  7th Grade

[ ]  8th Grade

[ ]  9th Grade

[ ]  10th Grade

[ ]  11th Grade

[ ]  12th Grade, no diploma

[ ]  High school graduate

[ ]  GED or equivalent

[ ]  Some college, no degree

[ ]  Associate degree: occupational, technical, or vocational program

[ ]  Associate degree: academic program

[ ]  Bachelor's degree (e.g., BA, AB, BS, BBA)

[ ]  Master's degree (e.g., MA, MS, MEng, MEd, MBA)

[ ]  Professional school degree (e.g., MD, DDS, DVM, JD)

[ ]  Doctoral degree (e.g., PhD, EdD)

[ ]  Unknown

1. Participant/subject school status

[ ]  Going to school

[ ]  On vacation from school (between grades)

[ ]  Neither

[ ]  Unknown

1. Pre-injury hand preference: (Hand participant/subject used predominantly, not necessarily he/she wrote with exclusively)

[ ]  Left hand

[ ]  Right hand

[ ]  Both hands

[ ]  Unknown

1. Current hand preference: (Hand participant/subject uses predominantly, not necessarily he/she writes with exclusively)

[ ]  Left hand

[ ]  Right hand

[ ]  Both hands

[ ]  Unknown

1. Birthplace (state, include country if outside of US):

State:

Country:

1. Primary language (ISO 639-2 code)

[ ]  English (eng) [ ]  French (fre)

[ ]  Spanish (spa) [ ]  German (ger)

[ ]  Sign Languages (sgn) [ ]  Other, specify ISO 639-2 code:

[ ]  Chinese languages (chi)

1. \*\*Primary caregiver’s[[2]](#footnote-2) level of education:

What is the highest grade or level of school the participant’s/subject’s primary caregiver has completed or the highest degree obtained? (Choose one):

[ ] Never attended/ Kindergarten only

[ ]  1st Grade

[ ]  2nd Grade

[ ]  3rd Grade

[ ]  4th Grade

[ ]  5th Grade

[ ]  6th Grade

[ ]  7th Grade

[ ]  8th Grade

[ ]  9th Grade

[ ]  10th Grade

[ ]  11th Grade

[ ]  12th Grade, no diploma

[ ]  High school graduate

[ ]  GED or equivalent

[ ]  Some college, no degree

[ ]  Associate degree: occupational, technical, or vocational program

[ ]  Associate degree: academic program

[ ]  Bachelor's degree (e.g., BA, AB, BS, BBA)

[ ]  Master's degree (e.g., MA, MS, MEng, MEd, MBA)

[ ]  Professional school degree (e.g., MD, DDS, DVM, JD)

[ ]  Doctoral degree (e.g., PhD, EdD)

[ ]  Unknown

1. Caregiver marital status (choose one):

[ ]  Never married

[ ]  Married

[ ]  Domestic partnership

[ ]  Divorced

[ ]  Separated

[ ]  Widowed

[ ]  Unknown

**General Instructions**

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables. All elements on this form are classified as Supplemental (unless otherwise specified) and should only be collected if the research team considers them appropriate for their study.

For pediatric studies, the data elements on this form reflect child, not caregiver, characteristics (unless otherwise specified).

As stated in the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic racial and ethnic categories, which are used below. NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories described below should be used as basic guidance, cognizant of the distinction based on cultural heritage. ([NIH Guideline on the Inclusion of Women and Minorities as Subjects in Clinical Research](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm))

Responses to categories are obtained from self-report when possible.

Birthplace – Record the state of birth. Include country if outside of the US. For country name, Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes.

Language spoken fluently text and corresponding ISO 639-2 code

Language written fluently text and corresponding ISO 639-2 code

**Specific Instructions**

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

Responses to the demographic elements should be obtained from self-report when possible.

* Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15
	+ Unspecified is defined as Undifferentiated/Indeterminant/Intersex
* Date of birth – Record the date of birth to the level of precision known
* Ethnicity – Choose only one with which the participant/ subject most closely identifies.
* Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.
* Type of occupation - International Standard Classification of Occupations 08, Major groups

**Reference**

[US Census Bureau](http://www.census.gov/)

\*Element is classified as Core.

\*\*Element is classified as Supplemental – Highly Recommended for studies in the US.

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

1. Household members are members who share in the home’s expenses. This is not related to those living in group homes, extended care or assisted-living facilities. [↑](#footnote-ref-1)
2. A primary caregiver or carer is the main person who helps a young person with spinal cord injury with his or her physical and/or emotional needs. In many cases this may be a parent, but in others it may be an extended family member or close friend. [↑](#footnote-ref-2)