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)