**[\*](#Core" \o "Element classified as Core)**Date Medical History Taken:

Does the participant/subject have a history of any medical problems/conditions in the following body systems[\*](#Core)?

Yes  No (leave rest of form blank)

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.

\*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
* Hepatobiliary

Table 1. Medical history data collection grid—example

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Body System\* | Medical History Term\*(one item per line) | Start Date\*(mm/dd/yyyy) | Ongoing\*? | End Date\*(mm/dd/yyyy) |
| Cardiovascular | Example: Hypertension | 03**/**31**/**2009 | YesNo |  |

Table 2. Medical history data collection grid

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Body System**[\*](#Core) | Medical History Term[**\***](#Core)(one item per line) | Start Date[**\***](#Core)(mm/dd/yyyy) | Ongoing?[\*](#Core) | End Date[**\***](#Core)(mm/dd/yyyy) |
|  |  |  | YesNo |  |
|  |  |  | YesNo |  |
|  |  |  | YesNo |  |
|  |  |  | YesNo |  |
|  |  |  | YesNo |  |

\*Element is classified as Core

**The following interview questions can be used to help make sure a complete medical history is documented:**

1. eyes
   1. Is vision affected? Yes  No  Unknown
   2. Strabismus Yes  No  Unknown
   3. Retinopathy of prematurity Yes  No  Unknown
   4. High myopia Yes  No  Unknown
   5. Optic atrophy Yes  No  Unknown
   6. Cerebral visual impairment Yes  No  Unknown
   7. Visual field deficits Yes  No  Unknown
2. Ears, Nose, Mouth, Throat
   1. Is hearing affected Yes  No  Unknown
      1. Conductive impairment Yes  No  Unknown
      2. Sensori-neural impairment Yes  No  Unknown
   2. Is speech affected? Yes  No  Unknown
   3. Dysphagia indicator Yes  No  Unknown
   4. Recurrent ear infections Yes  No  Unknown
3. Cardiovascular History:
   1. Cardiac condition: Yes  No  Unknown
   2. Arrhythmia: Yes  No  Unknown
      1. Atrial fibrillation Yes  No  Unknown
      2. Atrial flutter Yes  No  Unknown
      3. Supraventricular tachycardia Yes  No  Unknown
      4. Ventricular tachycardia Yes  No  Unknown
      5. Bradycardia Yes  No  Unknown
      6. Other, specify
   3. Heart failure: Yes  No  Unknown
   4. Ischemia heart disease: Yes  No  Unknown
   5. Abnormal echocardiogram: Yes  No  Unknown
      1. LVH: Yes  No  Unknown
      2. Decreased LV function: Yes  No  Unknown
      3. Other, specify:
   6. Cardiac surgery/mechanical intervention: Yes  No  Unknown
      1. If Yes, indicate type (Choose all that apply):

Coronary artery bypass graft (CABG)

Cardiac valve surgery, including non-open surgery (i.e., percutaneous valvuloplasty)

Pacemaker

Implantable cardic defibrillator

Other, specify:

* + 1. Date of most recent surgery (mm/dd/yyyy):
  1. Congenital heart disease: Yes  No  Unknown

1. RESPIRATORY
   1. Respiratory support/ ventilation assist Yes  No
      1. If yes, indicate type:

CPAP/BiPAP  Oxygen at home Percussion vest  Other, specify

* 1. Pulmonary aspiration diagnosis indicator Yes  No  Unknown
  2. Respiratory distress syndrome Yes  No  Unknown
  3. Bronchopulmonary dysplasia Yes  No  Unknown
  4. Recurrent pneumonia Yes  No  Unknown
  5. Bronchiectasis Yes  No  Unknown
  6. Restrictive airway disease Yes  No  Unknown
  7. Tracheomalacia Yes  No  Unknown
  8. Laryngomalacia Yes  No  Unknown
  9. Pneumonnia/Respiratory infections in the

last 12 months Yes  No  Unknown

1. Gastrointestinal
   1. Nutritional supplements Yes  No  Unknown
      1. If yes, indicate type
      2. Gastronomy tube Yes  No  Unknown
   2. Fecal incontinence past three month average frequency

Never; Not applicable  Less than once per month

Not every day, but at least once per week  Not every week, but at lease once per month

Once every month  One episode per day  Two or more episodes per day

Unknown

c. Gastroesophageal reflux disease (GERD) Yes  No  Unknown

d. Delayed gastric emptying Yes  No  Unknown

e. Chronic constipation Yes  No  Unknown

f. Oropharyngeal dysphagia Yes  No  Unknown

g. Sialorrhea (drooling) Yes  No  Unknown

1. genitourinary
   1. Urinary incontinence past three months frequency Yes  No  Unknown
   2. Neurogenic detrusor, detrusor sphincter dysserngia Yes  No  Unknown
   3. Recurrent urinary tract infections Yes  No  Unknown
   4. Pregnant ever (female participants) Yes  No  Unknown
   5. Sexual dysfunction indicator Yes  No  Unknown
2. musculoskeletal history:
   1. Scoliosis Yes  No  Unknown
      1. Scoliosis maximum spine curvature measurement:
   2. Developmental hip dysplasia Yes  No  Unknown
   3. Prior traumatic event Yes  No  Unknown
      1. Prior traumatic injury type: Brain injury  Spinal injury  Other Extracranial injury
3. NEUROLOGICAL HISTORY:
   1. Seizures/epilepsy Yes  No  Unknown
      1. Seizure diagnosis method type Clinical manifestations  EEG  Unknown
      2. Seizure classification type Generalized  Focal  Unknown
      3. Epilepsy type Medically intractable Well controlled
      4. Seizure generalized classification type

Tonic clonic Absence Typical Atypical Myoclonic absence Eyelid myoclonia

Myoclonic Myoclonic atonic Myoclonic tonic Clonic Tonic Atonic

* + 1. Seizure focal classification type

Without impairment of consciousness or responsiveness  With observable motor or autonomic components  Involving subjective sensory or psychic phenomena only With impairment of consciousness or responsiveness  Evolving to a bilateral, convulsive seizures

* 1. Hypoxic-ischemic encephalopathy Yes  No  Unknown
  2. Presence of cerebral hemorrhages, regardless of size in any region of the brain Yes  No  Unknown
     1. Abnormal sleep EEG Yes  No  Unknown

1. Endocrine History:
   1. Diabetes mellitus (type I or type II)? Yes  No  Unknown

**If Yes:**

* + 1. Indicate type:  Type I  Type II
    2. Indicate age when diabetes was first diagnosed (years):
    3. Indicate the complications of diabetes (Choose all that apply):

Nephropathy  Neuropathy  Retinopathy

Other, specify:  None

* + 1. Indicate the treatments taken for diabetes (Choose all that apply):

Diet Oral medication Insulin None

1. Psychiatric History**:**
   1. Behavior difficulties Yes  No  Unknown
   2. Attention Deficit Hyperactivity Disorder (ADHD) Yes  No  Unknown
   3. Autism Yes  No  Unknown
   4. Obsessive Compulsive Disorder (OCD) Yes  No  Unknown
   5. Oppositional defiance Yes  No  Unknown
   6. Disruptive behavior disorder Yes  No  Unknown
   7. Self-injurious behavior disorder Yes  No  Unknown
   8. Aggressive behavior disorder Yes  No  Unknown
   9. Clinical depression within the past year:  Yes  No  Unknown
      1. Depressive disorder diagnosis:  Yes  No  Unknown
      2. Age at which participant/subject experienced first depressive episode or was first diagnosed with depression, whichever is earlier (years):
   10. Clinical anxiety within the past year:  Yes  No  Unknown
       1. Anxiety disorder diagnosis:  Yes  No  Unknown
   11. Psychotic disorder diagnosis:  Yes  No  Unknown
       1. If Yes, choose all disorders that apply:

Schizophrenia  Bipolar disorder Depression with psychotic features

Dementia with psychotic ideation  Other, specify:

11) Integumentary (skin and/or breast):

i % Body fat:

1. Miscellaneous History:
   * 1. Pain indicator  Yes  No  Unknown
     2. If yes, where:

* 1. Cancer:  Yes  No  Unknown

**If Yes:**

* + 1. Type of cancer diagnosed with:
    2. Treated with head or neck radiation? Yes No/Not documented Unknown
  1. Genetic diagnoses established Yes  No Unknown
     1. Genetic disorder type
     2. No known single gene disorder  Medelian  Mitochondrial Other, specify

Genetic diagnosis point mutation result?

* + 1. Genetic diagnosis confirmation type Participant/subject report  Medical record

Commerical testing  Research testing

* 1. Medical/developmental checkups at recommended intervals  Yes  No  Unknown
  2. Difficulty scheduling/attending healthcare appointments  Yes  No  Unknown

# GENERAL INSTRUCTIONS

Medical history data are collected to help verify the inclusion and exclusion criteria (e.g., no history of cognitive disabilities), ensure the participant/ subject receives the appropriate care and describe the study population. Typically, the Medical History CRF captures conditions that EVER occurred at some point in time within a protocol-defined period (e.g., the last 12 months). The General Medical History CRF captures conditions that occurred at some point in time within a protocol defined period as opposed to the Medical History of Friedreich’s Ataxia CRF which captures conditions specifically related to Cerebral Palsy.

# SPECIFIC INSTRUCTIONS

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

The majority of the data elements on the CRF have the following instructions:

When asking participant/ subject use the following: Has a doctor or other medical professional ever told you that you have/ have had a(n)\_\_\_\_\_\_\_\_? History can also be obtained from a family member, friend, or chart/ medical record. If the informant is unable to answer the question or is deemed unreliable (e.g., the participant/ subject has dementia) the history should be obtained from the medical record.

Additional instructions for the elements are already included on the CRF.

Percent body fat calculations: Slaughter equations based on the triceps and subscapular skinfolds can be adapted for CP. See Table II, Original Slaugter equations and corrections for children with cerebral palsy, in Gurka MJ, Kuperminc MN, Busby MG, Bennis JA, Grossberg RI, Houlihan CM, et al. Assessment and correction of skinfold thickness equations in estimating body fat in children with cerebral palsy. Dev Med Child Neurol. 2010;52(2):e35–e41 for equations and corrections.Surgical and hospitalization history available on separate CRF.

\*Element is classified as Core.