**[\*](#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 | [x] Yes[ ] No |  |

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) |
|  |  |  | [ ] Yes[ ] No |  |
|  |  |  | [ ] Yes[ ] No |  |
|  |  |  | [ ] Yes[ ] No |  |
|  |  |  | [ ] Yes[ ] No |  |
|  |  |  | [ ] Yes[ ] No |  |

\*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.