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

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

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

Medical history data collection grid—Example

| \*Body System | **\*Medical History Term** (one item per line) | **\*Start Date** (m m/d d/y y y y) | \*Ongoing? | **\*End Date** (m m/d d/y y y y) |
| --- | --- | --- | --- | --- |
| Cardiovascular | Example: Hypertension | Example: 03/31/2009 | Yes  No |  |

Medical history data collection grid

| \*Body System | **\*Medical History Term** (one item per line) | **\*Start Date** (m m/d d/y y y y) | \*Ongoing? | **\*End Date** (m m/d d/y y y y) |
| --- | --- | --- | --- | --- |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |
| Data to be filled out by site | Data to be filled out by site | Data to be filled out by site | Yes  No | Data to be filled out by site |

\*Element is classified as Core

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

1. Cardiovascular History:
   1. Cardiac condition:

Yes

No

Unknown

* 1. Arrhythmia:

Yes

No

Unknown

* + 1. Atrial fibrillation:

Yes

No

Unknown

* + 1. Atrial flutter:

Yes

No

Unknown

* + 1. Supraventricular tachycardia:

Yes

No

Unknown

* + 1. Ventricular tachycardia:

Yes

No

Unknown

* + 1. Bradycardia:

Yes

No

Unknown

* + 1. Other, specify:
  1. Heart failure:

Yes

No

Unknown

* 1. Ischemia heart disease:

Yes

No

Unknown

* 1. Abnormal echocardiogram:

Yes

No

Unknown

* + 1. LVH:

Yes

No

Unknown

* + 1. Decreased LV function:

Yes

No

Unknown

* + 1. Other, specify:
  1. 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 (m m/d d/y y y y):
  1. Congenital heart disease:

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

* + 1. Indicate age when diabetes was first diagnosed (years):
    2. 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. Clinical depression within the past year:

Yes

No

Unknown

* + 1. Depressive disorder diagnosis:

Yes

No

Unknown

* + 1. Age at which participant/subject experienced first depressive episode or was first diagnosed with depression, whichever is earlier (years):
  1. Clinical anxiety within the past year:

Yes

No

Unknown

* + 1. Anxiety disorder diagnosis:

Yes

No

Unknown

* 1. 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:

1. Miscellaneous History:
   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

### 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 FA.

### 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.