\*Date Medical History Taken:

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 table:

* 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

\*\*\*Table of subject’s/participant’s medical history items

| Body System | Medical History Term (one item per line) | Start Date  | Ongoing? | End Date  |
| --- | --- | --- | --- | --- |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |
| Data to be entered by site | Data to be entered by site | Data to be entered by site | [ ]  Yes[ ]  No | Data to be entered by site |

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

## Has a doctor or other medical professional ever told you that you have or have had the following?

1. \*Any stroke:

[ ]  Yes

[ ]  No (Skip to 2)

[ ]  Unknown (Skip to 2)

* 1. Ischemic stroke:

[ ]  Yes

[ ]  No (Skip to 1B)

[ ]  Unknown (Skip to 1b)

* + 1. Number of ischemic strokes:

[ ]  None

[ ]  1

[ ]  ≥ 2

[ ]  Unknown

* + 1. Recency of ischemic strokes:

[ ]  < 3 mos ago

[ ]  ≥ 3 mos ago

[ ]  Unknown

* 1. Hemorrhagic stroke:

[ ]  Yes

[ ]  No (Skip to 2)

[ ]  Unknown (Skip to 2)

If YES, indicate type(s):

[ ]  Intracerebral hemorrhage (ICH)

[ ]  Subarachnoid hemorrhage (SAH)

[ ]  Hemorrhage unspecified

[ ]  Unknown

1. \*Unruptured aneurysm:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Dural sinus thrombosis/cerebral venous thrombosis:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*Transient ischemic attack (TIA):

[ ]  Yes

[ ]  No (Skip to 5)

[ ]  Unknown (Skip to 5)

* 1. Number of TIAs:

[ ]  None

[ ]  1

[ ]  2-10

[ ]  >10

[ ]  Unknown

* 1. Recency of TIA:

[ ]  < 24h ago

[ ]  24h - 7d ago

[ ]  7d – 3 mos ago

[ ]  > 3 mos ago

[ ]  Unknown

1. \*\*Arteriovenous malformation (AVM):

[ ]  Yes

[ ]  No

[ ]  Unknown

1. Cavernous malformation:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. Transient monocular blindness:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. Migraine(s):

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, migraine(s) with aura:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Active migrane within last year?

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Carotid stenosis:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Carotid endarterectomy:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate location:

[ ]  Left side

[ ]  Right side

[ ]  Both

[ ]  Unknown

1. \*\*\*Carotid artery stenting:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate location:

[ ]  Left side

[ ]  Right side

[ ]  Both

[ ]  Unknown

## Has a doctor or other medical professional ever told you that you have or have had the following?

1. \*\*\*Seizure episode:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Epilepsy/ Seizure disorder:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Central nervous system infection:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Meningitis

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Dementia:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Current clinical depression:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Depressive disorder diagnosis:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, age experienced first depressive episode/ diagnosed with depression (years):

1. \*\*\*Current clinical anxiety:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Anxiety disorder diagnosis:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Psychotic disorder:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate type(s):

(choose all that apply)

[ ]  Schizophrenia

[ ]  Depression w/ psychotic features

[ ]  Bipolar disorder

[ ]  Dementia with psychotic ideation

[ ]  Other, specify:

1. \*\*\*Head trauma:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate if head trauma resulted in any of the following (choose all that apply):

[ ]  Loss of consciousness > 30 minutes [ ]  Post traumatic amnesia > 24 hours

[ ]  Abnormal brain imaging findings

[ ]  None of the above

1. \*\*\*Neck trauma:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate recency:

[ ] < 8 days before current stroke/TIA

[ ]  8 days- 4 weeks ago

[ ]  > 4 weeks ago

[ ]  Unknown

1. \*\*\*Atrial fibrillation (AF)/ flutter:

[ ]  Yes

[ ]  No (Skip to 27)

[ ]  Unknown (Skip to 27)

1. \*\*\*Other cause of AF:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, specify other cause:

1. \*\*\*Rheumatic heart disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Coronary artery disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

## Has a doctor or other medical professional ever told you that you have or have had the following?

1. \*\*\*Myocardial infarction:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Angina:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Valvular heart disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Cardiac surgery:

[ ]  Yes

[ ]  No (Skip to 33)

[ ]  Unknown (Skip to 29)

* 1. Indicate type(s):

[ ]  Coronary artery bypass graft (CABG)

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

[ ]  Other, specify:

* 1. Date of most recent cardiac surgery:

Artificial valve:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate type:

[ ]  Biological/ Tissue valve

[ ]  Mechanical/ Non-tissue valve

[ ]  Valvuloplast

[ ]  Unknown type of valve

1. \*\*\*Coronary stent or PTCA:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Congestive heart failure:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Congenital heart disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Cardiac catheritization:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate recency:

[ ]  ≤ 2 weeks

[ ]  > 2 weeks ago

[ ]  Unknown

1. \*\*\*Peripheral arterial disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*Aortic or thoracic aneurysm:

[ ]  Yes

[ ]  No

If YES, specify type

1. \*Hypertension:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, age hypertension first diagnosed (years):

1. Average Blood Pressure(if checked before)

[ ]  <120/70 [ ]  >140/<90

[ ]  120-140/70-90 [ ]  >140/ 90

[ ]  <140/>90

1. \*\*\*Past treatment for hypertension:
2. Diabetes mellitus:

[ ]  Yes

[ ]  No (Skip to 43)

[ ]  Unknown (Skip to 37)

* 1. Age diabetes first diagnosed (years):
	2. Complications of diabetes (choose all that apply):

[ ]  Nephropathy

[ ]  Neuropathy

[ ]  Retinopathy

[ ] None of the above

[ ]  Other, specify:

* 1. Treatment for diabetes (choose all that apply):

[ ]  Diet

[ ]  Oral medication

[ ]  Insulin

[ ]  None of the above

## Has a doctor or other medical professional ever told you that you have or have had the following?

1. High blood cholesterol / Hypercholesterolemia:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate treatment(s): (choose all that apply)

[ ]  Diet

[ ]  Statins

[ ]  Other medicines

[ ]  None of the above

1. \*\*\*Hypertriglyceridemia:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Cancer:

[ ]  Yes

[ ]  No (Skip to 46)

[ ]  Unknown (Skip to 46)

* 1. Type(s) of cancer:

[ ]  Brain

[ ]  Breast

[ ]  Colorectal

[ ]  Endometrial

[ ]  Esophagus

[ ]  Lung

[ ]  Prostate

[ ]  Renal (kidney)

[ ]  Skin

[ ]  Other, specify:

* 1. Did you receive head or neck radiation to treat the cancer?

[ ]  Yes

[ ]  No

[ ]  Unknown

1. Infection within two weeks:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, indicate type(s) (choose all that apply):

[ ]  Respiratory infection

[ ]  Urinary tract infection (UTI)

[ ]  Cellulitis

[ ]  Sepsis

[ ]  Otitis media

[ ]  Mastoiditis

[ ]  Viral gastroenteritis

[ ]  Fever lasting > 48 hours

[ ]  Other infection, specify:

1. Dental disease:

[ ]  Yes [ ]  Unknown

[ ]  No

If YES, specify type:

1. \*\*\*Sickle cell anemia:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, are blood transfusions used as treatment?

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Hypercoagulable disorder:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, specify type:

1. Bleeding disorder:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, specify type:

1. \*\*\*Lupus:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Other connective tissue disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, specify type:

1. \*\*\*Sleep apnea:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, specify type:

## Has a doctor or other medical professional ever told you that you have or have had the following?

1. Renal (kidney) failure:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Nephrotic syndrome:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Chronic liver failure:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Iron deficiency/ Anemia:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Inflammatory bowel disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Hemorrhoids:

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Moyamoya disease (MMD):

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Down syndrome:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Neurofibromatosis type I (NF1):

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Sturge-Weber syndrome:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Inborn error metabolism:

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Mitochondrial disease:

[ ]  Yes

[ ]  No

[ ]  Unknown

If YES, do you have/ have you had Mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes (MELAS)?

[ ]  Yes

[ ]  No

[ ]  Unknown

1. \*\*\*Hereditary hemorrhagic telangiectasia

[ ]  Yes [ ]  Unknown

[ ]  No

1. Ehlers-Danlos Syndrome Type IV

[ ]  Yes [ ]  Unknown

[ ]  No

1. Marfan syndrome

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Fibromuscular dysplasia

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Coarctation of the aorta

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Alpha1-antitrypsin deficiency

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Pheochromocytoma

[ ]  Yes [ ]  Unknown

[ ]  No

1. \*\*\*Menarche

 Age:

1. \*\*\*Menopause

 Age:

## 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).

Important note: The elements on this CRF are classified as supplemental (should only be collected if the research team considers them appropriate for their study), unless specified by asterisks as indicated below:

\*Element is classified as Core

\*\*Element is classified as Supplemental – Highly Recommended

\*\*\*Element is classified as Exploratory

## Specific Instructions

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

* Date Medical History Taken -- Record the date (and time) the medical history was taken. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Does this participant/subject have…? – Choose one. If this question is answered NO then the rest of the form is blank. If the question is answered YES then the medical history for at least one body system should be recorded.
* Body System – Record the appropriate body system for each line of medical history.
* Condition/Disease - Record one Medical History term per line. See the data dictionary for additional information on coding the condition using SNOMED CT.
* Start Date –Record the date the medical condition/disease started. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Ongoing? – Check Yes or No to indicate if the medical condition/disease is still present.
* End Date – If the condition is not ongoing, record the date (and time) the medical condition/disease stopped. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.