Date Medical History Taken (MM/DD/YYYY):

For women:

\*\*Is the participant/subject pregnant?  Yes  No Unknown

IF YES, specify current state:

Pre-partum 1st trimester

Pre-partum 2nd trimester

Pre-partum 3rd trimester

Active labor

\*\*Is the participant/subject post-partum (up to 12 weeks)?  Yes  No Unknown

IF YES, specify current state:

Postpartum first 24 hrs

Postpartum first week

Postpartum > 1 week

Number of weeks since delivery:

\*\*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 (mm/dd/yyyy) | Ongoing? | End Date (mm/dd/yyyy) |
| --- | --- | --- | --- | --- |
| 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:

1

≥ 2

Unknown

* + 1. Most recent ischemic stroke:

< 3 mos ago

≥ 3 mos ago

Unknown (mos = months)

* 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

\*\*\*Number of hemorrhagic strokes:

1

≥ 2

Unknown

Most recent hemorrhagic stroke:

< 3 mos ago

≥ 3 mos ago

Unknown (mos = months)

1. Transient ischemic attack (TIA):

Yes

No (Skip to 5)

Unknown (Skip to 5)

* 1. Number of TIAs:

1

2-10

>10

Unknown

* 1. Most recent TIA:

< 24 hrs ago

24hrs-7days ago

7days-3mos ago

> 3mos ago

Unknown

1. Transient monocular blindness:

Yes

No

Unknown

1. Unruptured aneurysm:

Yes

No

Unknown

1. Dural sinus thrombosis/cerebral venous thrombosis:

Yes

No

Unknown

1. Arteriovenous malformation (AVM):

Yes

No

Unknown

1. Cavernous malformation:

Yes

No

Unknown

1. Migraine(s):

Yes

No

Unknown

If YES, migraine(s) with aura:

Yes

No

Unknown

\*\*\*If YES, active migraine within last year?

Yes

No

Unknown

1. Carotid stenosis:

Yes

No

Unknown

1. Carotid endarterectomy:

Yes

No

Unknown

If YES, indicate location:

Left side

Right side

Both

Unknown

\*\*\*Date of most recent carotid endarterectomy (MM/DD/YYYY):

1. Carotid artery stenting:

Yes

No

Unknown

If YES, indicate location:

Left side

Right side

Both

Unknown

\*\*\*Date of most recent carotid artery stenting (MM/DD/YYYY):

## 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

No

Unknown

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/panic 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

Psychotic disorder, not otherwise specified

Other, specify:

Unknown

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

Unknown

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

Unknown

1. Rheumatic heart disease:

Yes

No

Unknown

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

Yes

No

Unknown

\*\*\*If YES, specify other cause:

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 32)

Unknown (Skip to 32)

* 1. \*\*\*Indicate type(s):

Coronary artery bypass graft (CABG)

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

Pacemaker

Implantable cardiac defibrillator

Other, specify:

* 1. \*\*\*Date of most recent cardiac surgery (MM/DD/YYYY):

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 catheterization:

Yes

No

Unknown

\*\*\*If YES, indicate recency:

≤ 2 weeks

> 2 weeks ago

30 days or more

Unknown

1. Other cardiac disorders, specify:
2. Peripheral arterial disease:

Yes

No

Unknown

1. Aortic aneurysm:

Yes

No

Unknown

If YES, specify type:

1. Hypertension:

Yes

No

Unknown

If YES, age hypertension first diagnosed (years):

Treatment for hypertension (choose all that apply):

Lifestyle modification only

Oral medication

None

Unknown

1. Orthostatic hypotension:

Yes

No

Unknown

1. Diabetes mellitus:

Yes

No (Skip to 42)

Unknown (Skip to 42)

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

Nephropathy

Neuropathy

Retinopathy

Other, specify:

None of the above

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

Diet

Oral medication

Insulin

None of the above

Unknown

## 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 the apply)

Diet

Statins

Other medicines

None of the above

Unknown

1. Hypertriglyceridemia:

Yes

No

Unknown

1. Cancer:

Yes

No (Skip to 45)

Unknown (Skip to 45)

* 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

Influenza

Zoster/Shingles

Other infection, specify:

1. \*\*\*Periodontal disease:

Yes

No

Unknown

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. Indwelling catheter:

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

No

Unknown

1. Moyamoya Syndrome:

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

No

Unknown

1. Ehlers-Danlos Syndrome Type IV:

Yes

No

Unknown

1. Marfan syndrome:

Yes

No

Unknown

1. Fibromuscular dysplasia:

Yes

No

Unknown

1. Coarctation of the aorta:

Yes

No

Unknown

1. Alpha1-antitrypsin deficiency:

Yes

No

Unknown

1. Pheochromocytoma:

Yes

No

Unknown

1. Other, specify:
2. \*\*\*Are you in menopause?

Yes

No

\*\*\*At what age did you start menopause (if applicable)?

\*\*\*Treatment for menopause:

Hormone therapy

Other, specify:

Unknown

## Additional Pediatric-specific Elements

These elements are recommended for pediatric stroke studies.

1. Acquired heart disease:

Yes

No

Unknown

1. \*\*\*Chickenpox in past 12 months:

Yes

No

Unknown

1. \*\*\*Facial Segmental Hemangioma/PHACE syndrome:

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). Some of the data elements included on this CRF Module are considered Core, Supplemental – Highly Recommended or Exploratory, as indicated by asterisks below:

\* Element is classified as Core

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

\*\*\*Element is classified as Exploratory

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

## 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.
* Pregnancy current state – Answer only if female participant/subject is pregnant.
* In postpartum period current state – Answer only if female participant/subject is in postpartum state.
* 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.

## References

Kamel H, Navi BB, Sriram N, Hovsepian DA, Devereux RB, Elkind MSV. Risk of a thrombotic event after the 6-week postpartum period. New Engl J Med. 2014;370(14):1307-1315.