NINDS Common Data Element (CDE) Project
Stroke Version 2.0 Public Review
Medical History and Prior Health Status Subgroup Materials

Instrument:

- Modified Rankin Scale

Case Report Forms:

- Behavioral History
- Demographics
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- History Data Source and Reliability
- Medical History
- Prior Functional Status
- Prior and Concomitant Medications
- Pregnancy and Perinatal History
- Social Status

NINDS CDE Notice of Copyright
Modified Rankin Scale (mRS)

Availability	The van Swieten mRS scale is in the public domain and a free training program was prepared by Professor KR Lees in association with the Media Services Department of the University of Glasgow to certify physicians, nurses, and first responders on how to use the mRS scale. The program consists of a series of digital video recordings and accompanying written material which includes a self paced Instruction-Demonstration module and the certification modules. However, sponsors and institutions wanting to use this program to document rater competency, interater reliability and educational compliance for their studies, programs and clinical trials must obtain copyright permissions as clinical trials will need additional documentation in order to comply with regulatory requirements. ~~For additional information about the mRS training programs for healthcare professionals and for clinical research teams, visit t~~The Modified Rankin Scale ~~website~~can be found here: Modified Rankin Scale.
Classification	**Supplemental - Highly Recommended**: Unruptured Cerebral Aneurysm and Subarachnoid Hemorrhage (SAH) and Stroke (based on study type, disease stage and disease type) **Exploratory**: Myasthenia Gravis (MG)
Short Description of Instrument	**Purpose:** The modified Rankin Scale (mRS) is a scale commonly used for measuring the degree of disability or dependence in the daily activities of individuals who have suffered a stroke, and it has become the most widely used clinical outcome measure for stroke clinical trials. **Overview:** The mRS was originally introduced in 1957 by Rankin, and first modified to its currently accepted form by Prof. C. Warlow's group at Western General Hospital in Edinburgh for use in the UK-TIA study in the late 1980s. The first publication of the current modified Rankin Scale was in 1988 by van Swieten, et al., who also published the first interobserver agreement analysis of the modified Rankin Scale. **Time:** The assessment requires 5 minutes to complete. **Prestroke Scoring:** On a scale from 0 to 5; Score=6 is not possible as someone would not be in a study if they were dead at presentation. For Score=1, symptoms may refer to those of a prior stroke in patients with a past history of stroke. **Other Important Notes:**

NINDS CDE Notice of Copyright
Modified Rankin Scale (mRS)

	English and eleven different language translations are available. Consider employing a formal scoring system for the mRS such as the Structured Interview for the mRS, or a training program to determine the score that best describes the subject's current state.The mRS is highly reliable at pre-stroke, 30 and 90 days, and upon return to the community, but caution should be exercised when trying to apply it at hospital arrival or discharge. There are currently no published instructions on the use of the mRS to assess initial stroke disability. Raters using this at admission or discharge should develop a standard methodology and scoring instructions for use in hospital setting.
Comments/Special Instructions	Decisions about further medical management, the need for PT/OT therapy and the degree of care that a patient requires can be partially informed by the mRS, but final determinations should be made on an individual basis. The mRS is used to evaluate the degree of disability in patients who have suffered a stroke, but individual quality of life and independence are influenced by a wide variety of factors including the presence of comorbidities and socioeconomic status. The use of a structured interview may lead to increased reliability among those conducting assessments using the mRS.
Scoring and Psychometric Properties	**Scoring:** Typical Scoring: On a scale from 0 to 6; 0 indicating 'no symptoms' and 6 indicating 'death'. **Psychometric Properties:** Multiple types of evidence attest to the validity and reliability of the mRS. The reported data support the view that the mRS is a valuable instrument for assessing the impact of new stroke treatments. Inter-observer reliability of the mRS can be improved by using a structured interview, by using structured assessment forms, and by having raters undergo a multimedia training process.
References	Bruno A, Akinwuntan AE, Lin C, Close B, Davis K, Baute V, Aryal T, Brooks D, Hess DC, Switzer JA, Nichols FT. Simplified modified rankin scale questionnaire: reproducibility over the telephone and validation with quality of life. Stroke. 2011;42(8):2276-2279. Bruno A, Shah N, Lin C, Close B, Hess DC, Davis K, Baute V, Switzer JA, Waller JL, Nichols FT. Improving modified Rankin Scale assessment with a simplified questionnaire. Stroke. 2010;41(5):1048–1050.

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Modified Rankin Scale (mRS)

Cheng B, Forkert ND, Zavglia M, Hilgetag CC, Golsari A, Siemonsen S, Fiehler J, Pedraza S, Puig J, Cho T, Alawneh J, Baron J, Ostergaard L, Gerloff C, Thomalla G. Influence of Stroke Infarct Location on Functional Outcome Measured by the Modified Rankin Scale. Stroke;45(6):1695-1702.

Farrell B, Godwin J, Richards S, Warlow C. The United Kingdom transient ischaemic attack (UK-TIA) aspirin trial: final results. J Neurol Neurosurg Psychiatry. 1991;54(12):1044–1054.

Lansberg M, Schrooten M, Bluhmki E, Thijs VN, Saver JL. Treatment Time-Specific Number Needed to Treat Estimates for Tissue Plasminogen Activator Therapy in Acute Stroke Based on Shifts Over the Entire Range of the Modified Rankin Scale. Stroke. 2009; 40(6):2079-2084.

Rankin J. Cerebral vascular accidents in patients over the age of 60. II. Prognosis. Scott Med J. 1957;2(5):200–215.
van Swieten JC, Koudstaal PJ, Visser MC, Schouten HJ, van Gijn J. Interobserver agreement for the assessment of handicap in stroke patients. Stroke. 1988;19(5):604–607.

Uyttenboogaart M, Stewart RE, Vroomen CAJ, De Keyser J, Luijckx G. Optimizing Cutoff Scores for the Barthel Index and Modified Ranking Scale for Defining Outcome in Acute Stroke Trials. Stroke. 2005;36:1984-1987.

Wilson JT, Hareendran A, Hendry A, Potter J, Bone I, Muir KW. Reliability of the modified Rankin Scale across multiple raters: benefits of a structured interview. Stroke. 2005;36(4):777–781.

Behavioral History

[Study Name/ID pre-filled

Site Name:

Subject ID:

**Date behavioral history taken (M M/D D/Y Y Y Y):

SMOKING HISTORY

1) **Current tobacco use? (Regular use of cigarettes, cigars, chewing tobacco or pipes within past year)
   ☐ Yes ☐ Unknown
   ☐ No
2) **Past tobacco use? (Regular use of cigarettes, cigars, chewing tobacco or pipes prior to the past year)
   ☐ Yes ☐ Unknown
   ☐ No
3) Age started tobacco use (years):
   (Skip if Q1 and Q2 are both NO)
4) Age stopped tobacco use (years)
   ☐ N/A – still using tobacco
   (Skip if Q1 and Q2 are both NO)
5) Type(s) of tobacco used (Choose all that apply):
   ☐ Filtered cigarettes (Answer Q6) ☐ Pipes
   ☐ Non-filtered cigarettes (Answer Q6) ☐ Chewing tobacco
   ☐ Low tar cigarettes (Answer Q6) ☐ e-cigarette or vaping products
   ☐ Cigars ☐ Other, specify:
6) Average number of cigarettes smoked per day (Skip if cigarettes is NOT an answer in Q5):
   ☐ Less than one cigarette per day ☐ 2 to 5 cigarettes per day
   ☐ 16 to 25 cigarettes per day (about 1 pack) ☐ More than 35 cigarettes per day (about 2 packs or more)
   ☐ 1 cigarette per day ☐ 6 to 15 cigarettes per day (about ½ pack)
   ☐ 26 to 35 cigarettes per day (about 1 ½ packs) ☐ Unknown
7) **For former or current cigarette smokers only, the number of pack-years of smoking:
   [(average number of cigarettes smoked daily)/20] x (number of years smoked): ____ pack-years
8) Have you ever used an e-cigarette or other electronic vaping product, even just one time, in your entire life?
   ☐Yes
   ☐No
   ☐Don't know/Not sure
   ☐Refused
9) Do you now use e-cigarettes or other electronic vaping products every day, some days, or not at all?
   ☐Every day
   ☐Some days
   ☐Not at all
   ☐Don't know/Not sure
   ☐Refused

ALCOHOL HISTORY

1) Current drinker?
   a. ~~(~~**Consumed at least one drink within past year~~)~~
      ☐ Yes ☐ No

Behavioral History

[Study Name/ID pre-filled

Site Name:

Subject ID:

☐ Unknown

b. **Consumed at least one drink within past 30 days
☐ Yes ☐ Unknown
☐ No

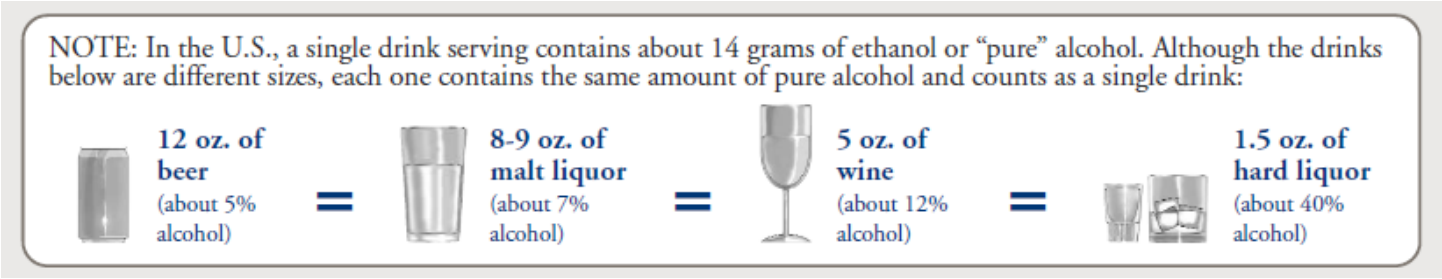
2) **Past drinker? (Consumed at least one drink per month prior to the past year)
☐ Yes ☐ Unknown
☐ No

3) Age started drinking (years):
(Skip if Q1 and Q2 are both NO)

4) Age quit drinking (years):
☐ N/A – still drinking alcohol (Skip if Q1 and Q2 are both NO)

5) **How often do you have a drink containing alcohol?
☐ Never (Skip to 8) ☐ 2 - 3 times/ week
☐ Monthly or less ☐ 4 or more times/ week
☐ 2 - 4 times/ month

Illustration of the level of alcohol in a single drink of beer, malt liquor, wine, and hard liquor



The above graphic was taken from the Alcohol Use Disorders Identification Test (AUDIT) available for free download from NIAAA resources on alcohol consumption and alcohol-related problems.

6) How many alcoholic drinks do you have on a typical day when you are drinking?
☐ 1 or 2 ☐ 7, 8, or 9
☐ 3 or 4 ☐ 10 or more
☐ 5 or 6 ☐ N/A (Don't drink)

7) How often do you have six or more drinks on one occasion?
☐ Never ☐ Weekly
☐ < Monthly ☐ Daily or almost daily
☐ Monthly

8) Have you ever been hospitalized for an alcohol related problem? (e.g., esophageal varices, delirium tremens (DTs), cirrhosis, etc.)
☐ Yes ☐ Unknown
☐ No

Drug History

9) **Current illicit or recreational drug or substance user? (Use of any illicit or recreational drug within the past year)
☐ Yes ☐ Unknown
☐ No
**IF YES, specify type(s) used (select all that apply):

Behavioral History

[Study Name/ID pre-filled

Site Name:

Subject ID:

☐ Sedatives (e.g., sleeping pills, barbiturates, Seconal, Quaaludes, or Chloral Hydrate)
☐ Tranquilizers or anti-anxiety drugs (e.g., Valium®, Librium, muscle relaxants, or Zanax)
☐ Painkillers (e.g., Codeine, Darvon, Percodan, Dilaudid, or Demerol)
☐ Stimulants (e.g., Preludin, Benzedrine, Methadrine, uppers, or speed)
☐ Marijuana, hash, THC, or grass
☐ Cocaine or crack
☐ Hallucinogens (e.g., Ecstasy, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)
☐ Inhalants or Solvents (e.g., amyl nitrate, nitrous oxide, glue, toluene, or gasoline)
☐ Heroin
☐ **Other, specify (e.g., Methadone, Elavil, steroids,Thorazine, or Haldol):

EXERCISE HISTORY

10) Regular aerobic exercise (moderate intensity physical activity, such as brisk walking, bicycling, swimming, or golf)
Moderate-intensity physical activities cause small increases in breathing or heart rate and are done for at least 10 minutes continuously.
☐ Yes
☐ No
☐ Unknown

11) On how many days in a typical week do you do at least moderate-intensity aerobic exercise, such as brisk walking, bicycling, swimming, or golf?

Behavioral History CRF Module Instructions

General Instructions

Some studies may need to collect behavioral history information related to tobacco, alcohol and illicit drug use. It may be appropriate to collect these data elements once (e.g., at baseline) or at multiple time points. The suggested elements may be utilized and/or modified to reflect study requirements and population.

Some of the CDEs are Supplemental- Highly Recommended based on study type, disease stage and disease type as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended

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 behavioral history taken - Record the date (and time) the behavioral 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.
- Current tobacco use - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Past tobacco use - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Age started tobacco use - History can be obtained from participant/ subject, family member, friend, or chart/ medical record.
- Age stopped tobacco use - History can be obtained from participant/ subject, family member, friend, or chart/ medical record.
- Type(s) of tobacco used - Choose all that apply. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Average number of cigarettes smoked per day - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Pack-years of smoking: If participant is a former or current cigarette smoker, [(average number smoked daily)/20] x (number of years smoked) = pack-years
- Current drinker - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Past drinker - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Age started drinking - History can be obtained from participant/ subject, family member, friend, or chart/ medical record.
- Age quit drinking- History can be obtained from participant/ subject, family member, friend, or chart/ medical record.
- How often do you have a drink containing alcohol? - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- How many alcoholic drinks do you have on a typical day when you are drinking?- Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- How often do you have six or more drinks on one occasion? - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.
- Regular aerobic exercise (moderate intensity physical activity) - Moderate-intensity physical activities cause small increases in breathing or heart rate and is done for at least 10 minutes continuously.

Behavioral History CRF Module Instructions

- Have you ever been hospitalized for an alcohol related problem? - Choose one. Response is obtained from participant/ subject, family member, friend, or chart/ medical record.

REFERENCES

Centers for Disease Control and Prevention (CDC). *Behavioral Risk Factor Surveillance System Survey Questionnaire*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, **2018**.

Adapted from: Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Questionnaire (or Examination Protocol, or Laboratory Protocol). Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2017 https://wwwn.cdc.gov/nchs/data/nhanes/2017-2018/questionnaires/PAQ_J.pdf.

Demographics

[Study Name/ID pre-filled

Site Name:

Subject ID:

1) *Sex assigned at birth:
   - ☐ Female
   - ☐ Male
   - ☐ Intersex
   - ☐ Unknown
   - ☐ Other, specify:

2) *Gender identity:
   - ☐ Female
   - ☐ Male
   - ☐ Unknown
   - ☐ Other, specify:

   ~~*Gender (Choose one):~~
   - ~~☐ Male~~
   - ~~☐ Female~~
   - ~~☐ Unknown~~
   - ~~☐ Unspecified~~
   - ~~☐ Not reported~~

3) *Date of birth (M M/D D/Y Y Y Y):
4) *Ethnicity (Choose one with which you MOST CLOSELY identify):
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino
   - ☐ Unknown
   - ☐ Not Reported
5) ***Ethnicity pertinent to intracranial aneurysm
   - ☐ Japanese
   - ☐ Finnish
   - ☐ Eastern Asian
   - ☐ European
   - ☐ Persian
   - ☐ Arabic
   - ☐ Southeast Asian
   - ☐ South Asian
   - ☐ Pacific Islander
   - ☐ American Indian
6) *Race (Choose all those with which you identify):
   - ☐ American Indian or Alaska Native
   - ☐ Asian
   - ☐ Black or African-American
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ White
   - ☐ Unknown
   - ☐ Not reported
7) *** Race expanded category:
   - ☐ Black African American
   - ☐ Black Afro-Caribbean
   - ☐ North American Indian
   - ☐ Inuit
   - ☐ Far Eastern Asian
   - ☐ Black African
   - ☐ South/Central American Indian
   - ☐ Alaskan Native
   - ☐ South Asian
   - ☐ Western Asian
8) Language(s) fluently fluent (Choose all that apply):
   - ☐ English (eng)
   - ☐ Spanish (spa)
   - ☐ American Sign Language (sgn)
   - ☐ Chinese languages (Chi)
   - ☐ French/ Creole (cpf)
   - ☐ German (ger)
   - ☐ Other, specify:

   Country of residence:
   - ☐ USA (US)
   - ☐ Canada (CA)
   - ☐ United Kingdom (GB)
   - ☐ Mexico (MX)
   - ☐ Australia (AU)
   - ☐ China (CN)
   - ☐ India (IN)
   - ☐ Japan (JP)

Demographics

[Study Name/ID pre-filled

Site Name:

Subject ID:

- ☐ Germany (DE)
- ☐ France (FR)
- ☐ Other European
- ☐ Russia (RU)
- ☐ Other Asian
- ☐ Finland (FI)
- ☐ Other, specify:

9) First 3 digits of zip code:
10) Social security number:

ADDITIONAL PEDIATRIC-SPECIFIC ELEMENTS

These elements are recommended for pediatric stroke studies.

11) Maternal ethnicity (Choose one with which the mother MOST CLOSELY identifies):
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown
- ☐ Not Reported

12) Maternal race (Choose all those with which the mother identifies):
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Unknown
- ☐ Not reported

13) *** Maternal race expanded category:
- ☐ Black African American
- ☐ Black Afro-Caribbean
- ☐ North American Indian
- ☐ Inuit
- ☐ Far Eastern Asian
- ☐ Black African
- ☐ South/Central American Indian
- ☐ Alaskan Native
- ☐ South Asian
- ☐ Western Asian

14) Paternal ethnicity (Choose one with which the father MOST CLOSELY identifies):
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown
- ☐ Not Reported

15) Paternal race (Choose all those with which the father identifies):
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Unknown
- ☐ Not reported

16) *** Paternal race expanded category:
- ☐ Black African American
- ☐ Black Afro-Caribbean
- ☐ North American Indian
- ☐ Inuit
- ☐ Far Eastern Asian
- ☐ Black African
- ☐ South/Central American Indian
- ☐ Alaskan Native
- ☐ South Asian
- ☐ Western Asian

~~*Element is classified as Core~~

~~GENERAL INSTRUCTIONS~~

~~This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.~~

Demographics

[Study Name/ID pre-filled

Site Name:

Subject ID:

~~The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (NIH Guideline on The Inclusion of Women and Minorities as Subjects in Clinical Research) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as supplemental if a study requires that level of detail, otherwise the NIH standard should be used as the minimum standard.~~

~~Important note: The data elements noted with an asterisk on this CRF Module are classified as Core (i.e., required for all ALS studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.~~

~~SPECIFIC INSTRUCTIONS~~

- ~~Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically.~~
    - ~~Unspecified is defined as Undifferentiated/Indeterminant/Intersex~~
- ~~Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.~~
- ~~Ethnicity – Choose only one with which the participant/ subject most closely identifies.~~
- ~~Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.~~

Demographics CRF Module Instructions

General Instructions

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (NIH Guideline on The Inclusion of Women and Minorities) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as basic guidance, cognizant of the distinction based on cultural heritage.

Important note: ~~Four~~ Some of the data elements included on this CRF Module are considered Core (i.e., strongly recommended for all stroke clinical studies to collect) or Exploratory, as indicated by asterisks below.

*Element is classified as Core

***Element is classified as Exploratory

The remaining data elements (i.e., non Core) 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.

Responses to the demographic elements should be obtained from self-report when possible.

- ~~Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 (Click here for the NIH Guideline on The Inclusion of Women and Minorities)~~
    - ~~o – Unspecified is defined as Undifferentiated/Indeterminant/Intersex~~
- Birth sex: Self-reported sex at birth of the participant/subject. The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female.
- Gender ID type: Self-reported participant's/subject's internally held sense of their gender, which may or may not correspond to the individual's genotypic or phenotypic sex.
- Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
- Ethnicity – Choose only one with which the participant/subject most closely identifies.
- Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.
  The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic

Demographics CRF Module Instructions

categories. (Click here for the NIH Guideline on The Inclusion of Women and Minorities). Collection of Race and Ethnicity Data in Clinical Trials (FDA, ~~September 2005~~ October 2016 - Click here for FDA Guidance for Race and Ethnicity)

- Language(s) fully fluent – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
- Country of residence – Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes.
- First 3 digits of zip code – This is an optional field, if this information is not provided enter 000.
- Social security number – Providing this information is entirely voluntary and the participant/ subject may refuse. This information must be kept confidential according to the Privacy Act of 1974, and must only be used for research purposes.
- Maternal ethnicity – Choose only one with which the mother most closely identifies. This element is recommended for pediatric stroke studies.
- Maternal race – Choose all those with which the mother identifies. This element is recommended for pediatric stroke studies.
- Paternal ethnicity – Choose only one with which the father most closely identifies. This element is recommended for pediatric stroke studies.
- Paternal race – Choose all those with which the father identifies. This element is recommended for pediatric stroke studies.

Family History

[Study Name/ID pre-filled]

Site Name:

Subject ID:

*Date family history taken (M M/D D/Y Y Y Y):

HAS A DOCTOR OR OTHER MEDICAL PROFESSIONAL EVER TOLD AN IMMEDIATE FAMILY MEMBER (I.E., PARENT, SIBLING, CHILD) THAT HE/SHE HAS OR HAS HAD THE FOLLOWING?

- ☐ *Stroke
  Youngest age immediate family member suffered a stroke (years):
- ☐ *Ischemic stroke
- ☐ *Hemorrhagic stroke
- ☐ Subarachnoid hemorrhage (SAH)
  ***If YES, please indicate relationship to patient (i.e grandparents, parents, siblings, children, or other member):
- ☐ Brain aneurysm
  ***If YES, please indicate relationship to patient (i.e grandparents, parents, siblings, children, or other member):
- ☐ Migraines
- ☐ **Coronary artery disease (e.g., heart attack)
  If YES, youngest age immediate family member was diagnosed with condition suffered a heart attack (years):
- ☐ Epilepsy
- ☐ Dementia
- ☐ ***Abdominal aortic aneurysm
- ☐ Psychiatric illness
- ☐ Multiple miscarriages
- ☐ Bleeding disorder (e.g., hemophilia)
- ☐ Clotting disorder (e.g., thrombophilia)
- ☐ Sudden deaths of unknown etiology
- ☐ Intracranial vascular malformations
- ☐ Hereditary Hemorrhagic Telangiectasia (HHT)
- ☐ ***Polycystic kidney disease
- ☐ ***Multiple endocrine neoplasia type I
- ☐ ***Ehlers-Danlos Syndrome Type IV
- ☐ ***Marfan Syndrome
- ☐ ***Neurofibromatosis type I (NF1)
- ☐ Arterial dissection
- ☐ Mitochondrial disorders
- ☐ ***Other, specify:

Family History CRF Module Instructions

General Instructions

Family history data are collected to determine if stroke or other related diseases/disorders run in the participant's/ subject's immediate family.

Important note: Some~~Three~~ of the data elements included on this CRF Module are considered Core (i.e., strongly recommended for all stroke clinical studies to collect), Supplemental – Highly Recommended, or Exploratory as indicated by the asterisks below.

*Element is classified as Core
**Element is classified as Supplemental – Highly Recommended
***Element is classified as Exploratory

The remaining data elements (i.e., non Core) 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.
The majority of the data elements on the CRF have the following instructions:
History can be obtained from participant/ subject, family member, friend, or chart/ medical record.
There are no other specific instructions for the data elements not already included on the CRF.
~~*Element is classified as Core~~

History Data Source and Reliability

[Study Name/ID pre-filled]

Site Name:

Subject ID:

1. From whom/ what were the medical history data obtained? (Choose all that apply.)

   ☐ Participant/ subject ~~(Skip 63)~~
   ☐ Spouse
   ☐ Mother
   ☐ Father
   ☐ Sister
   ☐ Brother
   ☐ Son
   ☐ Daughter
   ☐ ~~Family, specify relation:~~
   ☐ Friend
   ☐ Physician
   ☐ Chart/Medical record
   ☐ Unknown
   ☐ Other, specify:

2. If the medical history data were NOT obtained from the participant/ subject, indicate the reason(s) why: (Choose all that apply. All permissible values describe the participant/ subject.)

   ☐ Dementia
   ☐ Other cognitive impairment
   ☐ Poor historian
   ☐ Participant/subject too young
   ☐ Aphasia
   ☐ Not fluent in examiner's language
   ☐ Other, specify:

3. Overall assessment of the reliability of the medical history data obtained:

   ☐ Definitely reliable ☐ Probably reliable ☐ Not reliable

History Data Source and Reliability CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to the data source and reliability of the responses and should be used to collect history data source information for each of the relevant study CRFs.

None of the data elements included on this CRF Module is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Rather, all of the data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific ~~Instructions~~ Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module. The CRF includes all instructions available for the data elements at this time.

Medical History

Date Medical History Taken (M M/D D/Y Y Y Y):

For women:
**Is the participant/subject pregnant? ☐ Yes ☐ No ☐Unknown

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

Medical History

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

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?

☐ Any stroke

☐ Ischemic stroke

Number of ischemic strokes:

- ~~☐ None~~
- ☐ 1
- ☐ ≥ 2
- ☐ Unknown

Most recent ~~Recency of~~ ischemic stroke~~s~~:

- ☐ < 3 mos ago
- ☐ ≥ 3 mos ago
- ☐ Unknown (mos = months)

☐ Hemorrhagic stroke:

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)

☐ Unruptured aneurysm

☐ Dural sinus thrombosis/cerebral venous thrombosis

☐ Transient ischemic attack (TIA)

Number of TIAs:

- ~~☐ None~~
- ☐ 1
- ☐ 2-10
- ☐ >10
- ☐ Unknown

Medical History

~~Recency of~~ Most recent TIA:

- ☐ < 24 hrs ago
- ☐ 24hrs-7dys ago
- ☐ 7days-3mos ago
- ☐ > 3mos ago
- ☐ Unknown

☐ Arteriovenous malformation (AVM)

☐ Cavernous malformation

☐ Transient monocular blindness

☐ Migraine(s)

If YES, migraine(s) with aura

- ☐ Yes
- ☐ No
- ☐ Unknown

***Active migraine within last year?

- ☐ Yes
- ☐ No
- ☐ Unknown

☐ Carotid endarterectomy

If YES, indicate location:

- ☐ Left side
- ☐ Right side
- ☐ Both
- ☐ Unknown

***Date of most recent carotid endarterectomy (M M/D D/Y Y Y Y):

☐ Carotid artery stenting

If YES, indicate location:

- ☐ Left side
- ☐ Right side
- ☐ Both
- ☐ Unknown

***Date of most recent carotid artery stenting (M M/D D/Y Y Y Y):

☐ Seizure episode

☐ Epilepsy/ Seizure disorder

☐ Central nervous system infection

☐ Meningitis

☐ Dementia

☐ Current clinical depression

☐ Depressive disorder diagnosis

Medical History

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

☐ Current clinical anxiety

☐ Anxiety/panic disorder diagnosis

☐ Psychotic disorder
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

☐ Head trauma
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

☐ Neck trauma
If YES, indicate recency:
- ☐< 8 days before current stroke/TIA
- ☐ 8 days- 4 weeks ago
- ☐ > 4 weeks ago
- ☐ Unknown

☐ Atrial fibrillation (AF)/ flutter

☐ Rheumatic heart disease

☐ ***Other cause of AF
- ☐ Yes
- ☐ No
- ☐ Unknown

***If YES, specify other cause:

☐ Coronary artery disease

☐ Myocardial infarction

☐ Angina

☐ Valvular heart disease

☐ Cardiac surgery
***Indicate type(s):
- ☐ Coronary artery bypass graft (CABG)

Medical History

- ☐ Cardiac valve surgery, including non-open surgery (i.e., percutaneous valvuloplasty)
- ☐ Other, specify:

***Date of most recent cardiac surgery (M M/D D/Y Y Y Y):

☐ Artificial valve

***If YES, indicate type:

- ☐ Biological/ Tissue valve
- ☐ Mechanical/ Non-tissue valve
- ☐ Valvuloplast
- ☐ Unknown type of valve

☐ Coronary stent or PTCA

☐ Congestive heart failure

☐ Congenital heart disease

☐ Cardiac catheterization

***If YES, indicate recency:

- ☐ ≤ 2 weeks
- ☐ > 2 weeks ago
- ☐ 30 days or more
- ☐ Unknown

☐ Other cardiac disorders, specify:

☐ Peripheral arterial disease

☐ Aortic aneurysm

If YES, specify type

☐ Hypertension

If YES, age hypertension first diagnosed (years):

Treatment for hypertension (choose all that apply):

- ☐ Lifestyle modification only
- ☐ Oral medication
- ☐ None
- ☐ Unknown

☐ Orthostatic hypotension

☐ Diabetes mellitus

Age diabetes first diagnosed (years):

Complications of diabetes (choose all that apply):

- ☐ Nephropathy
- ☐ Neuropathy
- ☐ Retinopathy
- ☐ Other, specify:
- ☐ None of the above

Treatment for diabetes (choose all that apply):

- ☐ Diet
- ☐ Oral medication

Medical History

- ☐ Insulin
- ☐ None of the above
- ☐ Unknown

☐ High blood cholesterol / Hypercholesterolemia

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

- ☐ Diet
- ☐ Statins
- ☐ Other medicines
- ☐ None of the above
- ☐ Unknown

☐ Hypertriglyceridemia

☐ Cancer

***Type(s) of cancer:

- ☐ Brain
- ☐ Breast
- ☐ Colorectal
- ☐ Endometrial
- ☐ Esophagus
- ☐ Lung
- ☐ Prostate
- ☐ Renal (kidney)
- ☐ Skin
- ☐ Other, specify:

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

- ☐ Yes
- ☐ No
- ☐ Unknown

☐ Infection within two weeks

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:

Periodontal disease:

- ☐ Yes
- ☐ No
- ☐ Unknown

☐ Sickle cell anemia

If YES, are blood transfusions used as treatment?

Medical History

- ☐ Yes
- ☐ No
- ☐ Unknown

☐ Hypercoagulable disorder
If YES, specify type:

☐ Bleeding disorder
If YES, specify type:

☐ Lupus

☐ Other connective tissue disease:
If YES, specify type:

☐ Sleep apnea
If YES, specify type:

☐ Renal (kidney) failure

☐ Nephrotic syndrome

☐ Indwelling catheter

☐ Chronic liver failure

☐ Iron deficiency/ Anemia

☐ Inflammatory bowel disease

☐ Hemorrhoids

☐ Moyamoya Syndrome ~~disease (MMD)~~

☐ Down syndrome

☐ Neurofibromatosis type I (NF1)

☐ Sturge-Weber syndrome

☐ Inborn error metabolism

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

- ☐ Yes
- ☐ No
- ☐ Unknown

☐ Hereditary hemorrhagic telangiectasia

☐ Ehlers-Danlos Syndrome Type IV

Medical History

☐Marfan syndrome

☐Fibromuscular dysplasia

☐Coarctation of the aorta

☐Alpha1-antitrypsin deficiency

☐Pheochromocytoma

☐Other, specify:

***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
2) ***Chicken pox in past 12 months:
   - ☐ Yes
   - ☐ No
   - ☐ Unknown
3) ***Facial Segmental Hemangioma/PHACE syndrome:
   - ☐ Yes
   - ☐ No
   - ☐ Unknown

Medical History CRF Module Instructions

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 Supplemental – Highly Recommended or Exploratory, as indicated by asterisks below:

**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.
- 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.

Prior Functional Status

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Date information collected: // m m/dd/yyyy

Answer the following items on this form about the participant's /subject's functional status *prior to the stroke event*.

1. Ambulatory status*:

☐ Able to ambulate independently (no help from another person) w/ or w/o device

☐ With assistance (from person)

☐ Unable to ambulate

☐ Unknown

2. Pediatric-specific Pre-morbid Developmental Status and Academic Function

These elements are recommended to collect from children who have experience a stroke event. They are not appropriate for neonates.

Does/did the participant/ subject have any of the following?

☐ Attention Deficit Hyperactivity Disorder (ADHD)

☐ Attention Deficit Disorder (ADD)

☐ Delayed acquisition of language ~~/cognitive~~ milestones, diagnosed by a healthcare provider or educator ~~pediatrician or neurologist~~

☐ Delayed acquisition of cognitive milestones, diagnosed by a healthcare provider or educator

☐ Delayed acquisition of motor milestones, diagnosed by a pediatrician or neurologist

☐ Social delays

☐ Hand preference before 12 months of age

☐ Abnormality of the gait noted by parents or a physician at the time the child began walking

☐ Received or receives for special education

☐ Other, specify:

3. School placement:

☐ Full-time regular education without aide
☐ Regular education with pull-out for certain areas
☐ Full time special education with no inclusion
☐ Home-school
☐ Other, specify:
☐ Full-time regular education with one to one aide
☐ Special education w/ minimal inclusion (e.g., lunch)
☐ Special (MR/DD) school
☐ Not in school

4. Specialized therapies and services: (choose all that the participant/ subject receives)

☐ Speech Therapy
☐ Sensory Integration
☐ Behavior Support Plan (or other management plan)
☐ Occupational Therapy
☐ Social Skills Training
☐ Physical Therapy
☐ Adaptive Physical Education
☐ Crisis Management Plan
☐ Other, specify:

Prior Functional Status CRF Module Instructions

~~*Element is classified as Core~~

General Instructions

This case report form (CRF) is intended to collect data about the participant's/ subject's functional status prior to the stroke event. However, many of the data elements may be appropriate to collect at subsequent time points to assess the participant's/ subject's function status after the stroke event. The first question on the CRF, ambulatory status, may be applicable to both adult and pediatric stroke studies. The later questions are labeled as "pediatric-specific" and are probably only applicable for stroke studies in children.

Important note: The ~~date collected and the~~ first data element (question #1) included on this CRF is ~~are~~ considered Core (i.e., strongly recommended for all stroke clinical studies to collect) as indicated by the asterisk below. All other data elements included on this CRF are Supplemental and should only be collected if the research team considers them appropriate for their study.

*Element is classified as Core

Specific Instructions

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

The data elements on this form may be obtained from the participant/subject, family and/or the medical record/chart. The CRF includes all other instructions available for the data elements at this time.

Prior and Concomitant Medications

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Did the participant/subject take any medications (please specify below) days before or during the study? ☐Yes ☐No (Leave rest of form blank) ☐Unknown

Table to Record Medications Taken by Participant/Subject

Medication Name (Trade or generic name)	Indication (If given for AE, enter exact term from AE CRF)	Dose	Dose Units	Frequency	Route[1]	Start Date (mm/dd/yyyy)	End Date (mm/dd/yyyy)	Ongoing?
Data to be entered by site	Data to be entered by site	Data to be entered by site	Data to be entered by site	Data to be entered by site	Data to be entered by site	//20	//20	☐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	Data to be entered by site	Data to be entered by site	//20	//20	☐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	Data to be entered by site	Data to be entered by site	//20	//20	☐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	Data to be entered by site	Data to be entered by site	//20	//20	☐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	Data to be entered by site	Data to be entered by site	//20	//20	☐Yes ☐No

[1] Select from the following for medication route: Buccal, Inhaled, Intramuscular, Intravenous, Nasal, Oral, Rectal, By ear, Topical, Subcutaneous, Sublingual, Transdermal, Unknown, Other specify

Prior and Concomitant Medications

[Study Name/ID pre-filled]

Site Name:

Subject ID:

The following interview questions can be used to help make sure a complete record of all prior and concomitant medications is documented.

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

1. Antiplatelets:

☐Yes ☐No ☐Unknown

a. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Aspirin (ASA)

☐Clopidogrel (Plavix)

☐Cilostazol (Pletal)

☐ASA/Dypiridamole (in separate formulations or as Aggrenox)

☐Ticlopidine (Ticlid)

☐Ticagrelor (Brilinta)

☐Pentoxiphylline (Trental)

☐Prasugrel (Effient)

☐Other, specify:

2. Anticoagulants:

☐Yes ☐No ☐Unknown

b. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Unfractionated heparin IV

☐Warfarin (Coumadin)

☐Full dose LMW heparin (Enoxaparin, Others)

☐Fondaparinux (Arixtra)

☐Phenprocoumon

☐Acenocumarol

☐Dabigatran

☐Fondaparinux

☐Rivaroxaban

☐Edoxaban

☐Other, specify:

3. Cholesterol-reducing/ controlling medications:

☐Yes ☐No ☐Unknown

c. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Statin ☐Fibrate ☐Other, specify:

4. Diabetic medications:

☐Yes ☐No ☐Unknown

d. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Insulin

☐Metformin

☐Acarbose

☐1st generation sulfonylurea (chlorpropramide)

☐2nd generations sulfonylurea (glyburide, glipizide)

☐Rosiglitazone, piolitazone and other "glitazones"

☐Repaglinide/ Nateglinide

☐Other, specify:

Prior and Concomitant Medications

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

5. ANTIHYPERTENSIVE MEDICATIONS:

☐Yes ☐No (Skip to Question 6) ☐Unknown (Skip to Question 6)

a. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Diuretic (Answer 5B)

☐Beta-blocker (Answer 5C)

☐Angiotensin receptor blocker (Answer 5D)

☐Calcium-channel blocker (Answer 5E)

☐Ace inhibitor (Answer 5F)

☐Potassium supplement

☐Other (Answer 5G)

b. If diuretic history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Thiazides (HCTZ, chlorthalidone)

☐Furosemide/ loop diuretic

☐Potassium sparing

☐Other, specify:

If beta-blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Propranolol

☐Atenolol

☐Metoprolol

☐Carvedilol

☐Other, specify:

c. If angiotensin receptor blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Candestartan ☐Losartan ☐Other, specify:

d. If calcium-channel blocker history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Verapamil–ER

☐Felodipine

☐Amlopidine

☐Other, specify:

If ace inhibitor history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Enalapril

☐Lisinopril

☐Fosinopril

☐Ramapril

☐Other, specify:

e. If other medication history, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Central alpha agonists (clonidine)

☐Alpha-blockers (prazosin, terazosin)

☐Vasodilator: minoxidil

☐Vasodilator: hydralazine

☐Other antihypertensive, specify:

6. HORMONAL REPLACEMENT MEDICATIONS:

Prior and Concomitant Medications

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐Yes ☐No ☐Unknown

a. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Estrogen ☐Progesterone ☐Combination of Estrogen and Progesterone ☐Other, specify:

b. If YES, indicate the route of hormonal replacement therapy:

☐Oral ☐Topical ☐Transdermal ☐Other, specify: ☐Unknown

7. Oral contraceptives

☐Yes ☐No ☐Unknown

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

8. Implanted, estrogen-containing contraceptives

☐Yes ☐No ☐Unknown

11. Stimulants

☐Amphetamine derivatives

☐Caffeine (Xanthine derivative)

☐Theophylline (Xanthine derivative)

☐Others, specify

Duration of use (months):
Age when use started (years):
Age when use ended (years):

12.***Potency-enhancing drugs:

Duration of use (months):
Age when use started (years):
Age when use ended (years):

13.***Immunosuppressants:

☐Corticosteroids systemic

☐Corticosteroids local

☐Others, specify:

Any other medications not already listed:
☐Yes ☐No ☐Unknown

a. If YES, indicate medication(s) the patient took within the past week: (choose all that apply)

☐Digoxin/cardiac glycosides

☐Antiarrhythmic drugs (quinidine, amiodarone)

☐Thyroid preparations

☐Benzodiazepines (Valium, Librium, Ativan, Xanax)

☐Anti-Parkinsonian meds (including selegiline)

☐Non-aspirin salicylates (salsa late)

☐Other nonsteroidal anti-inflammatory drugs

☐Gingko derivatives/other herbals

☐Vitamin E (more than multivitamins)

☐Nitrates

☐SSRIs and new-generation antidepressants

☐Tricyclic antidepressants (amitriptyline, imipramine, doxepin)

Prior and Concomitant Medications

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐H2 blocker (e.g. cimetidine) or proton pump inhibitor (e.g. omeprazole)

☐Donazepril and related meds

☐Analgesics (acetaminophen, codeine)–daily

☐ COX~~ox~~ 2 inhibitors (e.g.~~rofecoxib,~~ celecoxib, ~~valdecoxib~~) ~~(e.g. ibuprofen, naproxen)~~

☐Multivitamin

☐Other, specify:

☐ COX inhibitors (e.g. ibuprofen, naproxen)

Cocaine: Exposure to cocaine within one year of clinical presentation:

☐ Yes
☐ No
If yes:
Duration of use (months):
Age when use started (years):
***Age when use ended (years):

SUPPLEMENTS

1) ***Taking supplements?
☐ Yes
☐ No
☐ Unknown
***If YES, type(s) of supplements (Choose all that apply):
☐ Beta Carotene
☐ Calcium
☐ Dehydroepiandrosterone (DHEA)
☐ Echinacea
☐ Flax Seed Oil
☐ Folic Acid
☐ Ginko
☐Ginseng
☐ Saw Palmetto
☐ Soy Protein Powder
☐ Soy Supplements
☐ St. John's Wort
☐ Vitamin A
☐ Vitamin C
☐ Vitamin E
☐ Weight Loss Supplements
☐ Wheat Germ
☐ Other, specify:

ADDITIONAL PEDIATRIC-SPECIFIC ELEMENTS

These elements are recommended for pediatric stroke studies.

Was the participant/ subject taking any of the following medications prior to admission or at the time of evaluation?

1. ***Attention Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) medications:
   ☐Yes ☐No ☐Unknown
2. ***Cold preparations/ medications:
   ☐Yes ☐No ☐Unknown
3. ***L-asparaginase
   ☐Yes ☐No ☐Unknown

Prior and Concomitant Medications CRF Module Instructions

General Instructions

Collecting medications taken prior to the study in a defined time window (e.g., 30 days) is important when there may be potential interactions with the study intervention. Thus, a potential participant/subject may need to stop a medication prior to starting the study intervention (washout period). Furthermore, the study exclusion criteria may identify drugs that cannot be taken during the study and so prior medications are identified to determine whether an individual may be eligible for the study.

Collecting concomitant medications taken during a study is also important for safety reasons. Some drugs may interact with the study intervention and must not be taken during the study. Additionally, there may be some drugs that are not known to interact with the study intervention and may be identified through an adverse event. It may be helpful to ask study participants/subjects or their caregivers to bring prescription and over-the-counter medications to follow-up visits so that the medications can be more easily and accurately recorded on the CRF.

The Prior and Concomitant Medications form should be filled out at the baseline visit and every study visit/time point thereafter.

Studies that plan to submit their data to regulatory authorities are recommended to code their medication data using a standard terminology such as RXNorm.

Important note: Some data elements included on this CRF Module are considered Exploratory as specified by asterisks below:

***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.

- Any Medications?–Choose one. If this question is answered YES then at least one prior/concomitant medication record needs to be recorded. Do NOT record study medications taken (if study has a drug intervention) on this form. Refer to the Study Drug Dosing form to record study medications.
- Medication Name–Record the verbatim name (generic or trade name) of the medication the participant/subject reports taking. See the data dictionary for additional information on coding the medication name using RXNorm.
- Indication–Record the reason the participant/subject gives for taking the medication. If given for an AE, enter exact term from Adverse Event CRF.
- Dose–Record the strength and units of the medication the participant/subject is taking.
- Dose Units–Record the units of the medication the participant/subject is taking. See the data dictionary for additional information on coding the dosage unit of measure using Unified Code for Units of Measure (UCUM).
- Frequency–Record how often the medication is being taken. See the data dictionary for additional information on coding the frequency using CDISC SDTM Frequency Terminology.
- Route–Record the route of administration. Acceptable responses for Route are shown below the medication table.
- Start Date and Time–Record the date (and time if applicable to the study) the participant/subject started taking the medication. 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. Start Date can be used to distinguish between prior medications and concomitant medications. Studies that need to collect Start Time will need to add fields for time to the form template.

- Cocaine use: Exposure of cocaine within one year of clinical presentation

Pregnancy and Perinatal History

[Study Name/ID pre-filled]

Site Name:

Subject ID:

**DATE FAMILY HISTORY TAKEN (MM/DD/YYYY):

PREGNANCY HISTORY

1. **Prior pregnancy (both term and not to term): ☐ Yes ☐ No (Skip A-D) ☐ Unknown (Skip A-D)
   a. Number of prior pregnancies: pregnancies
   b. Year of last delivery / miscarriage/ medical termination:
   c. Number of miscarriages: miscarriages
   d. Number of medical terminations: medical terminations

PEDIATRIC-SPECIFIC PERINATAL HISTORY

These elements are recommended for pediatric stroke studies of neonates ONLY (i.e., not appropriate for stoke studies of children).

2. **Mother's age at the time she gave birth to the participant/subject: years
3. **Number of live born children the participant/subject's mother has delivered? children
4. **Total number of times the participant/subject's mother has been pregnant, regardless of whether these pregnancies were carried to term (A current pregnancy, if any, is included in this count):
5. **Did the mother experience any of the following during the prenatal period, at the time of delivery, or soon after delivery with the participant/subject?

   ☐ Preeclampsia

   ☐ Other hypertensive disorder

   If YES, specify: ☐ Prenatal ☐ Perinatal

   ☐ Oligohydramnios

   ☐ Gestational diabetes

   ☐ Prolonged (i.e., > 24 hours) rupture of membranes during delivery

   ☐ Chorioamnionitis

   IF YES, specify: ☐ Prenatal ☐ Perinatal

   ☐ Other illness(es)

   **If YES, specify illness(es):

   If YES, specify: ☐ Prenatal ☐ Perinatal ☐ Postnatal

   ☐ Decreased fetal movement

   If YES, specify: ☐ Prenatal ☐ Perinatal

   ☐ Fever during delivery of participant/subject

   ☐ Meconium staining of the amniotic fluid

Pregnancy and Perinatal History

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ Intravascular catheter placed in newborn period

☐ Placenta sent for pathology

☐ Placental abnormalities

☐ Fetal heart rate abnormality

If YES, specify: ☐ Prenatal ☐ Perinatal

☐ Fetal abnormalities recognized in utero

If YES, specify abnormality(ies):

☐ Maternal infection

**If YES, specify infection(s):

If YES, specify: ☐ Prenatal ☐ Perinatal ☐ Postnatal

☐ Lack of prenatal care

☐ Maternal drug abuse

☐Other, specify:

If YES, specify:☐ Prenatal ☐ Perinatal ☐ Postnatal

PEDIATRIC-SPECIFIC DELIVERY HISTORY

These elements are recommended for pediatric stroke studies of neonates ONLY (i.e., not appropriate for stoke studies of children).

6. **Birth weight: pounds and ounces OR grams
7. **Gestational age at birth: weeks
8. **APGAR 1 minute score: ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
9. **APGAR 5 minute score: ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
10. **APGAR 10 minute score: ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
11. ***Was the child delivered full–term (>36 weeks)?

    ☐ No
    ☐ Yes
12. **Mode of delivery of the neonate:

    ☐ Spontaneous ☐ Induced, specify reason: ☐ Unknown
13. **Route of delivery of the neonate:

    ☐ Vaginal

    ☐ Caesarean

    **If yes, timing of the caesarean: ☐ Emergency ☐ Elective

Pregnancy and Perinatal History

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ Unknown

14. **Delivery modality type of the neonate:

☐ Breech ☐ Cephalic ☐ Unknown ☐ Other

15. **Instrument(s) used to assist with the delivery of the participant/subject?

☐ None ☐ Vacuum ☐ Forceps ☐ Vacuum and Forceps ☐ Unknown

16. ***Timing of intracranial aneurysm rupture during pregnancy

a. ☐ Before event

☐ During event
☐ After event

b. ***Date of Delivery:

Pregnancy and Perinatal History CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to pregnancy and perinatal history. The first question on the CRF may be applicable to both adult and pediatric stroke studies. The later questions are labeled as "pediatric-specific" and probably are only applicable for stroke studies in neonates.

Important note: None of the data elements included on this CRF is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Rather, all of the data elements are either Supplemental – Highly Recommended (for studies of perinatal stroke) or Exploratory, as indicated by asterisks below, and should only be collected if the research team considers them appropriate for their study.

** Element is Supplemental – Highly Recommended

*** Element is Exploratory

Specific Instructions

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

The CRF includes all instructions available for the data elements at this time.

- Timing of rupture during pregnancy: Before event; during event; after event: Event is defined as the diagnosis or rupture of the intracranial aneurysm

Social Status

[Study Name/ID pre-filled]

Site Name:

Subject ID:

1) What is the highest grade or level of school you have completed or the highest degree you have received?
   - ☐ Never attended/ Kindergarten only
   - ☐ 1st Grade
   - ☐ 2nd Grade
   - ☐ 3rd Grade
   - ☐ 4th Grade
   - ☐ 5th Grade
   - ☐ 6th Grade
   - ☐ 7th Grade
   - ☐ 8th Grade
   - ☐ 9th Grade
   - ☐ 10th Grade
   - ☐ 11th Grade
   - ☐ 12th Grade, no diploma
   - ☐ High school graduate
   - ☐ GED or equivalent
   - ☐ Some college, no degree
   - ☐ Associate degree: occupational, technical, or vocational program
   - ☐ Associate degree: academic program
   - ☐ Bachelor's degree (e.g., BA, AB, BS, BBA)
   - ☐ Master's degree (e.g., MA, MS, MEng, MEd, MBA)
   - ☐ Professional school degree (e.g., MD, DDS, DVM, JD)
   - ☐ Doctoral degree (e.g., PhD, EdD)
   - ☐ Unknown

~~2) *Years of education (0-30):~~

3) Current employment status:
   - ☐ Working now
   - ☐ Only temporarily laid off, sick leave or maternity leave
   - ☐ Looking for work, unemployed
   - ☐ Retired
   - ☐ Disabled, permanently or temporarily
   - ☐ ~~Keeping house~~ Homemaker
   - ☐ Student
   - ☐ Other, specify:
   - ☐ Unknown

   a. If working now, do you usually work 35 hours or more per week?
      - ☐ Yes
      - ☐ No
      - ☐ Hours vary
      - ☐ Unknown

4) ***Type of paid occupation (four-digit code as defined by the ILO/ISCO):

5) ***Primary occupation *(Choose one)*:
   - ☐ Paid work (employed/self-employed, including military)
   - ☐ Homemaker
   - ☐ Student (including on the job training)
   - ☐ Retired (disability pension)
   - ☐ Retired (non-disability)
   - ☐ Unpaid work (volunteer)
   - ☐ Unemployed (none of the above)

Social Status

[Study Name/ID pre-filled]

Site Name:

Subject ID:

- ☐ Other, specify:
- ☐ Unknown

6) ***Secondary occupation *(Choose all that apply):*
   - ☐ N/A
   - ☐ Paid work (employed/self-employed, including military)
   - ☐ Homemaker
   - ☐ Student (including on the job training)
   - ☐ Retired (disability pension)
   - ☐ Retired (non-disability)
   - ☐ Unpaid work (volunteer)
   - ☐ Unemployed (none of the above)
   - ☐ Other, specify:
   - ☐ Unknown

7) ***Workload (hours/week) all occupations:

8) Marital/ Partner status:
   - ☐ Never married
   - ☐ Married
   - ☐ Domestic partnership
   - ☐ Divorced
   - ☐ Separated
   - ☐ Widowed

9) Number of people living with:
   a. If one or more people, describe the individual(s) with whom you live (Choose all that apply):
   - ☐ Husband or wife
   - ☐ Biological son or daughter
   - ☐ Adopted son or daughter
   - ☐ Stepson or stepdaughter
   - ☐ Brother or sister
   - ☐ Father or mother
   - ☐ Stepfather or stepmother
   - ☐ Grandchild
   - ☐ Grandparent
   - ☐ Parent-in-law
   - ☐ Son-in-law or daughter-in-law
   - ☐ Other relative
   - ☐ Roomer or boarder
   - ☐ Housemate or roommate
   - ☐ Unmarried partner
   - ☐ Foster child
   - ☐ Other patient/resident in care facility
   - ☐ Personal care attendant
   - ☐ Military unit member
   - ☐ Other non-relative
   - ☐ N/A – Homeless
   - ☐ N/A – Alone
   - ☐ Unknown

6) Income group that best represents your total combined family income for the past 12 months:

Social Status

[Study Name/ID pre-filled]

Site Name:

Subject ID:

(This includes the total income before taxes in the past year by all family members living with you. Please include money from jobs, net income from business, farm or rent, pensions, dividends, welfare, social security payments and any other money received by you or any other family member living with you.)

- ☐ Under $15,000
- ☐ $15,000 to $24,999
- ☐ $25,000 to $34,999
- ☐ $35,000 to $49,999
- ☐ $50,000 to $74,999
- ☐ $75,000 to $99,999
- ☐ $100,000 and over
- ☐ Refused
- ☐ Unknown

a. Number of people supported by this income, including you:

ADDITIONAL PEDIATRIC-SPECIFIC ELEMENT

This element is recommended for pediatric stroke studies.

7) What is the highest grade or level of school the primary care giver has completed or the highest degree she/he has received?

- ☐ Never attended/ Kindergarten only
- ☐ 1st Grade
- ☐ 2nd Grade
- ☐ 3rd Grade
- ☐ 4th Grade
- ☐ 5th Grade
- ☐ 6th Grade
- ☐ 7th Grade
- ☐ 8th Grade
- ☐ 9th Grade
- ☐ 10th Grade
- ☐ 11th Grade
- ☐ 12th Grade, no diploma
- ☐ High school graduate
- ☐ GED or equivalent
- ☐ Some college, no degree
- ☐ Associate degree: occupational, technical, or vocational program
- ☐ Associate degree: academic program
- ☐ Bachelor's degree (e.g., BA, AB, BS, BBA)
- ☐ Master's degree (e.g., MA, MS, MEng, MEd, MBA)
- ☐ Professional school degree (e.g., MD, DDS, DVM, JD)
- ☐ Doctoral degree (e.g., PhD, EdD)
- ☐ Unknown

Social Status CRF Module Instructions

General Instructions

This form contains data elements, beyond the basic demographic information, that are collected to describe the study population. The study team should decide if it make sense to collect these data elements once (i.e., at baseline) or at multiple time points.

~~Important note: All of the data elements included on this CRF Module are considered supplemental and should only be collected if the research team considers them appropriate for their study. One data element is Supplemental – Highly Recommended (strongly recommended to collect based on study type or design) as indicated by an asterisk (*).~~

Some of the data elements included on this CRF Module are considered Exploratory, as indicated by asterisks below:

***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.

- Education – Choose highest level attained. It may be helpful to code education numerically if the data are needed for neuropsychological testing. Please refer to the data element named "Education for scoring of neuropsychological tests" for more information.
- Education in years – Code the highest level of formal education completed using the coding procedures specified.
- Full-time employment – This item should be skipped if the participant/ subject is not currently working.
- Persons living with – Skip this data element if the participant/ subject lives alone. If he/she lives with one or more people, choose all that apply.
- Primary care giver's education – Choose highest level attained. This element is recommended for pediatric stroke studies.

References

Full-time employment: Current Population Survey (CPS) 2009 - monthly survey of households conducted by the Bureau of Census for the Bureau of Labor Statistics