NINDS Common Data Element (CDE) Project
Stroke Version 2.0 Public Review
Stroke Presentation and Vital Signs Subgroup Materials

Instruments:

- Glasgow Coma Scale (GCS)

Case Report Forms:

- Assessment of Transient Signs or Symptoms Prior to Presentation
- Hospital/Arrival Admission
- Physical/Neurological Exam
- Pre-Hospital/Emergency Medical Service (EMS) Course
- Vital Signs

NINDS CDE Notice of Copyright
Glasgow Coma Scale (GCS)

Availability	**The instrument is freely available here: Glasgow Coma Scale Link**
Classification	**Supplemental – Highly Recommended**: Stroke (based on study type, disease stage and disease type)
Short Description of Instrument	The Glasgow Coma Scale (GCS) was developed to overcome the misunderstandings and confusion about comatose patients. The GCS is also used to assess neurological trauma as well as to document and predict neurological changes. It is considered the gold standard in this regard and is widely used.
Comments/Special Instructions	The timing and frequency of assessment that are appropriate varies according to the stage after onset of the impairment of consciousness and the pattern in any previous observations of a patient. Observation should begin as soon as possible after onset of the impaired consciousness in order to guide initial management and to establish a baseline against which to interpret later findings. Observations initially should be repeated frequently to establish if the patient is stable or to detect any trends of improvement, or of deterioration from developing complications. When a stable pattern emerges as time passes, the frequency can be reduced. The scale can be applied without modification to children over 5 years old. In younger children and infants, an assessment of a verbal response as “orientated” and motor response as “obeys commands” is usually not possible. A ‘Paediatric Glasgow Coma Scale’ was therefore described in the Adelaide Coma Scale in which responses were modified.
Scoring and Psychometric Properties	**Scoring:** Three questions must be answered in regards to unconsciousness and coma with the first addressing eye opening, the second motor function and the third verbal response. Scores range from 3-15 total points with lower scores indicating patients in comatose. **Psychometric Properties:** Consistency in its findings is a key feature of a clinical assessment and during the development of the Glasgow Coma scale it was shown to be better than existing methods. Although some subsequent studies reported levels ranging from very poor to excellent a definitive systematic review has shown that the reproducibility of the scale is usually high.
References	Balestreri M, Czosnyka M, Chatfield DA, Steiner LA, Schmidt EA, Smielewski P, . . . Pickard JD. Predictive value of Glasgow Coma Scale after brain trauma: change in trend over the past ten years. J Neurol Neurosurg Psychiatry 2004;75(1), 161–162.

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~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

1. Stroke symptoms/ Comorbid events:

~~Table for Recording Stroke Symptoms and Cormorbid Events Experienced and Resolved at the Time of~~Assessment of Transient Signs or Symptoms Prior to Presentation

Stroke symptom~~/ Comorbid event~~	Experienced?	Duration
~~Numbness~~Sudden sensory symptoms~~or weakness~~ of the face, arm or leg	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown
Sudden weakness of the face, arm or leg	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown
Sudden ~~C~~confusion, trouble speaking or understanding	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown
Sudden ~~T~~trouble seeing in one or both eyes	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown
Sudden ~~T~~trouble walking, dizziness, loss of balance or coordination	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

Stroke symptom~~/ Comorbid event~~	Experienced?	Duration
~~Headache~~	~~☐ Yes~~ ~~☐ No~~ ~~☐ Unknown~~	~~☐ < 10 minutes~~ ~~☐ 10 – 59 minutes~~ ~~☐ ≥ 60 minutes~~ ~~☐ Unknown~~
~~Seizure or convulsion~~	~~☐ Yes (Answer #2)~~ ~~☐ No~~ ~~☐ Unknown~~	~~☐ < 10 minutes~~ ~~☐ 10 – 59 minutes~~ ~~☐ ≥ 60 minutes~~ ~~☐ Unknown~~
~~Vomiting~~	~~☐ Yes~~ ~~☐ No~~ ~~☐ Unknown~~	~~☐ < 10 minutes~~ ~~☐ 10 – 59 minutes~~ ~~☐ ≥ 60 minutes~~ ~~☐ Unknown~~
Other, specify:	☐ Yes ☐ No ☐ Unknown	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

1. ~~IF seizure was a symptom/ comorbid event:~~
   ~~a. Type of seizure:~~
   - ☐ ~~Focal~~
   - ☐ ~~Generalized~~
   - ☐ ~~Epileptic Spasm~~
   - ☐ ~~Unclassified seizure type~~
   - ☐ ~~Unknown~~

   ~~b. How was the diagnosis of seizure established? (Choose all that apply)~~
   - ☐ ~~Clinical manifestations~~
   - ☐ ~~EEG~~
   - ☐ ~~Unknown~~
2. Pregnant / Postpartum state:
   a. IF FEMALE, is she pregnant or in the postpartum period?
   - ☐ Yes
   - ☐ No
   - ☐ Unknown

   b. IF YES, specify current state:
   - ☐ Pre-partum 1st trimester
   - ☐ Pre-partum 2nd trimester
   - ☐ Pre-partum 3rd trimester
   - ☐ Postpartum first 24 hrs
   - ☐ Postpartum first week
   - ☐ Postpartum > 1 week
   - ☐ Active labor
3. Pediatric-specific stroke symptoms/ comorbid events:

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

Table for Recording Pediatric-Specific Stroke Symptoms and Comorbid Events Experienced and Resolved at the Time of Presentation

Stroke symptom/ Comorbid event	Experienced ?	Resolved at time of presentation?	Date and Time of resolution	Duration	Timing in relation to stroke onset
Neonatal respiratory abnormalities	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown
Neonatal poor feeding	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

Stroke symptom/ Comorbid event	Experienced ?	Resolved at time of presentation?	Date and Time of resolution	Duration	Timing in relation to stroke onset
Neonatal hypotonia	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown
Neonatal abnormal level of consciousness	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

Stroke symptom/ Comorbid event	Experienced ?	Resolved at time of presentation?	Date and Time of resolution	Duration	Timing in relation to stroke onset
Neonatal encephalopathy	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown
Neonatal clinical seizure	☐ Yes (Answer #2) ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

Stroke symptom/ Comorbid event	Experienced ?	Resolved at time of presentation?	Date and Time of resolution	Duration	Timing in relation to stroke onset
Neonatal subclinical seizure	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown
Other, specify:	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	//20 (M M/DD/YYYY) : HH:MM ☐ AM ☐ PM ☐ 24-hr clock ☐ Unknown date/time	☐ < 10 minutes ☐ 10 – 59 minutes ☐ ≥ 60 minutes ☐ Unknown	☐ Preceded stroke onset by ≥ 24 hrs ☐ Preceded stroke onset by ≥ 6 but < 24 hrs ☐ Preceded stroke onset by <6 hrs ☐ Onset coincident with stroke onset ☐ Followed stroke onset by < 6 hr ☐ Unknown

4. IF neonatal abnormal level of consciousness was a symptom/ comorbid event, describe level of consciousness:
   - ☐ Hyperalert
   - ☐ Lethargic
   - ☐ Stuporous/ Comatose
5. IF neonatal encephalopathy was a symptom/ comorbid event, describe level of encephalopathy:
   - ☐ Mild Encephalopathy

~~Stroke Symptoms/ Comorbid Events~~Assessment of Transient Neurologic Deficits Resolved Prior to Presentation

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Moderate Encephalopathy
- ☐ Severe Encephalopathy

Assessment of Transient Neurologic Deficits Resolved Prior to Presentation ~~Stroke Symptoms/ Comorbid Events~~ CRF Module Instructions

General Instructions

This CRF collects data about symptoms and comorbid events that the participant/ subject experienced around the time of the stroke event. It is assumed these data would be collected at stroke presentation.

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 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.

- Stroke symptom~~/ comorbid event type~~ – *No additional instructions*
- Stroke symptom/ comorbid event experienced – If answered NO or UNKNOWN then 'Resolved at time of presentation', 'Date and time of resolution', 'Duration', and 'Timing in relation to stroke onset' should be left blank for the stroke symptom/ comorbid event.
- ~~Stroke symptom/ comorbid event resolved at the time of presentation – *No additional instructions*~~
- ~~Stroke symptom/ comorbid event date and time of resolution – The preferred format for recording date and time is MM/DD/YYYY HH:MM (24-hour clock). 99/99/9999 can be used to indicate an unknown date. Similarly, 99:99 can be used to indicate an unknown time.~~
- Stroke symptom/ comorbid event duration – Estimate the time of symptom duration for patients with transient neurological symptoms that are felt to be due to cerebral ischemia. When a range of time duration is provided in the record, choose the upper most limit. For example, if it states, “symptoms lasted between 5-20 minutes”, then select "10-59 minutes" since 20 minutes would fall into the “10-59 minutes” range.
- ~~Stroke symptom/ comorbid event timing in relation to stroke onset – *No additional instructions*~~
- ~~Type of seizure – Answer only if seizure was reported as a stroke symptom/ comorbid event.~~
- ~~Seizure diagnosis method – Answer only if seizure was reported as a stroke symptom/ comorbid event. Check all that apply.~~
- Pregnant or in postpartum period – *No additional instructions*
- Pregnant or in postpartum period current state – Answer only if female participant/ subject is pregnant or in postpartum state.
- Stroke symptom/ comorbid event pediatric-specific type – *No additional instructions*
- Neonatal level of consciousness – Answer only if neonatal abnormal level of consciousness was reported as a stroke symptom/ comorbid event for the neonate.
- Neonatal encephalopathy level – Answer only if neonatal encephalopathy was reported as a stroke symptom/ comorbid event for the neonate.

Hospital Arrival/ Admission

[Study Name/ID pre-filled] Site Name:

Subject ID:

1. Patient location when stroke symptoms discovered:

- ☐ Not in a healthcare setting (e.g. at place of residence and not in a hospital or clinic)
- ☐ Chronic healthcare facility (e.g. skilled nursing facility)
- ☐ Outpatient healthcare setting (e.g. clinic)
- ☐ Another acute care facility (e.g. outside hospital)
- ☐ Stroke occurred while patient was an inpatient in your hospital
- ☐ Unknown

2. Date and Time patient last known to be well (or at pre-stroke baseline)~~Error! Bookmark not defined.~~[1]*: // (m m/dd/yyyy) : (hh:m m, 24 hr clock)

3. Date and Time of discovery of stroke symptoms: // (mm/dd/yyyy) : (hh:mm, 24 hr clock)

4. Symptom discovery on awakening:

- ☐ Yes
- ☐ No
- ☐ Unknown

5. Type of transport to hospital:

- ☐ EMS from home/scene
- ☐ Transfer from another hospital
- ☐ Private transportation/taxi/other from home/scene
- ☐ Mobile stroke unit
- ☐ Unknown
- ☐ Other, specify:

6. Date and Time of hospital arrival~~Error! Bookmark not defined.~~[1]*: // (mm/dd/yyyy) : (hh:mm, 24 hr clock)

~~7. Was the patient placed on a 24-hour observation status rather than formally admitted?~~

- ~~☐ Yes~~
- ~~☐ No~~
- ~~☐ Unknown~~

7. Was patient evaluated in the Emergency Department (ED) for acute Stroke or TIA and subsequently transferred to another acute care hospital rather than being admitted to your hospital?

- ☐ Yes
- ☐ No
- ☐ Unknown

8. Date of ~~hospital~~ admission to your hospital~~Error! Bookmark not defined.~~[1]*: // (m m/dd/yyyy)

- ☐ N/A – not admitted

Hospital Arrival/ Admission

[Study Name/ID pre-filled] Site Name:

Subject ID:

9. Point of origin for admission/visit:
   - ☐ ~~Non-Health Care Facility Point of Origin~~Not in a healthcare facility
   - ☐ ~~Transfer from a Skilled Nursing Facility (SNF) or Intermediate Care Facility (ICF)~~Another acute care facility
   - ☐ ~~Court/Law Enforcement~~Chronic healthcare facility
   - ☐ ~~Transfer from Ambulatory Surgery Center~~Outpatient healthcare facility
   - ☐ ~~Clinic~~Stroke occurred after hospital arrival (in ED/observation unit/inpatient)
   - ☐ ~~Transfer from a Hospital (Different Facility)~~
   - ☐ ~~Transfer from another Health Care Facility~~
   - ☐ ~~Emergency Room~~
   - ☐ ~~Transfer from One Distinct Unit of the Hospital to another Distinct Unit of the Same Hospital Resulting in a Separate Claim to the Payer~~
   - ☐ ~~Transfer from Hospice and is Under a Hospice Plan of Care or Enrolled in a Hospice Program~~
   - ☐ Unknown
10. Location patient first received care at hospital:
    - ☐ Emergency Department/ Urgent Care
    - ☐ Imaging suite
    - ☐ Direct Admit, not through ED (emergency department)
    - ☐ Unknown
11. Patient care upon admission: (Choose all that apply)
    - ☐ Neurology inpatient Admission~~t~~
    - ☐ ~~Other~~ (non-stroke) ~~Service Admission~~
    - ☐ Stroke Consult
    - ☐ No Stroke Consult
    - ☐ In Stroke Unit
    - ☐ Not in Stroke ~~Consult~~Unit
12. Presumptive diagnosis at time of hospital admission ~~diagnosis~~:
    - ☐ Ischemic Arterial Stroke
    - ☐ Ischemic Venous Stroke
    - ☐ Intracranial Hemorrhage
    - ☐ Intracerebral Hemorrhage
    - ☐ Transient Ischemic Attack
    - ☐ Not stroke related diagnosis
    - ☐ Subarachnoid Hemorrhage
    - ☐ Unknown
13. Was stroke a complication of a recent medical or surgical procedure or therapy (i.e. less than 30 days)?
    - ☐ Definitely
    - ☐ Possibly
    - ☐ Probably
    - ☐ Unlikely
    - ☐ Not applicable

Hospital Arrival/ Admission **CRF Module Instructions**

General Instructions

This CRF includes data typically collected upon arrival and admission to a hospital for a stroke event. Many of the data elements are taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental- Highly Recommended based on study type, disease stage and disease type. Supplemental-Highly Recommended CDEs are indicated by an asterisk (*). Please refer to Start-Up document for additional details.

Specific Instructions

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

Patient location when stroke symptoms discovered – If the patient was a resident of a nursing home, but was out with family for the day and suffered a stroke and the family/EMS brought the patient to your hospital, choose "Not in a healthcare setting". If the patient was at home, at work or~~f~~ even a visitor in your hospital and had stroke symptoms, then choose "Not in a healthcare setting". If the patient was transferred to your hospital from another hospital's ED or inpatient unit but was outside of a healthcare facility when the stroke occurred, choose "Not in a healthcare setting". If the patient was a resident of a nursing home and the stroke occurred at the NH, choose "Chronic healthcare facility". A chronic care facility would include nursing home, long-term care facility, inpatient rehab facility, and assisted-living facility. If the patient is at a clinic or physician office visit, or at your hospital but receiving outpatient procedure or service that did not require the patient to be admitted as an inpatient, select "Outpatient healthcare setting". If the patient was an inpatient in your hospital choose "Stroke occurred while patient was an inpatient at your hospital". If the patient was already within your ED or hospital and experienced new onset of stroke symptoms, then this is considered an inpatient stroke or TIA. Only those hospitals that are interested in collecting information regarding inpatient stroke care should enter these patients. Patients who have transient symptoms that are present on arrival to the ED but resolve, and then later return during the hospitalization and meet criteria for ischemic stroke should all be entered as inpatient strokes. The answer to this question is independent of the answer for Point of Origin for Admission or Visit. That question asks where the patient was located prior to arriving at your hospital, not where the patient was when they first developed stroke symptoms.

- Date and Time patient last known to be well – The purpose of this data element is to identify the earliest possible time that stroke symptoms began. This is sometimes known as "Onset Time" although the use of this term has been confusing to many in the past. If a patient experiences the onset of their symptoms in the company of another individual who can verify that the patient was functioning normally up until the time of start of symptoms, then in this patient the time "last known well" is also the time of symptom discovery. In many cases, however, no one is present at the exact start of symptoms. In this situation, we need to document the time when symptoms were first discovered (time of symptom discovery) as well as the time that the patient was last known to be well or at their baseline (time last known well), and record both of these. The time last known well should be the time closest to the time of discovery for which we have clear evidence that the patient was at their previous baseline. Depending on the type of stroke symptoms, this might be established by a telephone or in person conversation. Family members, EMS personnel, and others, often mistakenly record the time of symptom discovery as the time the patient was last known well. It is imperative to distinguish these two times to avoid inappropriate use of IV t-PA (Intravenous Tissue Plasminogen Activator) in patients who are recently discovered to have symptoms but are many hours (>3 hrs.) from their time of last being well.
- Date and Time of discovery of stroke symptoms – This date and time should generally not vary between observers unless a witness noticed the onset of symptoms but did not alert anyone else, and a different individual is the one who contacted EMS or sought medical attention. If the event was

witnessed, then the last known well date and time and the discovery date and time will be identical. Record both, even if identical. (To within 15 minutes of exact time of discovery is acceptable.)

- Symptom discovery on awakening – No additional instructions
- Type of transport to hospital – This refers to the method of transport to your hospital, not to the method of initial transport to another facility if the patient was subsequently transferred to your hospital.
- Date and Time of hospital arrival – No additional instructions
- Was the patient placed on a 24 hour observation status rather than formally admitted? – No additional instructions
- Was patient evaluated in the Emergency Department (ED) for acute Stroke or TIA and subsequently transferred to another acute care hospital rather than being admitted to your hospital? – No additional instructions
- Date of ~~hospital~~ admission to your hospital – The dates of Emergency Department (ED) triage or an observation admission are not included. Hospital arrival date and admission date are usually the same for direct admissions but frequently differ for ED admissions. If the patient arrives through the ED and is held in observation for a day or two, use the actual date of admission to the hospital for the admission date, not the arrival date to the ED.
- Point of origin for admission/visit – The answer to this question is independent of the answer for Patient Location When Stroke Symptoms Discovered. This question asks where the patient was located prior to arriving at your hospital, not where the patient was when they first developed stroke symptoms. This element is intended to capture data about patients who are admitted to the hospital because of stroke events and is not for use with inpatient strokes (i.e., inpatient stroke = stroke that occurs while a patient is an inpatient in the hospital).
    - If the patient was a resident of a nursing home, but was out with family for the day and suffered a stroke and the family/EMS brought the patient to your hospital, choose "Not in a healthcare setting".
    - If the patient was at home, at work, or even a visitor in your hospital and had stroke symptoms, then choose "Not in a healthcare setting".
    - If the patient was transferred to your hospital from another hospital's ED or inpatient unit but was outside of a healthcare facility when the stroke occurred, choose "Not in a healthcare setting".
    - If the patient was a resident of a nursing home and the stroke occurred at the NH, choose "Chronic healthcare facility".
    - A chronic care facility would include nursing home, long-term care facility, inpatient rehab facility, psychiatric hospital, and transitional care unit. This is in alignment with the designation of this type of facility as Value 5-Other Healthcare Facility for the Discharge Disposition data element.
    - If the patient was a resident of an assisted living facility, and the stroke occurred at the assisted living facility, choose "Not in a healthcare setting." This is in alignment with the designation of an assisted living facility as Value 1- Home for the Discharge Disposition data element.
    - If the patient is at a clinic or physician office visit, or at your hospital but receiving outpatient procedure or service that did not require the patient to be admitted as an inpatient, select "Outpatient healthcare setting".
    - If the patient was already admitted as an inpatient in your hospital when stroke symptoms were first discovered choose "Stroke occurred after hospital arrival (in ED/Obs/inpatient)".
    - If the patient was already within your hospital ED, radiology suite, or observation unit and experienced a new onset of stroke symptoms, then choose "Stroke occurred after hospital arrival (in ED/Obs/inpatient)".
    - Only those hospitals that are interested in collecting information regarding inpatient stroke care should enter these patients. Patients who have transient symptoms that are present on arrival to the ED but resolve, and then later return during the hospitalization and meet criteria for ischemic stroke should all be entered as inpatient strokes.
- Location patient first received care at hospital – A patient presenting to the emergency department with stroke symptoms would have first received care in the Emergency Department (ED). However, for

patients who are transferred from an outside hospital and directly admitted, then the place of first care would be the service where they were admitted (e.g., neurology inpatient service, intensive care unit). Select imaging for patients with suspected acute stroke who are taken directly to the imaging area prior to the ED registration. This data element is not applicable to strokes that occur after a patient has already been admitted or receiving care in the ED for another condition.

- Patient care upon admission – Choose all that apply. To track the service on which care was rendered upon admission, select from the available options to indicate type of admission, whether a stroke consult was available, and whether this was in a stroke unit or not. First indicate if the patient was admitted by a neurologist or other service. Then indicate if the patient had a stroke consult. Finally indicate if the patient was cared for in a stroke unit.
- Presumptive diagnosis at time of hospital admission ~~diagnosis~~ – This field is useful in understanding why certain therapies were performed or omitted, and to understand the nature of missed or delayed diagnosis.
- Was stroke a complication of medical or surgical procedure or therapy? – No additional instructions

Physical/ Neurological Examination

[Study Name/ID pre-filled]

Site Name:

Subject ID:

MINI-MENTAL STATE EXAMINATION (MMSE)

Date and time of MMSE: // (m m/dd/yyyy) : (hh:mm, 24 hr clock)

MMSE total score:

ADDITIONAL PHYSICAL/ NEUROLOGICAL EXAMINATION FINDINGS

1. Consciousness:
   - ☐ Fully conscious (6)
   - ☐ Somnolent, can be awaked to full consciousness (4)
   - ☐ Reacts to verbal command, but is not fully conscious (2)
2. Orientation:
   - ☐ Correct for time, place and person (6)
   - ☐ Two of these (4)
   - ☐ One of these (2)
   - ☐ Completely disorientated (0)
3. Frontal lobe function:
   - ☐ Normal: No signs of social disinhibition or abulia
   - ☐ Primitive reflexes such as forced manual exploration of surroundings, grasp, traction response, rooting or snout as the only frontal signs
   - ☐ Mild impairment of frontal lobe function: Some social disinhibition or abulia
   - ☐ Hesitancy in speech functions with stuttering or difficulty speaking strings of consonants
   - ☐ Severe impairment: Gross signs of social disinhibition or abulia
   - ☐ Whispering or mutism
   - ☐ Untestable because of aphasia
4. Parietal lobe function:
   - ☐ Normal: No signs of impairment of auditory, visual, sensory or motor inattention, anosognosia, constructional or ideomotor dyspraxia
   - ☐ Loquacious or garrulous, history filled with irrelevant details. Or semantic verbal paraphasias when reading aloud long sentences or paragraphs or describing history of present illness.
   - ☐ Mild impairment: scattered slight signs of impairment of auditory, visual, sensory or motor inattention, anosognosia, constructional or ideomotor dyspraxia
   - ☐ Neglect for opposite space to visual or auditory testing as the only parietal sign
   - ☐ Refusal to acknowledge illness, personal body parts, offers wildly implausible explanations for failure to acknowledge illness or body parts. Or incoherent history of illness with numerous semantic verbal paraphasic errors.
   - ☐ Severe impairment: signs of impairment of auditory, visual, sensory or motor inattention, anosognosia, constructional or ideomotor dyspraxia.
   - ☐ Untestable because of aphasia
5. Hand preference: (Hand participant/subject uses predominately, not necessarily hand he/she writes with exclusively)
   - ☐ Left hand

Physical/ Neurological Examination

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ Right hand

☐ Both hands

☐ Unknown

6. Hand strength:

Right	Left
☐ Normal strength (6) ☐ Reduced strength in full range (4) ☐ Some movement, fingertips do not reach palm (2) ☐ Paralysis (0)	☐ Normal strength (6) ☐ Reduced strength in full range (4) ☐ Some movement, fingertips do not reach palm (2) ☐ Paralysis (0)

~~☐ Normal strength (6)~~

~~☐ Reduced strength in full range (4)~~

~~☐ Some movement, fingertips do not reach palm (2)~~

~~☐ Paralysis (0)~~

7. Hand function:

Right	Left
☐ Normal – No restriction upon the performance of any movement, even if there is a minimal weakness. (15) ☐ Skilled – Restriction of fine movements. The more complex movements are impaired, but there is no restriction upon the performance of common, daily-life movements, even if these are executed slowly or clumsily, antagonistic movements between finger and thumb possible. (10) ☐ Useful – Gross movements possible. Delicate movements cannot be performed, but patient can handle and carry objects of at least match-box size, use a fork or a pencil in approximate fashion, can handle a cane or grip a hand rail. (5) ☐ Useless – Useful movements impossible. Patient cannot hold or carry objects, even if some elementary movements can be performed. (0)	☐ Normal – No restriction upon the performance of any movement, even if there is a minimal weakness. (15) ☐ Skilled – Restriction of fine movements. The more complex movements are impaired, but there is no restriction upon the performance of common, daily-life movements, even if these are executed slowly or clumsily, antagonistic movements between finger and thumb possible. (10) ☐ Useful – Gross movements possible. Delicate movements cannot be performed, but patient can handle and carry objects of at least match-box size, use a fork or a pencil in approximate fashion, can handle a cane or grip a hand rail. (5) ☐ Useless – Useful movements impossible. Patient cannot hold or carry objects, even if some elementary movements can be performed. (0)

~~☐ Normal – No restriction upon the performance of any movement, even if there is a minimal weakness. (15)~~

Physical/ Neurological Examination

[Study Name/ID pre-filled] Site Name:

Subject ID:

☐ ~~Skilled – Restriction of fine movements. The more complex movements are impaired, but there is no restriction upon the performance of common, daily-life movements, even if these are executed slowly or clumsily, antagonistic movements between finger and thumb possible. (10)~~

☐ ~~Useful – Gross movements possible. Delicate movements cannot be performed, but patient can handle and carry objects of at least match-box size, use a fork or a pencil in approximate fashion, can handle a cane or grip a hand rail. (5)~~

☐ ~~Useless – Useful movements impossible. Patient cannot hold or carry objects, even if some elementary movements can be performed. (0)~~

8. Limb/muscle tone:
   a. Upper limb tone:

Right	Left
☐ Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the ~~healthy~~left side, even if the jerk reflexes are exaggerated. (5) ☐ Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the ~~healthy~~left side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)	☐ Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the right side, even if the jerk reflexes are exaggerated. (5) ☐ Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the right side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)

☐ ~~Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the healthy side, even if the jerk reflexes are exaggerated. (5)~~

☐ ~~Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the healthy side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)~~

   b. Lower limb tone:

Right	Left
☐ Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the left side, even if the jerk reflexes are exaggerated. (5) ☐ Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the left side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)	☐ Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the right side, even if the jerk reflexes are exaggerated. (5) ☐ Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the right side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)

☐ ~~Normal – Near Normal. No frank hypertonia or hypotonia in comparison with the healthy side, even if the jerk reflexes are exaggerated. (5)~~

☐ ~~Overtly spastic or flaccid – Frank hypertonia or hypotonia in comparison with the healthy side; permanent rigidity, or flexion or extension induced by painful stimuli. (0)~~

9. Dysphagia (difficulty swallowing):

☐ ~~Yes~~Normal

☐ Partial (swallows solids but not liquids)~~No~~

☐ Severe (cannot swallow, requires NGT feeds and suctioning)

Physical/ Neurological Examination

[Study Name/ID pre-filled]

Site Name:

Subject ID:

- ☐ Unknown

10. Gait:
    - ☐ Steady and brisk
    - ☐ Steady but slowed or widebased
    - ☐ Unsteady but self corrects and low risk of falling
    - ☐ Dangerously unsteady
11. Monocular visual loss:
    - ☐ Normal monocular vision
    - ☐ Partial monocular visual loss or blurring
    - ☐ Complete monocular visual loss or blurring
12. Dizziness~~/ Vertigo~~:
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
13. Vertigo:
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
14. Carotid bruit:
    - ☐ Yes
    - ☐ No
    - ☐ Unknown

If YES, select locality:

- ☐ Left
- ☐ Right
- ☐ Bilateral

If YES, select all that apply:

- ☐ Cranial
- ☐ Ocular
- ☐ Multi-select cervical
- ☐ Subclavicular

Physical/ Neurological Examination CRF Module Instructions

General Instructions

This CRF includes data that describe the results of a physical and/or neurological examination of the study participant/ subject. Such an exam would commonly be conducted at stroke presentation.

Important note: The NIH Stroke Scale is recommended as a Core measure (i.e., strongly recommended for all stroke clinical studies to collect) for assessing neurological impairment.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module. To avoid redundancy, the data elements from the NIH Stroke Scale are not included on this form or in the Data Dictionary but are included separately under the Outcomes and End Points domain and Neurological Impairment sub-domain.

- Mini-Mental State Examination (MMSE) – Record the data and time the MMSE was administered and the total score. The official MMSE version, which is copyright protected, should be ordered from the publisher. Please see Mini-Mental State Examination 2nd Edition for more information.
- Consciousness (assessed by Scandinavian Stroke Scale) – The points associated with the permissible values may be less relevant when the entire Scandinavian Stroke Scale is not being used. This would be an alternative to the NIHSS LOC Items.
- Frontal lobe function: Choose one [derived from the Northern Manhattan Study (NOMAS)].
- Parietal lobe function: Choose one [derived from the Northern Manhattan Study (NOMAS)].
- Orientation (assessed by Scandinavian Stroke Scale) – The points associated with the permissible values may be less relevant when the entire Scandinavian Stroke Scale is not being used. This would be an alternative to the NIHSS LOC Items.
- Hand preference - Choose one - the hand which the participant/subject uses predominantly, not necessarily the hand the participant/subject writes with exclusively. Participants who were originally left handed but forced to switch to right should be coded as left handed.
- Hand strength (assessed by Scandinavian Stroke Scale) – The points associated with the permissible values may be less relevant when the entire Scandinavian Stroke Scale is not being used.
- Hand function (assessed by Orgogozo Stroke Scale) – Numeric scores may not be needed if the full Orgogozo Stroke Scale is not administered.
- Upper limb/muscle tone (assessed by Orgogozo Stroke Scale) – Numeric scores may not be needed if the full Orgogozo Stroke Scale is not administered.
- Lower limb/muscle tone (assessed by Orgogozo Stroke Scale) – Numeric scores may not be needed if the full Orgogozo Stroke Scale is not administered.
- Dysphagia – The use of the term dysphagia should be based on the results of a standardized bedside assessment rather than a reference in the chart.
- Gait – Identify if an assistive device is used such as cane, multipronged cane, walker, etc.
- Vertigo – Indicate if the participant feels the illusion of movement and/or sensation of spinning.
- Carotid bruit – If YES, specify the locality and type(s) of carotid bruit.
- Carotid bruit type – Choose all that apply.

Pre-Hospital/ Emergency Medical Services (EMS) Course

[Study Name/ID pre-filled] Site Name:

Subject ID:

1. Date and Time first call received by EMS: // (m m/dd/yyyy) : (hh:m m, 24 hr clock)
2. Date and Time of EMS dispatch: / / (m m/dd/yyyy) : (hh:m m, 24 hr clock)
3. EMS dispatch priority:
   - ☐ High acuity
   - ☐ Moderate acuity
   - ☐ Other
4. EMS dispatch type/code:
   - ☐ Stroke
   - ☐ Other, specify:
5. From whom/ what were the medical history data obtained? (Choose all that apply.)
   - ☐ Participant/ subject
   - ☐ Friend
   - ☐ Chart/Medical record
   - ☐ Family, specify relation:
   - ☐ Physician
   - ☐ Other, specify:
6. Type of ~~EMS vehicle~~transport to hospital:
   - ☐ Ground ambulance with physician
   - ☐ Ground ambulance no physician
   - ☐ Private transportation/taxi/other from home/scene
   - ☐ By foot
   - ☐ Mobile stroke unit
   - ☐ Air (e.g. Helicopter)
   - ☐ Other
7. Date and Time of EMS arrival at scene: // (m m/dd/yyyy) : (hh:m m, 24 hr clock
8. Date and Time of EMS departure from scene: // (m m/dd/yyyy) : (hh:m m, 24 hr clock
9. Highest level of EMS ~~service~~personnel:
   - ☐ EMT-Basic~~Life SupportLS~~
   - ☐ EMT-Intermediate~~Advanced Life Support~~
   - ☐ EMT-Paramedic
   - ☐ ~~Flight nurse~~
   - ☐ ~~Licensed physicianMD~~
10. Was a pre-hospital stroke identification ~~stroke~~ screen documented by EMS personnel?
    - ☐ Yes

Pre-Hospital/ Emergency Medical Services (EMS) Course

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ No
- ☐ Unknown

11. Was a pre-hospital neurologic impairment screen documented by EMS personnel?
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
12. Indicate the stroke screen tool used:
    - ☐ Cincinnati Prehospital Stroke Scale (CPSS)
    - ☐ Los Angeles Prehospital Stroke Scale (LAPSS)
    - ☐ Melbourne Ambulance Stroke Scale (MASS)~~,~~
    - ☐ Ontario Prehospital Stroke Screening Tool (OPSST)~~,~~
    - ☐ Face Arm Speech Test (FAST)~~.~~
    - ☐ Other, Specify:
    - ☐ Stroke screen tool used, but tool used is unknown
    - ☐ No stroke screen tool used
    - ☐ Not documented
13. Stroke screen outcome:
    - ☐ Positive
    - ☐ Negative
    - ☐ Not documented
14. Indicate the severity scale used:
    - ☐ Cincinnati Stroke Triage Assessment Tool (CSTAT)
    - ☐ Field Assessment Stroke Triage for Emergency Destination (FAST-ED)
    - ☐ Los Angeles Motor Scale (LAMS)
    - ☐ Rapid Arterial Occlusion Evaluation (RACE)
    - ☐ Other, Specify:
    - ☐ Severity scale used, but tool used is unknown
    - ☐ No severity scale used
    - ☐ Not documented
15. Positive for Large Vessel Occlusion (LVO):
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
16. If severity scale assessment completed, enter total score:
    - ☐ Not documented

Pre-Hospital/ Emergency Medical Services (EMS) Course

[Study Name/ID pre-filled] Site Name:

Subject ID:

17. Type of residence (choose one):
    - ☐ Home
    - ☐ Hospital
    - ☐ Rehabilitation center
    - ☐ Nursing home
    - ☐ N/A – patient died
    - ☐ Unknown
    - ☐ Other, specify:

PRE-HOSPITAL GLASGOW COMA SCORE (GCS)

1. GCS Best Motor Response:
   - ☐ 6 - Obeys commands fully
   - ☐ 5 - Localizes to noxious stimuli
   - ☐ 4 - Withdraws from noxious stimuli
   - ☐ 3 - Abnormal flexion, i.e. decorticate posturing
   - ☐ 2 - Extensor response, i.e. decerebrate posturing
   - ☐ 1 - No response
2. GCS Best Verbal Response:
   - ☐ 5 - Alert and Oriented
   - ☐ 4 - Confused, yet coherent, speech
   - ☐ 3 - Inappropriate words and jumbled phrases consisting of words;
   - ☐ 2 - Incomprehensible sounds
   - ☐ 1 - No sounds
3. GCS Best Eye Opening:
   - ☐ 4 - Spontaneous eye opening
   - ☐ 3 - Eyes open to speech
   - ☐ 2 - Eyes open to pain
   - ☐ 1 - No eye opening
4. GCS Total Score: (3 – 15)**

PRE-HOSPITAL LOS ANGELES MOTOR SCALE (LAMS)

1. LAMS Facial Smile/ Grimace: [0 = Normal / Facial droop absent; 1 = Facial droop present (right and/or left side)]

   If not normal, check all that apply:

   - ☐ ~~Right~~ Droop on right side of face
   - ☐ ~~Left~~ Droop on left side of face
2. LAMS Grip: [0 = Normal grip strength; 1 = Weak grip (right and/or left side); 2 = No grip (right and/or left side)]

   If not normal, check all that apply:

   - ☐ ~~Right~~ Weak Grip with right hand
   - ☐ ~~Right~~No Grip with right hand
   - ☐ ~~Left~~ Weak Grip with left hand

☐ ~~Left~~ No Grip with left hand

3. LAMS Arm Strength: [0 = Arm drift absent; 1 = Arm (left and/or right) drifts down; 2 = Arm (left and/or right) falls rapidly]

   If not normal, check all that apply:

   ☐ Right arm drifts down and does not fall immediately~~Drift Down~~

   ☐ Right arm f~~F~~alls ~~Rapidly~~rapidly

   ☐ Left arm drifts down and does not fall immediately~~Drift Down~~

   ☐ Left arm f~~F~~alls rapidly~~Rapidly~~

4. LAMS Total Score: (0 – 5)

Pre-Hospital/ Emergency Medical Services (EMS) Course CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements that are collected before the study participant/ subject is seen at a hospital for the stroke event. The majority of the data elements relate to the emergency medical services (EMS) course. The Glasgow Coma Scale (GCS) and Los Angeles Motor Scale (LAMS) are included to record information about the participant's/ subject's neurological impairment prior to being admitted at a hospital.

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~~ Most of the data elements are supplemental and should only be collected if the research team considers them appropriate for their study.

The GCS score is Supplemental- Highly Recommended for based on study type, disease stage and disease type. Please refer to Start-Up document for details.

Specific Instructions

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

- Date and Time first call received by EMS – This data element is looking to capture the date and time that EMS was first called to the scene of the stroke (and not meant to capture those patients that are transferred between hospitals via EMS). If a patient is transported by EMS from the scene of the stroke to an outside hospital and is then transferred to EMS to your hospital, enter the time when the first call was received by the EMS.
- Date and Time first call received by EMS – No additional instructions
- Date and Time of EMS dispatch – No additional instructions
- EMS dispatch priority – No additional instructions
- EMS dispatch type/code – No additional instructions
- From whom/ what were the medical history data obtained? – Choose all that apply.
- Type of transport to hospital – This refers to the method of transport to your hospital, not to the method of initial transport to another facility if the patient was subsequently transferred to your hospital.
- ~~Type of EMS vehicle – No additional instructions~~
- Date and Time of EMS arrival at scene – This data element refers to the original scene and is not applicable to inter-facility transport or to patients arriving by means other than EMS. Note that EMS includes response by volunteer and professional paramedics, EMTs, fire, police and other municipal service officers responding to 911 calls.
- Date and Time of EMS departure from scene – No additional instructions
- Highest level of EMS personnel~~service~~ – Choose only one response. ~~BLS = Basic Life Support. ALS = Advanced Life Support. MD = physician.~~
- Was a pre-hospital stroke identification ~~stroke~~ screen documented by EMS personnel? – Pre-hospital stroke identification screens are defined as published validated screening algorithms or those required by state EMS agencies (e.g., LAPSS, CPSS, MASS, etc.).
- Was a pre-hospital neurologic impairment screen documented by EMS personnel? – Pre-hospital neurologic impairment scales are defined as published validated scales or those required by state EMS agencies (e.g., GCS for suspected hemorrhagic stroke or any stroke with impaired consciousness, Los Angeles Motor Scale, etc.).
- Indicate the stroke screen tool used – Choose only one response.
- Stroke screen outcome – Choose only one response.
- Indicate the severity scale used – Choose only one response.

Pre-Hospital/ Emergency Medical Services (EMS) Course CRF Module Instructions

- Positive for Large Vessel Occlusion (LVO) – Choose only one response.
- If severity scale assessment completed, enter total score – Enter severity scale total score or~~f~~ check "Not documented".
- Type of residence – Choose only one response.
- Glasgow Coma Score (GCS) – Intubation and severe facial/eye swelling or damage make it impossible to test the verbal and eye responses. ~~In these circumstances, the score is given as 1 with a modifier attached e.g. 'E1c' where 'c' = closed, or 'V1t' where t = tube. A composite might be 'GCS 5tc'. This would mean, for example, eyes closed because of swelling = 1, intubated = 1, leaving a motor score of 3 for 'abnormal flexion'. Often the 1 is left out, so the scale reads Ec or Vt.~~
- Los Angeles Motor Scale (LAMS) – Select the check boxes and also choose the appropriate numeric score according to the scoring instructions that appear in brackets ([ ]).

Vital Signs

[Study Name/ID pre-filled] Site Name:

Subject ID:

1) *Date and time (M M/D D/Y Y Y Y / H H: M M):
   ☐ am
   ☐ pm
   ☐ 24-hour clock
2) *Heart rate/Pulse (beats per minute):
3) *Blood pressure (BP) mmHg (systolic/ diastolic):
   Participant's/Subject's Position:
   ☐ Sitting
   ☐ Standing
   ☐ Supine
4) **Temperature:
   ☐ ○F
   ☐ ○C
   Temperature method:
   ☐Oral
   ☐Rectal
   ☐Axillary
   ☐Tympanic
   ☐Bladder
   ☐Esophageal
   ☐Brain
   ☐Other, specify:
5) **Respiratory rate (breaths per minute):
6) **Oxygen saturation (%):
7) **Weight:
   ☐ pounds (lb)
   ☐ kilograms (kg)
8) **Height:
   ☐ inches (in)
   ☐ centimeters (cm)
9) Head circumference:
   ☐ inches (in)
   ☐ centimeters (cm)
10) Waist circumference:
   ☐ inches (in)
   ☐ centimeters (cm)
11) Hip circumference:
   ☐ inches (in)
   ☐ centimeters (cm)
12) Waist-Hip Ratio:
13) Body Mass Index (BMI) kg/m:

Vital Signs

[Study Name/ID pre-filled] Site Name:

Subject ID:

ADDITIONAL CRITICAL CARE MEASUREMENTS

1) Intracranial pressure (mmHg):
2) Central venous pressure (CVP):
   ☐ mmHg ☐ cm H^2O
3) Cardiac output (Liters per minute (L/min)):
4) Pulmonary artery wedge pressure (mmHg):
5) Systemic vascular resistance:
   ☐ dyn·s/cm^{-5} ☐ mmHg·min/L (~ HRU/Woods units)
   ☐ MPa·s/m^3
6) Partial pressure of oxygen in brain tissue (mmHg):
7) Respiratory support type:
   ☐ Bag/mask ventilation
   ☐ BiPAP
   ☐ CPAP
   ☐ Mechanical ventilation
   ☐ No support needed
   ☐ Oral airway
8) Respiration type:
   ☐ Apneic
   ☐ Spontaneous regular
   ☐ Spontaneous irregular
   ☐ Non-assemble due to mechanical ventilation
   ☐ Unknown
9) Airway treatment type:
   ☐ Endotracheal intubation
   ☐ Supraglottic adjunctive airway
   ☐ Tracheostomy
   ☐ No specific treatment
   ☐ Unknown

Vital Signs CRF Module Instructions

General Instructions

Vital signs are likely to be captured at study visits to help monitor the health of the participant/ subject and in clinical trials to help assess the safety of the intervention.

Height and weight are commonly collected at the baseline visit. Depending on the study population and/or the protocol it may or may not be appropriate to collect height and weight at subsequent study visits.

Important note: Some of the vital signs and other measurements on this CRF Module are considered Core (i.e., strongly recommended for all stroke clinical studies to collect).

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

*Element is classified as Core if protocol includes imaging

** Element is classified as Supplemental – Highly Recommended

Specific Instructions

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

- Heart rate/ Pulse – Measure heart rate in beats per minute (bpm).
- Blood Pressure – Measure blood pressure in mmHg. Blood pressure is the ratio of systolic to diastolic.
- Temperature – It is important to record whether the temperature is measured in degrees Celsius (°C) or degrees Fahrenheit (°F).It may also be important to record the location where the temperature measurement was made.
- Temperature method– Choose one.
- Respiratory rate – Measure respiratory rate in breaths per minute.
- Oxygen saturation – Record the value as a percent (%)
- Height – It is important to record the units used to measure height. Height and weight measurements can be used to calculate BMI (body mass index).
- Weight – It is important to record the units used to measure weight. Height and weight measurements can be used to calculate BMI (body mass index).
- Body Mass Index (BMI) – BMI is not ~~include~~included on the CRF because it is derived using the height and weight data and should be automatically calculated by a database/ data system.
- Head circumference – It is important to record the units used to measure head circumference.
- Waist circumference – It is important to record the units used to measure waist circumference. Waist circumference and hip circumference can be used to calculate the waist-hip ratio.
- Hip circumference – It is important to record the units used to measure hip circumference. Waist circumference and hip circumference can be used to calculate the waist-hip ratio
- Waist-hip ratio –Derived using the waist circumference and hip circumference data and should be automatically calculated by a database/ data system.
- Intracranial pressure – Measure intracranial pressure in mmHg.
- Central venous pressure (CVP) – It is important to record the units used to measure CVP.
- Cardiac output – Measure cardiac output in liters per minute (L/min or LPM).
- Pulmonary artery wedge pressure (PAWP) – Measure PAWP in mmHg.
- Systemic vascular resistance – It is important to record the units used to measure systemic vascular resistance.
- Partial pressure of oxygen in brain tissue – Measure partial pressure of oxygen in brain tissue in mmHg.
- Respiratory support type – Choose all that apply.
- Respiration type – Choose one.

Vital Signs CRF Module Instructions

- Airway treatment type – Choose all that apply.