1. \*Date and time (M M/D D/Y Y Y Y / H H: M M):

am

pm

24-hour clock

1. \*Heart rate/Pulse (beats per minute):
2. \*Blood pressure (BP) mmHg (systolic/ diastolic):

Participant’s/Subject’s Position:

Sitting

Standing

Supine

1. \*\*Temperature:

○F

○C

Temperature method:

Oral

Rectal

Axillary

Tympanic

Bladder

Esophageal

Brain

Other, specify:

1. \*\*Respiratory rate (breaths per minute):
2. \*\*Oxygen saturation (%):
3. \*\*Weight:

pounds (lb)

kilograms (kg)

1. \*\*Height:

inches (in)

centimeters (cm)

1. Head circumference:

inches (in)

centimeters (cm)

1. Waist circumference:

inches (in)

centimeters (cm)

1. Hip circumference:

inches (in)

centimeters (cm)

1. Waist-Hip Ratio:
2. Body Mass Index (BMI) kg/m:

## Additional Critical Care Measurements

1. Intracranial pressure (mmHg):
2. Central venous pressure (CVP):

mmHg

cm H2O

1. Cardiac output (Liters per minute (L/min)):
2. Pulmonary artery wedge pressure (mmHg):
3. Systemic vascular resistance:

dyn·s/cm-5

MPa·s/m3

mmHg·min/L (~ HRU/Woods units)

1. Partial pressure of oxygen in brain tissue (mmHg):
2. Respiratory support type:

Bag/mask ventilation

BiPAP

CPAP

Mechanical ventilation

No support needed

Oral airway

1. Respiration type:

Apneic

Spontaneous regular

Spontaneous irregular

Non-assemble due to mechanical ventilation

Unknown

1. Airway treatment type:

Endotracheal intubation

Supraglottic adjunctive airway

Tracheostomy

No specific treatment

Unknown

## 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](https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/Stroke/CDEStartupResource_Stroke.pdf) document for details.

\*Element is classified as Disease Core

\*\*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 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 – Measure the waist circumference at the end of several consecutive natural breaths, at a level parallel to the floor, midpoint between the top of the iliac crest and the lower margin of the last palpable rib in the mid axillary line. Make the measurement with a stretch‐resistant tape that is wrapped snugly around the subject, but not to the point that the tape is constricting. Keep the tape level and parallel to the floor at the point of measurement. Ensure that the subject is standing upright during the measurement, with arms relaxed at the side, feet evenly spread apart and body weight evenly distributed.
* Hip circumference – Measure the hip circumference at a level parallel to the floor, at the largest circumference of the buttocks. Make the measurement with a stretch‐resistant tape that is wrapped snugly around the subject, but not to the point that the tape is constricting. Keep the tape level and parallel to the floor at the point of measurement. Ensure that the subject is standing upright during the measurement, with arms relaxed at the side, feet evenly spread apart and body weight evenly distributed. 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.
* Airway treatment type – Choose all that apply.