1. Date and Time\*
2. Heart Rate/ Pulse (beats per minute)
3. Respiratory Rate (breaths per minute)
4. Blood Pressure\* (millimeters of mercury): systolic: diastolic:

Participant’s/Subject’s Position: Sitting  Standing  Supine

1. Temperature:  degrees Fahrenheit degrees Celsius

Temperature Method: Oral Rectal  Axillary  Tympanic

1. Weight\*:  pounds  kilograms
2. Height/Length\*:  inches  centimeters
3. Body Mass Index (BMI) (kilograms per square meter):

\*Element classified as Core.

## GENERAL INSTRUCTIONS

Vital signs are likely to be captured at study visits to help monitor the health of study participants/subjects and possibly to assess the safety of the intervention.

Height and weight are commonly collected at the baseline visit. Depending on the study population and study intervention it may be appropriate to collect height and weight at subsequent study visits.

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

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

* Date and Time – Record the date vital signs are taken. If the exact month/day is not known, some "unknown" convention should be used. Record the time vital signs are taken. If the exact time is not known, some "unknown" convention should be used. From study inception, specify the manner in which time will be collected. If a twelve hour clock is used, then AM or PM must be designated. If it is your institution’s custom to use military time (24-hour clock), that designation will not be necessary.
* Heart Rate/ Pulse – Record the pulse of the participant/subject in beats per minute.
* Respiratory Rate – Record the respiratory rate of the participant/subject in breaths per minute.
* Blood Pressure – Record the systolic and diastolic blood pressure (systolic / diastolic) of the participant/subject.
* Participant’s/Subject’s Blood Pressure Position – Record the position the participant/subject was in when blood pressure was taken.
* Temperature – Record the temperature of the participant/subject. Also indicate the scale used to capture temperature.
* Temperature Method – Record the location where the temperature was measured (Oral, Rectal, Axillary, or Tympanic).
* Weight – Record the weight of the participant/subject. To be collected at the visit, not self-reported. Also, indicate whether weight was measured in pounds (lbs) or kilograms (kg).
* Height/Length – Record the height of the participant/subject. To be collected at the visit, not self-reported. Also, indicate whether height was measured in inches (in) or centimeters (cm).
* Body Mass Index (BMI) – This is a derived field that can be calculated from Weight and Height