1. \*Date and Time:  AM  PM  24-hour clock
2. Heart Rate/ Pulse: (#) beats per minute
3. \*Blood pressure:
   1. First reading:
   2. Blood pressure: ( ) / ( ) mmHg (systolic/diastolic)
   3. Blood pressure measurement position: (please specify)

Supine  Sitting (preferred position)  Standing

* 1. Second reading:

1. Blood pressure: ( ) / ( ) mmHg (systolic/diastolic)
2. Blood pressure measurement position: (please specify)

Supine  Sitting (preferred position)  Standing

* 1. Third reading:

1. Blood pressure: ( ) / ( ) mmHg (systolic/diastolic)
2. Blood pressure measurement position: (please specify)

Supine  Sitting (preferred position)  Standing

1. Temperature:
   1. Temperature: (please specify) °F  °C
   2. Temperature measurement location (Choose one):

Oral

Rectal

Tympanic

Axillary

Forehead Cutaneous Infrared

Other, specify:

1. Respiratory rate: (please specify) breaths per minute
2. Oxygen saturation: (please specify) %
3. \*Weight and Height Measurements:
   1. Weight: (please specify) Pounds (lb)  Kilograms (kg)
4. Measurement type (Choose one):  Self-reported  Measured
5. Weight percentile (Pediatric ONLY): (please specify)
   1. Height : (please specify)  Inches (in)  Centimeters (cm)
6. Measurement type (Choose one):  Self-reported  Measured
7. Height percentile (Pediatric ONLY): (please specify)
   1. Weight-height ratio: [derived field]:
8. Body Mass Index (BMI) Measurements:
   1. BMI: [derived field]
   2. Measurement type (Choose one):

Self-reported

Measured

Mixed (e.g., Height/Weight measured and the other self-reported)

* 1. BMI percentile (Pediatric ONLY): (please specify)

1. Waist and Hip Measurements:
   1. Waist circumference: (please specify)  Inches (in)  Centimeters (cm)
   2. Hip circumference: (please specify)  Inches (in)  Centimeters (cm)

## Additional Pediatric-specific Elements

This element is recommended for pediatric studies.

1. Head circumference: (please specify) Inches (in)  Centimeters (cm)

\*Element is classified as Core

### **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: There are a few vital signs and other measurements on this CRF Module which are considered Core (i.e., required for recommended for all headache clinical studies to collect). The remaining measurements 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 and time – Record the date vital signs are 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. Not every study will need to collect time and this field should be removed if not applicable.
* Heart Rate/ Pulse – Measure in beats per minute (bpm).
* Blood Pressure – Measure in mmHg. The preferred position for measuring blood pressure is sitting. Blood pressure is the ratio of systolic to diastolic. It is recommended that standard operating procedures be developed for measuring blood pressure in your study. The Atherosclerosis Risk in Communities (ARIC) and Multi-Ethnic Study of Atherosclerosis (MESA) studies offer examples on their Web sites of the procedures they used for measuring blood pressure. Both of these studies measured blood pressure more than once (e.g., three times) at a given study visit.
  + Please refer to the manuals posted on [Atherosclerosis Risk in Communities Study](https://www2.cscc.unc.edu/aric/) and The Multi-Ethnic Study of Atherosclerosis (MESA)
* Temperature – Indicate the units used to measure temperature – degrees Celsius (°C) or degrees Fahrenheit (°F).
* Temperature measurement location – Choose one.
* Respiratory rate – Measure in breaths per minute.
* Oxygen saturation – No additional instructions.
* Weight type – Choose one.
* Weight – Indicate the units used to measure weight – Pounds (lb) or Kilograms (km). Height and weight measurements can be used to calculate BMI (body mass index).
* Weight percentile – For pediatric participant’s/subject’s until 18 year of age only. Indicate the weight percentile.
* Height type – Choose one.
* Height – Indicate the units used to measure height – Inches (in) or Centimeters (cm). Height and weight measurements can be used to calculate BMI (body mass index).
* Height percentile – For pediatric participant’s/subject’s until 18 year of age only. Indicate the height percentile.
* BMI type – No additional instructions.
* BMI – BMI is derived using the height and weight data recorded above and can be automatically calculated by a database/data system.
* BMI percentile – For pediatric participant’s/subject’s until 18 year of age only. Indicate the BMI percentile.
* Waist circumference – Indicate the units used to measure waist circumference – Inches (in) or Centimeters (cm). Waist circumference and hip circumference can be used to calculate the waist-hip ratio.
* Hip circumference – Indicate the units used to measure hip circumference – Inches (in) or Centimeters (cm). Waist circumference and hip circumference can be used to calculate the waist-hip ratio.
* Head circumference – For pediatric participant’s/subject’s until 18 year of age only. Indicate the units used to measure head circumference – Inches (in) or Centimeters (cm).