1. Vital sign date and time\*: (m m / d d / y y y ) am pm 24-hour clock
2. \*Heart rate/pulse:\* (beats per minute):
3. \*Respiratory Rate:\* (beats per minute):
4. Respiratory Pattern: Normal Abnormal
5. Systolic blood pressure measurement (mmHg):
6. Diastolic blood pressure measurement (mmHg):

Blood pressure (/diastolic) measurement position: Sitting Standing Supine

1. Temperature measurement:\* ○F ○C

Temperature method:

Oral

Rectal

Axillary

Tympanic

Cutaneous Infrared

Other, specify:

1. \*Weight measurement:\* Pounds Kilograms
2. Standing Height: Inches Centimeters
3. Recumbent Length: Inches Centimeters
4. Ulna length: Inches Centimeters
5. Birth Weight: Pounds Kilograms Unknown
6. Birth Length: Inches Centimeters Unknown
7. \*Body Mass Index (BMI) [derived field] kg/m2

\*Elements is 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.

## 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 – Record the heart rate/pulse of the participant/subject in beats per minute.
* Respiratory rate – Record the respiratory rate of the participant/subject in breaths per minute.
* Respiratory pattern – Choose one.
* Systolic Blood Pressure – Record the systolic blood pressure of the participant/subject. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Diastolic Blood Pressure – Record the diastolic blood pressure of the participant/subject. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Participant’s/Subject’s Blood Pressure Position – Record the position the participant/subject was in when blood pressure was measured. Standing blood pressure is an optional element and should only be recorded as needed.
* Temperature – Record the temperature of the participant/ subject in degrees C or F.
* Temperature method – Record the location where the temperature was measured. Choose one. This element is most relevant to pediatric clinical studies.
* Weight –To be collected at the visit, not self-reported. Choose either pounds (lb) or kilograms (kg).
* Height or length – Indicate the type of height/length measured and then record the measurement along with the associated units. Choose either inches (in) or centimeters (cm).
* Standing Height- Record the height of the participant/subject in centimeters when standing. To be collected at the visit, not self-reported. If standing height not possible to take or inaccurate, collect ulna length.
* Recumbent Length- Record the recumbent length of the participant/subject in inches or centimeters. To be collected at the visit, not self-reported.
* Ulna Length- Record in inches or centimeters.
* BMI – This value should be derived/calculated using the height and weight measurements. Formula: weight (kg) / [height (m)]2 OR weight (lb) / [height (in)]2 x 703.