1. **[\*](#Core" \o "Element is classified as Core)**Date and Time:(mm/dd/yyyy) , (hh:mm)
2. [**\***](#Core)Heart Rate or Pulse (beats per minute): (please specify)
3. \*\*Blood Pressure (millimeters of mercury): systolic: (please specify) / diastolic: (please specify)
4. \*\*Temperature: (please specify)  degrees Fahrenheit  degrees Celsius
5. \*\*Respiratory Rate (breaths per minute):(please specify)
6. Oxygen Saturation (percent): (please specify)
7. \*\*Weight: (please specify)  pounds  kilograms
8. \*\*Height or Length:(please specify)  inches  centimeters
9. Body Mass Index (BMI):(please specify)  pounds per square inch  kilograms per square meter
10. Heart Rhythm:(please specify)

Normal sinus rhythm

Sinus tachycardia

Sinus bradycardia

Atrial arrhythmia

Ventricular arrhythmia

## 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 pulse of the participant/subject in beats per minute.
* Blood Pressure–Record the systolic and diastolic blood pressure (systolic / diastolic) of the participant/subject.
* Temperature–Record the temperature of the participant/subject. Also indicate the scale used to capture temperature.
* Respiratory Rate–Record the respiratory rate of the participant/subject in breaths per minute.
* Oxygen Saturation–Record the oxygen saturation as a percentage.
* 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–Indicate whether body mass index was measured in pounds per square inch (lb/in2) or kilogram per square meter (kg/m2).
* Heart Rhythm–No additional instructions.

\* Element is classified as Core

\*\* Element is classified as Supplemental – Highly Recommended