1. Date and time:

am

pm

24-hour clock

1. Heart rate/pulse (beats per minute):
2. Respiratory rate (breaths per minute):
3. Blood pressure (systolic/diastolic) mmHg:

Blood pressure cuff size:  Centimeters  Inches

Participant’s position:

Sitting

Standing

Supine

1. Temperature:

○F

○C

Temperature method:

Oral

Rectal

Axillary

Tympanic

Forehead Cutaneous Infrared

Other, specify:

Recorder Signature: Date:

## General Instructions

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

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all mitochondrial disease clinical studies to collect). All of the data elements are classified as Supplemental 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. 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 an unambiguous format acceptable to the study database like DD-MMM-YYYY. When date/time data are prepared for aggregation or sharing, they should be converted to the format specified by [ISO 8601](https://www.iso.org/iso-8601-date-and-time-format.html);  YYYY-MM-DD T:hh:mm:ss.
* Pulse – Record the pulse of the participant in beats per minute.
* Respiratory rate – Record the respiratory rate of the participant in breaths per minute.
* Blood pressure systolic measurement – Record the systolic blood pressure of the participant. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Blood pressure diastolic measurement - Record the diastolic blood pressure of the participant. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Blood pressure cuff size – Record the blood pressure cuff size and indicate whether the size is in centimeters or inches. Use a consistent size throughout the trial that is appropriate for the participant’s age and stature.
* Blood pressure position – Record the position the participant was in when blood pressure was measured. The position should be justified based on the participant symptoms such as orthostatic hypotension or dysautonomia.
* Temperature – Record the temperature of the participant. Also indicate the scale used to capture temperature.
* Temperature unit of measure – Choose either F (degrees Fahrenheit) or C (degrees Celsius).
* Temperature method – Choose one. Record the location where the temperature was measured. This element is most relevant to pediatric clinical studies.