Vital Signs (all)

1. Date and Time (m m /d d/ y y y y):

am

pm

24-hour clock

1. Heart Rate/Pulse (beats per minute):
2. Respiratory Rate (breaths per minute):
3. Blood Pressure (systolic/diastolic) mmHg:

Participant’s/Subject’s Position:

Sitting

Standing

Supine

1. Temperature:

○F

○C

Temperature Method:

Oral

Rectal

Axillary

Tympanic

Bladder

Esophageal

Brain

Other, specify:

Anthropometrics (≥ 21 years of age)

1. Weight:

Pounds

Kilograms

1. Height:

Inches

Centimeters

## BMI:

BMI categorization:

Anthropometrics (< 21 years of age)

Use these elements for pediatric studies.

1. Weight: %tile:

Pounds  Kilograms

1. Length (infants < 24 mo) %ile, Z-score, standard used:

Inches  Centimeters

1. Height (children > 2 years) %ile, Z-score, standard used:

Inches  Centimeters

1. Weight/length (infants < 24 mo) %ile, Z-score, standard used:
2. BMI (children > 2 years) %ile, Z-score, standard used:
3. Head Circumference:

Inches  Centimeters

1. Head Circumference %ile, Z-score, standard used:
2. Tanner Stage (pubic hair):

I II III IV V

1. Tanner Stage (genitalia):

I II III IV V

## 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. Because different measurement techniques and standards for assessing height and weight are used in pediatrics as compared to in adults, this form separates data collection into pediatric and adult standards..

Important note: For studies focused on growth, nutrition, and endocrine or gastrointestinal disease in children and adults with mitochondrial disease, data elements included on this CRF are considered Supplemental – Highly Recommended (i.e., strongly recommended to collect). For other studies, these data elements may be supplemental, as they are frequently needed clinical trials, and should 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.
* 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 systolic measurement– Record the systolic blood pressure of the participant/ subject. 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/ subject. The standard unit for measuring blood pressure is mmHg, which is approximately equivalent to Torr.
* Blood pressure position – Record the position the participant/subject was in when blood pressure was measured.
* Temperature – Record the temperature of the participant/subject. 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.
* Anthropometrics, Adults (≥ 21 years of age)
* Weight – Obtain weight of the participant/subject in light clothing without shoes and record. To be collected at the visit, not self-reported. Also, indicate whether weight was measured in pounds (lb) or kilograms (kg).
* Weight unit of measure – Choose either pounds (lb) or kilograms (kg).
* Height – Measure the height of the participant/subject using a fixed statiometer and record. To be collected at the visit, not self-reported. Also, indicate whether height was measured in inches (in) or centimeters (cm).
* Height unit of measure – Choose either inches (in) or centimeters (cm)
* Body Mass Index (BMI) – calculate BMI [National Heart, Lung and Blood Institute BMI Calculator](http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm)) –OR-

BMI = weight (lb) \* 703 ÷ height2 (in2)

weight (kg) ÷ height2 (m2)

* BMI Categories:   
  Underweight = <18.5  
  Normal weight = 18.5–24.9   
  Overweight = 25–29.9   
  Obesity = BMI of 30 or greater

30 to 34.99 Obesity (Class 1)

35 to 39.99 Obesity (Class 2)

40 or greater Morbid Obesity

Anthropometrics, Pediatric (< 21 years of age)

* Weight – Obtain weight of the participant/subject in light clothing without shoes and record. Infants should be weighed in a pan scale and children older than 2 years on a beam balance scale. To be collected at the visit, not self-reported. Also, indicate whether weight was measured in pounds (lb) or kilograms (kg).
* Weight unit of measure – Choose either pounds (lb) or kilograms (kg).
* Length/Height – Measure recumbent length (for children < 2 years) using a length board or standing height (for children > 2 years) using a fixed statiometer and record. To be collected at the visit, not self-reported. Also, indicate whether height was measured in inches (in) or centimeters (cm).
* Length/Height unit of measure – Choose either inches (in) or centimeters (cm)
* Body Mass Index (BMI, index of adiposity in children ages 2 years and older) –calculate using [National Heart, Lung and Blood Institute BMI Calculator](http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm)), that is:

BMI = weight (lb) \* 703 ÷ height2 (in2)

weight (kg) ÷ height2 (m2)

* Head circumference measurement – Using a flexible, non-stretchable tape, measure over the most prominent part of the occiput and just above the supraorbital ridges (this is the largest part of the head). Record the head circumference of the participant/ subject as well as the units for the measurement
* Head circumference unit of measure – Choose only one unit

Application of Growth Standards

Use WHO (http://www.who.int/childgrowth/standards) and CDC growth charts ([Centers for Disease Control and Prevention Growth Charts](http://www.cdc.gov/growthcharts/)) to determine %iles and Z-scores for age and sex. (In order to allow pooling of observational and clinical trials data across diverse populations, use of international standards is favored over country-specific standards.) Z-scores correspond approximately to standard deviations above or below the median or mean, and may provide additional information, particularly at the extremes of the distributions. Detailed references on the development of WHO standards are provided.1,2,3 Briefly, for infants under age 2 years, all percentiles should be derived from WHO 2006 standards. There is no “standard” metric to assess overweight in children under age 2 years, but weight-for-length %ile is most frequently used for this purpose.4 For children ages 2 years to < 5 years, there are two options. CDC 2000 continues to be used in most circumstances. WHO 2007 standards (designed to assess children under “optimal environmental conditions”) also exist for this age group, but it remains to be determined when these are most appropriate to use. Additional details are beyond the scope of this guidance, but can be found in the links included and references below.

| Measurement | Under 2 years | 2 - < 5 years | 5 - < 21 years |
| --- | --- | --- | --- |
| Weight-for-age | WHO 2006 | CDC 2000 | CDC 2000 |
| Length-for-age | WHO 2006 | CDC 2000 | CDC 2000 |
| Height-for-age | WHO 2006 | CDC 2000 | CDC 2000 |
| Weight-for-length | WHO 2006 | - | - |
| Body Mass Index | \* | CDC 2000 | CDC 2000 |
| Head circumference | WHO 2006 | CDC 2000 (through age 3 years, then PMID: 20304425)\*\* | PMID: 20304425\*\* |

\*BMI not a currently used metric of adiposity in this group, although these standards exist (WHO 2006).

\*\* Note that an additional reference is cited that can be used for estimating percentiles for head circumference in older children (these are derived from United States standards, and so may not be generalizable to other populations). For adults, head circumference percentiles can be estimated using a different reference (PMID: 1444530), although these are obtained from British centers, and thus may not be generalizable.

Detailed variable descriptions follow for application of anthropometric standards.

Weight

* Weight %ile (under 2 years, adjust for gestational age), standard used
* Weight Z-score (under 2 years, adjust for gestational age), standard used

Length, Height

* Length %ile (under 2 years, adjust for gestational age), standard used
* Length Z-score (under 2 years, adjust for gestational age), standard used
* Height %ile (over 2 years), standard used
* Height Z-score (over 2 years), standard used

Weight-for-length, BMI

* Weight for length %ile (index of adiposity in children < 2 years), standard used
* Weight for length Z-score (index of adiposity in children < 2 years), standard used
* BMI %ile, standard used
* BMI Z-score, standard used

Head Circumference

* Head circumference %ile, standard used
* Head circumference Z-score, standard used

Sexual Maturation

Tanner Stage Definitions

* Pubic hair (both male and female)
* Tanner I
  + no pubic hair at all (prepubertal Dominic state) [typically age 10 and younger]
* Tanner II
  + small amount of long, downy hair with slight pigmentation at the base of the penis and scrotum (males) or on the labia majora (females) [10–11.5]
* Tanner III
  + hair becomes more coarse and curly, and begins to extend laterally [11.5–13]
* Tanner IV
  + adult-like hair quality, extending across pubis but sparing medial thighs [13–15]
* Tanner V
  + hair extends to medial surface of the thighs [15+]
* Genitals (male)
* Tanner I
  + prepubescent (testicular volume less than 1.5 ml; small penis of 3 cm or less) [typically age 9 and younger]
* Tanner II
  + testicular volume between 1.6 and 6 ml; skin on scrotum thins, reddens and enlarges; penis length unchanged [9-11]
* Tanner III
  + testicular volume between 6 and 12 ml; scrotum enlarges further; penis begins to lengthen to about 6 cm [11-12.5]
* Tanner IV
  + testicular volume between 12 and 20 ml; scrotum enlarges further and darkens; penis increases in length to 10 cm and circumference [12.5-14]
* Tanner V
  + testicular volume greater than 20 ml; adult scrotum and penis of 15 cm in length [14+]
* Breasts (female)
* Tanner I
  + no glandular tissue: areola follows the skin contours of the chest (prepubertal) [typically age 10 and younger
* Tanner II
  + breast bud forms, with small area of surrounding glandular tissue; areola begins to widen [10-11.5]
* Tanner III
  + breast begins to become more elevated, and extends beyond the borders of the areola, which continues to widen but remains in contour with surrounding breast [11.5-13]
* Tanner IV
  + increased breast size and elevation; areola and papilla form a secondary mound projecting from the contour of the surrounding breast [13-15]
* Tanner V
  + breast reaches final adult size; areola returns to contour of the surrounding breast, with a projecting central papilla. [15+]

CITATIONS

1. Onyango AW. [World Health Organization child growth standards: background, methodology and main results of the Multicentre Growth Reference Study]. Archives de pediatrie : organe officiel de la Societe francaise de pediatrie. 2009;16(6):735-6. Epub 2009/06/23. doi: 10.1016/S0929-693X(09)74131-4. PubMed PMID: 19541149.
2. de Onis M, Siyam A, Borghi E, Onyango AW, Piwoz E, Garza C. Comparison of the World Health Organization growth velocity standards with existing US reference data. Pediatrics. 2011;128(1):e18-26. Epub 2011/06/29. doi: 10.1542/peds.2010-2630. PubMed PMID: 21708799.
3. de Onis M, Onyango A, Borghi E, Siyam A, Blossner M, Lutter C. Worldwide implementation of the WHO Child Growth Standards. Public health nutrition. 2012;15(9):1603-10. Epub 2012/06/22. doi: 10.1017/S136898001200105X. PubMed PMID: 22717390.
4. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. JAMA : the journal of the American Medical Association. 2014;311(8):806-14. Epub 2014/02/27. doi: 10.1001/jama.2014.732. PubMed PMID: 24570244.