Date of Exam:

1. \*Hand preference: (Hand participant/subject uses predominately, not necessarily hand he/she writes with exclusively)

Left hand

Right hand

Both hands

Unknown

Not Established

1. Was a physical exam performed on the participant/subject?

Yes (Specify results below)

No

1. Tanner Stage: I II III IV  V

Unknown

Physical Exam Table

| Body System | Result | Describe Abnormality or Comment if Body System is Not Examined | If Abnormality, Clinically Significant? |
| --- | --- | --- | --- |
| Constitutional symptoms (e.g., fever, weight loss) | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Eyes | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Ears, Nose, Mouth, and Throat | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Cardiovascular | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Respiratory | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Gastrointestinal | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Genitourinary | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Musculoskeletal | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Integumentary (skin and/or breast) | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Neurological | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Psychiatric | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Endocrine | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Hematologic/Lymphatic | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Allergic/Immunologic | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Hepatobiliary | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |

\*Element is classified as Core.

## **General Instructions**

The physical exam is generally administered at screening and/or baseline to determine study eligibility. It may also be administered at follow-up visits to track a participant’s/subject’s physical status.

## **Specific Instructions**

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

Important note: Some of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). The other data elements are supplemental and should be collected on clinical trials only if the research team considers them appropriate for their study.

* Date of Exam – Record the date (and time) the physical exam was performed. 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.
* Hand preference – Choose one - the hand which the participant/subject uses predominantly, not necessarily the hand the participant/subject writes with exclusively.
* Exam Performed – Choose one. Specify whether or not a physical exam was performed on the participant/subject Hand.
* Body System – Each body system is pre-populated on the case report form.
* Result – Choose one. Indicate whether each body system examined had any abnormal findings.
* Description of Result – Provide a description of each abnormal result found during the physical exam, or provide an explanation of why the body system was not examined. See the data dictionary for additional information on coding the abnormality using the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT).
* If Abnormality, Clinically Significant? – Choose one. If the body system had an abnormal finding, record whether the abnormality is Clinically Significant. Any Abnormal, Clinically Significant finding at screening should be recorded on the Medical History as well.

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+]

Pictoral representation may be found at:[Pictoral representation shown here](http://www.addison.ac.uk/endocrine_modules/module1/lecturers_material/html_files/END1.14/sld019.htm)