# CDEs

Date of Exam: (month/day/year)\*

Was a physical exam performed on the participant/subject?\*

[ ]  Yes (Specify results below) [ ]  No

Table 1 \*Physical exam data collection grid

| Body System | Result | Describe Abnormality or Comment if Body System is Not Examined |
| --- | --- | --- |
| Allergic/Immunologic | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Cardiovascular | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Constitutional symptoms (e.g., fever, weight loss) | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Ears, Nose, Mouth, and Throat | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Endocrine | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Eyes | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Gastrointestinal | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Genitourinary | [ ]  Normal-[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Hematologic/Lymphatic | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Integumentary (skin and/or breast) | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Musculoskeletal (separate from ALS exam) | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Neurological (separate from ALS exam) | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Psychiatric | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |
| Respiratory | [ ]  Normal[ ]  Abnormal[ ]  Not examined | Data to be filled in by site |

Hand preference: (Hand participant/subject uses predominantly, not necessarily hand he/she writes with exclusively)

[ ]  Left hand [ ]  Right hand [ ]  Both hands [ ]  Unknown

\*Element 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.

Important note: The data elements noted with an asterisk on this CRF Module are classified as Core (i.e., required for all ALS studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) 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 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.
* Exam Performed – Choose one. Specify whether or not a physical exam was performed on the participant/subject.
* 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).
* Hand preference – Choose one - the hand which the participant/subject uses predominantly, not necessarily the hand the participant/subject writes with exclusively.