

Friedreich's ataxia CDE Revision History Document

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August 2022 Revisions

- Added the Listening in Spatialized Noise – Sentences (LiSN-S) Test Guidance document to the Outcomes and End Points/Ataxia Performance and Measures Domain/Subdomain.
- F0923 Prenatal and Perinatal History CDE Details
 - Removed C00311 Birth weight report value
 - Added C59019 Birth weight measurement
- F0940 Activities of Daily Living and Gait CRF and CDE Details
 - Added Permissible Value (PV) 'Without any difficulty' to CDEs C10692 Speech level status; C10693 Swallowing level status; C10694 Cutting food or use of items functioning level status; C10696 Personal hygiene level status; C10698 Walking ability status; C10699 Sitting ability status; C10700 Bladder control status and C10695 Dressing level status to PV Set IDs.
 - Revised 'Normal' to 'Without any difficulty' in the PV Subsets for these CDEs and updated 'Normal' to 'Without any difficulty' for Questions 1-5, 7-9 on the F0940 Activities of Daily Living and Gait CRF.
 - Added Permissible Value (PV) 'Never' to CDE C10697 Fall rate.
 - Revised 'Normal' to 'Never' in the PV Subset for this CDE C10697 and for Question 6 on the F0940 Activities of Daily Living and Gait CRF.

January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to CRF: C58676 (Birth sex assigned type) and C58677 (Gender identity type). C00035 has been removed.
- Start-Up document updated to reflect these changes.

April 2015 Revisions

No changes.

March 2015 Revisions

- The Start-Up Resource Listings were revised.

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February 2015 Revisions

No changes.

January 2015 Revisions

- Changes to FA Acknowledgements page regarding Dr. Petra Kaufmann.

November 2014 Revisions

No changes.

September 2014 Revisions

No changes.

August 2014 Revisions

No changes.

July 2014 Revisions

No changes.

June 2014 Revisions

No changes.

May 2014 Revisions

No changes.

April 2014 Revisions

No changes.

March 2014 Revisions

No changes.

February 2014 Revisions

No changes.

January 2014 Revisions

- New Notices of Copyright loaded for FA.

December 2013 Revisions

- Updated highlight summaries and start-up resource documents.

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November 2013 Revisions

No changes.

July 2013 Revisions

Overview

There have been changes to the content and structure of the Friedreich's Ataxia (FA) CDE materials in Version 1.2 compared to Version 1.1, including the following:

Form Status Changes

New Forms:

Acoustic Analysis of Speech

Barthel Index

Functional Independence Measure (FIM)

Jebsen-Taylor Hand Function Test

PaTaKa Speech Test

Assessment of Intelligibility of Dysarthric Speech (AIDS)

Boston Diagnostic Aphasia Examination – Third Edition (BDAE-3)

Delis-Kaplan Executive Function System (D-KEFS)

International Cooperative Ataxia Rating Scale (ICARS)

Phonemic Verbal Fluency

Pediatric Quality of Life Inventory (Peds QL)

SF-10 Health Survey for Children

Updated Forms:

Notice of Copyright Created (NOC) (Will replace previously existing forms)

Bladder Control Scale (BLCS) (Component of Multiple Sclerosis Quality of Life)

Bowel Control Scale (BWCS) (Component of Multiple Sclerosis Quality of Life)

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Friedreich's Ataxia Impact Scale (FAIS)

Friedreich's Ataxia Rating Scale

Impact of Visual Impairment Scale (IVIS)

Modified Fatigue Impact Scale (MFIS)

MOS Pain Effects Scale (PES) (Component of Multiple Sclerosis Quality of Life)

Nine-Hole Peg Test

Scale for the Assessment and Rating of Ataxia (SARA)

Sloan Low Contrast Letter Acuity

Tardieu Scale

Timed 25-Foot Walk (T25FW)

36-Item Short Form Health Survey (SF-36)

Removed Forms:

None

Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page.

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Acoustic Analysis of Speech	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Barthel Index	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Functional Independence Measure	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Jebsen-Taylor Hand Function Test	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
PaTaKa Speech Test	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Assessment of Intelligibility of Dysarthric Speech (AIDS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Boston Diagnostic Aphasia Examination – Third Edition (BDAE-3)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Delis-Kaplan Executive Function System (D- KEFS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
International Cooperative Ataxia Rating Scale (ICARS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Phonemic Verbal Fluency	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Pediatric Quality of Life Inventory (Peds QL)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
SF-10 Health Survey for Children	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bladder Control Scale (BLCS) (Component of Multiple Sclerosis Quality of Life)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Bowel Control Scale (BWCS) (Component of Multiple Sclerosis Quality of Life)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Friedreich's Ataxia Impact Scale (FAIS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Friedreich's Ataxia Rating Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Impact of Visual Impairment Scale (IVIS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Modified Fatigue Impact Scale (MFIS)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
MOS Pain Effects Scale (PES) (Component of Multiple Sclerosis Quality of Life)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nine-Hole Peg Test	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Scale for the Assessment and Rating of Ataxia (SARA)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Sloan Low Contrast Letter Acuity	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Tardieu Scale	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Timed 25-Foot Walk (T25FW)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
36-Item Short Form Health Survey (SF-36)	2.0	1.2	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

August 2012 Revisions

Overview

There have been changes to the content and structure of the Friedreich's Ataxia (FA) CDE materials in Version 1.1 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the FA CDE(s)
- The FA CDE(s) were harmonized with other large national and international standardization initiatives and efforts [e.g., International Conference on Harmonization (ICH), Logical Observation Identifiers Names and Codes (LOINC), International Classification of Diseases (ICD), Unified Code for Units of Measure (UCUM)]
- The majority of element names and definitions were improved.
- The permissible values and references of some elements were revised; and
- The version numbers of all forms (excluding standardized scales/instruments) were updated.
- Several guideline documents were reorganized and consolidated to make it easier to understand which standardized instruments/scales are recommended, though the recommendations themselves remained unchanged.
- Some of the forms and guideline documents were re-categorized under a different domain or subdomain to be consistent with other NINDS CDEs.

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- The corresponding data dictionaries (i.e., CDE Detailed Report) have been modified in accordance with the form changes.

Form Status Changes

New Forms:

- Medical History of Friedreich's Ataxia (formerly part of the "Adult Medical History and Prior Health Status" CRF)
- Medical History (formerly part of the "Adult Medical History and Prior Health Status" CRF)
- Pediatric Developmental History (formerly part of the "Pediatric Medical History" CRF)
- Physical Examination
- Pregnancy History (formerly part of the "Behavioral and Social History" CRF)
- Prenatal and Perinatal History (formerly part of the "Pediatric Medical History" CRF)
- Prior and Concomitant Medications (created using the elements from the "Medication History" CRF)
- Social Status (formerly part of the "Demographics and Social Status CRF")

Updated Forms:

- Behavioral History
- Demographics
- Family History
- History Data Source and Reliability
- Laboratory Tests
- Plasma Collection Guidelines
- Urine Collection Guidelines

Removed Forms:

- Adult Medical History and Prior Health Status
- Medication History
- Pediatric Medical History

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Detailed Form Revisions:

Additional specific changes to the CRF modules are detailed in the table included on the subsequent page

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDE(s) and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDE(s); CDEs specifying unit; and CDE(s) specifying an "other, specify" response
Various	1.1	1.0	Minor	Modified CDEs	For a number of CDEs, "Unknown" was added to the permissible value set and in some cases "Unknown" replaced "Unknown/Don't Know"
Various	1.1	1.0	Minor	Modified Forms	For forms with Core items, the Core CDE(s) were identified with an asterisk and the following was added as a footnote: "*Element is classified as Core".
Various	1.1	1.0	Minor	Modified Forms	Instructions were updated to include additional details.
Various	1.1	1.0	Minor	Modified Forms	Friedreich's Ataxia was removed from the header of all forms.
Behavioral History	1.1	1.0	Minor	Modified Form	The form title was changed from "Behavioral and Social History" to "Behavioral History".
Behavioral History	1.1	1.0	Minor	Modified CDEs	Permissible values were modified for the following CDEs: "Tobacco current use indicator"; "Tobacco prior use indicator"; "Tobacco use started age value"; "Tobacco use stopped age value"; "Tobacco product used type"; "Tobacco cigarettes smoked daily average number"; "Drug or substance current illicit use indicator"; "Drug or substance illicitly used category"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Behavioral History	1.1	1.0	Minor	Added CDEs	The following CDE was added: "Behavioral history assessment date and time"
Behavioral History	1.1	1.0	Minor	Modified Form	Instructions were added for the following CDEs: "Behavioral history assessment date and time"; "Tobacco current use indicator"; "Tobacco prior use indicator"; "Tobacco use started age value"; "Tobacco use stopped age value"; "Tobacco product used type"; "Tobacco cigarettes smoked daily average number"; "Alcohol current use indicator"; "Alcohol prior use indicator"; "Alcohol use started age value"; "Alcohol use stopped age value"; "Alcohol use frequency"; "Alcohol drinking day average drinks consumed range"; "Alcohol consume six or more drinks frequency"; "Alcohol use related to hospitalization indicator"; "Drug or substance current illicit use indicator"; "Drug or substance illicitly used category"
Demographics	1.1	1.0	Minor	Modified CDEs	The following definition and/ or permissible values were updated for the following CDEs: "Gender type"; "Ethnicity USA category"; "Race USA category"
Demographics	1.1	1.0	Minor	Deleted CDEs	The following CDE was deleted: "Hand preference type" (moved to Physical Examination CRF). The CDE(s) on this form under the heading of "Social Status Information" were removed and moved to the Social Status CRF.
Demographics	1.1	1.0	Minor	Modified Form	Instructions were updated.
Family History	1.1	1.0	Minor	Added CDEs	The following CDE was added: "Family history medical condition relative type"

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
History Data Source and Reliability	1.1	1.0	Minor	Modified Form	The name of the form was changed from "Data Source and Reliability" to "History Data Source and Reliability".
Laboratory Tests	1.1	1.0	Minor	Added CDE(s)	The following CDE was added: "Lab test performed indicator"
Laboratory Tests	1.1	1.0	Minor	Modified CDE(s)	Permissible values were modified for the following CDEs: "Lab test result status"; "Lab test abnormality significance type"
Laboratory Tests	1.1	1.0	Minor	Modified Form	Instructions were updated.
Medical History of Friedreich's Ataxia	1.0	N/A	Minor	New Form	CDEs from the Adult Medical History and Prior Health Status CRF under the heading of "Medical History" were moved to this new form.
Medical History	1.0	N/A	Minor	New Form	CDEs from the Adult Medical History and Prior Health Status CRF related to the participant's/subject's overall medical history and not his/her medical history specific to Friedreich's Ataxia were moved to this new form.
Pediatric Developmental History	1.0	N/A	Minor	New Form	CDEs from the Pediatric Medical History CRF under the heading of "Pre-Morbid Developmental Status and Academic Function" were moved to this form.
Pregnancy History	1.0	N/A	Minor	New Form	CDEs from the Behavioral and Social History CRF under the heading of "Pregnancy History" were moved to this form.
Physical Exam	1.0	N/A	Major	New Form	The Physical Exam form was added to the Friedreich's Ataxia recommendations. All CDEs on this form are new with the exception of "Hand preference type".

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Plasma Collection	N/A	1.0	Major	Modified Form	This document is no longer associated with CDEs and serves as a guideline and not a CRF. The name of the document was changed from "Plasma Collection" to "Plasma Collection Guidelines".
Prenatal and Perinatal History	1.0	N/A	Minor	New Form	CDEs from the Pediatric Medical History CRF under the headings of "Delivery History" and "Prenatal History" were moved to this form.
Prior and Concomitant Medications	1.0	N/A	Major	New Form	CDEs from the Medication History CRF were moved to this form. Several of the CDEs on this form are new.
Social Status	1.0	N/A	Minor	New Form	The following CDEs were removed from the Demographics and Social Status CRF and added to this form: "Education level USA type"; "Employment status"; "Full-time employment status"; "Marital or partner status"; "Living with persons number"; "Living with person relationship type"; "Paid assistance per day hours number"; "Unpaid assistance per day hours number"; "In-home assistance for remembering, decision making, or judgment duration"; "Family income supported persons number"
Urine Collection Guidelines	N/A	1.0	Major	Modified Form	This document is no longer associated with CDEs and serves as a guideline and not a CRF. The name of the document was changed from "Urine Collection" to "Urine Collection Guidelines".