

Facioscapulohumeral muscular dystrophy (FSHD) CDE Revision History

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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 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.

April 2015 Revisions

- Loaded 508 compliant versions of documents for FSHD.
- Inserted additional reference on the 6 Minute Walk Test file.

March 2015 Revisions

- Start-Up Resource Listing was revised for FSHD.
- Repaired problem in FSHD roster preventing roster report from populating.

February 2015 Revisions

Overview

Version 1.0 of the FSHD CDEs was released. The recommendations were posted for public comment in November 2014 and version 1.0 was released at the end of February 2015.

- FSHD moved from “CDEs under Review” tab on the main landing page to the “CDEs Now Available” tab on the main landing page.
- New standardized disease-specific text explaining the mission of the NINDS CDE project and the CDE development process added to FSHD landing page.
- Eighty-eight CRFS and 113 NOCs were posted to FSHD.

Form Status Changes

New Forms:

NIH Resources Subdomain

- National Institutes of Health (NIH) Toolbox
- Patient-Reported Outcomes Measurement Information System (PROMIS)

- Quality of Life in Neurological Disorders (Neuro-QOL)

Summary Documents Subdomain

- Summary of Recommendations for FSHD

Demographics Subdomain

- General Core
- Demographics

Social Status Subdomain

- Social Status

General Health History Subdomain

- Family History

Imaging Diagnostics Subdomain

- Dual X-Ray Absorptiometry (DXA)
- Magnetic Resonance Imaging (MRI)
- MRI Quantitative Measurements Guidelines

Laboratory Tests and Biospecimens/Biomarkers Subdomain

- Laboratory Tests and Tracking
- Laboratory Tests Recommendations Table and Guidelines for Use
- Mutation Analysis

Non-Imaging Diagnostics Subdomain

- Electrocardiogram (ECG)

Physical/Neurological Examination Subdomain

- Electrical Impedance Myography (EIM)

Drugs Subdomain

- Prior and Concomitant Medications

Therapies Subdomain

- Respiratory Interventions

Functional Status Subdomain

- 2 Minute Walk Test
- 6 Minute Walk Test
- Goniometry
- Stair Climb
- Timed Up and Go (TUG)

Muscle Strength Testing Subdomain

- Grip Strength Fatigue
- Hand Held Dynamometry
- Manual Muscle Testing-Using the Medical Research Council Muscle Grading Scale
- Maximum Voluntary Isometric Contraction Testing (MVICT)
- Pinch Strength

Pain

- Brief Pain Inventory (Short Form)
- McGill Pain Questionnaire
- Pain Assessment in FSHD Guidelines for Use

Performance Measures Subdomain

- Motor Function Measure (MFM)

Pulmonary Function Testing/Respiratory Status Subdomain

- Measures of Gas Exchange
- Pulmonary Assessment Master Outline and Guidelines for Use

- Pulmonary Function Testing

Quality of Life Subdomain

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Disorders (Neuro-QOL)

Updated Forms:

- NA

Removed Forms:

- NA

Detailed Form Revisions:

Additional specific changes to the CRF Modules are detailed in the table included below.

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
National Institutes of Health (NIH) Toolbox	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Patient-Reported Outcomes Measurement Information System (PROMIS)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Quality of Life in Neurological Disorders (Neuro-QOL)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Summary of Recommendations for FSHD	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
General Core	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
Demographics	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Demographics
Social Status	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Social Status
Family History	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Family History
Dual X-Ray Absorptiometry (DXA)	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Dual X-Ray Absorptiometry

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Electrocardiogram (ECG)	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Electrocardiogram
Electrical Impedance Myography (EIM)	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
Physical Examination	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
Polysomnography	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
Prior and Concomitant Medications	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Prior and Concomitant Medications
Respiratory Interventions	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Respiratory Interventions

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
2 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
6 Minute Walk Test	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Goniometry	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to
Stair Climb	1.0	N/A	Major	New Form	A New Form was created and added to the CMD CDE materials to capture CDEs related to
Timed Up and Go (TUG)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the CMD CDE materials
Grip Strength Fatigue	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to
Hand Held Dynamometry	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Manual Muscle Testing- Using the Medical Research Council Muscle Grading Scale	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Maximum Voluntary Isometric Contraction Testing (MVICT)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Pinch Strength	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Motor Function Measure (MFM)	1.0	N/A	Major	New Form	A Notice of Copyright was created and added to the FSHD CDE materials
Pulmonary Assessment Master Outline and Guidelines for Use	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials
Pulmonary Function Testing	1.0	N/A	Major	New Form	A New Form was created and added to the FSHD CDE materials to capture CDEs related to Pulmonary Function Testing

January 2015 Revisions

- Revised Acknowledgement FSHD page.

November 2014 Revisions

- A banner announcing the Public Review period for FSHD was added to the website and is visible on every page.
- Disease-Specific language explaining the public review period and contents of the public review package was added to the FSHD disease page.
- FSHD was moved from the CDEs in Development tab to the CDEs Under Review Tab on the NINDS Common Data Elements website homepage.
- FSHD page was linked to the NMD homepage

September 2014 Revisions

- Updated Overview pages for diseases in development to include an updated timeline of development for FSHD.

August 2014 Revisions

- Committee membership for FSHD now displayed on History & Acknowledgement tab for FSHD
- Landing page for FSHD updated to read:” Please contact the NINDS CDE Project Officer, Joanne Odenkirchen or NINDSCDE@emmes.com for further information.”
- Links to NeruoQOL, The NIH Toolbox, and PROMIS added to FSHD webpage.