

# Multiple Sclerosis CDE Revision History Document

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## November 2023 Revisions

- The title of the Notice of Copyright '9-Hole Peg Test' was modified to 'Nine Hole Peg Test'.
- The Timed 25-Foot Walk (T25-FW) NOC document Availability, Short Description, Comments/Special Instructions, Scoring and Psychometric Properties, Rational/Justification, and References sections were revised and updated to correct a broken Availability link and reorganize section content to the new NOC template format.

## August 2022 Revisions

- The CDE C00311 Birth weight report value was removed from the Medical History CRF and replaced with CDE C59019 Birth weight measurement. CDE C59019 classified as Supplemental.

## June 2020 Revisions

- The Highlight Summary document has been updated to reflect these changes.
- The Social Status CRF and CDE Details in the Participant Characteristics; Social Status Domain; Subdomain were reclassified from Core to Supplemental – Highly Recommended.
- The Relapse CRF and CDE Details were added as Supplemental – Highly Recommended and the Visual Analog Scale CRF and CDE Details were added as Exploratory to the Disease/Injury Related Events; History of Disease/Injury Event Domain; Subdomain.
- The Grip Strength Fatigue CRF and CDE Details were added as Exploratory to the Assessments and Examinations; Physical/Neurological Examination Domain; Subdomain.
- The Imaging Analysis Technique and Results Baseline CRF and CDE Details were reclassified from Supplemental – Highly Recommended to Exploratory in the Assessments and Examinations; Imaging Diagnostics Domain; Subdomain.
- The Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test Notice of Copyright was reclassified from Supplemental to Exploratory in the Outcomes and Endpoints; Activities of Daily Living/Performance Domain; Subdomain.
- The Multiple Sclerosis Spasticity Scale (MSSS) classified as Supplemental was removed from Outcomes and Endpoints; Performance Measures Domain; Subdomain and added to the Outcomes and Endpoints; Quality of Life/ Patient Reported Outcomes Domain; Subdomain.
- Grip Strength CRF and CDE Details were removed from the Exploratory classification of the Outcomes and Endpoints; Performance Measures Domain/Subdomain.

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## April 2020 Revisions

- Additional references were added on the Nine Hole Peg Test, Multiple Sclerosis Quality of Life Inventory (MSQLI), and Patient Reported Impact of Multiple Sclerosis (PRIMuS).
- Current availability links updated for the Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test.
- The Biospecimens Summary Statement was updated.
- Text added to the Comments/Special instructions section on the Multiple Sclerosis Functional Composite Timed 25 Foot Walk 9-Hole Peg Test Paced Auditory Serial Addition Test.
- Strengths/Weaknesses section was updated on the 6 Minute Walk Test, 10 Meter Timed Walk Test, Sloan Low Contrast Acuity Test, and Timed 25 Foot Walk Test.
- Scoring section updated on the Sloan Low Contrast Acuity Test and Timed 25 Foot Walk Test.

## January 2020 Revisions

- General Core CRF updated to replace 'Gender' question with 'Sex assigned at birth' and 'Gender identity'.
- Two new CDEs added to General Core CRF: C58676 (Sex assigned at birth) and C58677 (Gender identity). C00035 has been removed
- Start-Up document updated to reflect these changes.
- Current instrument availability links were updated for the Patient Determined Disease Steps, Multiple Sclerosis Quality of Life-54 Instrument (MSQOL-54), and Patient Reported Impact of Multiple Sclerosis (PRIMuS).
- Reference added for Patient Reported Impact of Multiple Sclerosis (PRIMuS) NOC.

## April 2015 Revisions

- Inserted additional reference on the 6 Minute Walk Test file.

## March 2015 Revisions

No changes.

## February 2015 Revisions

No changes.

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## **January 2015 Revisions**

- Classifications for the Symbol Digit Modalities Test, Modified Ashworth Scale and Kurtzke Expanded Disability Status were updated for MS.

## **November 2014 Revisions**

No changes.

## **September 2014 Revisions**

- Revisions to Rosters in MS to list Joy Esterlitz and Maniza Sheikh under the NINDS CDE Team section.

## **August 2014 Revisions**

No changes.

## **July 2014 Revisions**

- Reassignment of several MS NOCs between Subdomains, to reflect committee recommendations.

## **June 2014 Revisions**

- A problem with the MS Committee Roster Report was corrected so that it reflects the correct report.

## **May 2014 Revisions**

No changes.

## **April 2014 Revisions**

No changes.

## **March 2014 Revisions**

No changes.

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## February 2014 Revisions

No changes.

## January 2014 Revisions

No changes.

## December 2013 Revisions

- Updated highlight summaries and start-up resource documents for MS.

## November 2013 Revisions

No changes.

## April 2013 Revisions

### Overview

There have been Major changes to the content and structure of the Multiple Sclerosis (MS) CDE materials in Version 3.0 compared to Version 2.0, including the following:

### Form Status Changes

#### New Forms:

Beck Depression Index

Beery-Buktencia VMI

Brief Visuospatial Memory Test

California Verbal Learning Test 2

California Verbal Learning Test Children

Center for Epi Studies Depression Scale

Clinical Evaluation of Language Fundamentals

Connors Continuous Performance Test

Contingency Naming Test

Controlled Oral Word Association Test

Delis Kaplan Executive Functioning System

Expressive One Word Picture Vocabulary Test

Multiple Sclerosis Severity Score

Nonverbal Selective Reminding Test

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Rey Auditory Verbal Learning Test

Stroop Test

Symbol Digit Modality Test

TOMAL-2

Wechsler Abbreviated Scale for Intelligence

Wechsler Scale for Intelligence for Children

Wide Range Assess of Memory and Learning

Wisconsin Card Sorting Test

Woodcock-Johnson Tests of Cognitive Abilities

### **Updated Forms:**

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

Godin Leisure-Time Exercise

Multiple Sclerosis Severity Score

Barthel Index

Berg Balance Scale

Bladder Control Scale

Bowel Control Scale

Brief Pain Inventory Short Form

Disease Steps

Fatigue Scale for Motor and Cognitive Functions

Fatigue Severity Scale

Functional Assessment in Multiple Sclerosis

Functional Independence Measure

Impact of Visual Impairment Scale

McGill Pain Questionnaire

Modified Fatigue Impact Scale

MOS Pain Effects Scale

Multiple Sclerosis Functional Composite

Multiple Sclerosis Impact Scale

Patient Determined Disease Steps

PROMIS Fatigue Short Form

PROMIS Pain Interference Short Form

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The Activities Specific Balance Scale

Expanded Disability Status Scale

10 Meter timed walk

6-minute walk Test

Grooved Pegboard Test

Hauser Ambulation Index

Modified Ashworth Scale

Multiple Sclerosis Walking Scale

National Eye Institute Visual Functioning Questionnaire

Pelli-Robson Test

Scale for the Assessment and Rating of Ataxia

Sloan Low Contrast Letter Acuity

Timed Up and Go

Short Form Health Survey-36

Clinical Global Impression

EuroQol -5 Dimension Test

EuroQol-VAS

ICIQ-LUTS Quality of Life

MOS Modified Social Support Survey

Multiple Sclerosis International Quality of Life Questionnaire

Multiple Sclerosis Quality of Life-54

Multiple Sclerosis Quality of Life Inventory

Patient Reported Impact of Multiple Sclerosis

Sexual Satisfaction Scale

Short Form Health Survey-12

Treatment Satisfaction Questionnaire for Medication

### **Removed Forms:**

None

### **Detailed Form Revisions:**

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

# Multiple Sclerosis CDE Revision History Document

**1 Multiple Sclerosis Revision History Table**

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
Beck Depression Index	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Beery- Buktencia VMI	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Brief Visuospatial Memory Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
California Verbal Learning Test 2	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
California Verbal Learning Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this



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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Children					form and will replace the existing form
Center for Epi Studies Depression Scale	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Clinical Evaluation of Language Fundamentals	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Connors Continuous Performance Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Contingency Naming Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Controlled Oral Word	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was

## Multiple Sclerosis CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Association Test					created for this form and will replace the existing form
Delis Kaplan Executive Functioning System	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Expressive One Word Picture Vocabulary Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Multiple Sclerosis Severity Score	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Nonverbal Selective Reminding Test	3.0	2.0	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
Rey Auditory Verbal Learning Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Stroop Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Symbol Digit Modality Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
TOMAL-2	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wechsler Abbreviated Scale for Intelligence	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the

## Multiple Sclerosis CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
					existing form
Wechsler Scale for Intelligence for Children	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wide Range Assess of Memory and Learning	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Wisconsin Card Sorting Test	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Woodcock- Johnson Tests of Cognitive Abilities	3.0	2.0	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
Woodcock- Johnson Tests of Cognitive Abilities	3.0	2.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

### October 2012 Revisions

#### Overview

There have been changes to the content and structure of the Multiple Sclerosis (MS) CDE materials in Version 2.0 compared to Version 1.0, including the following:

- Every attempt was made to remove duplication and redundancy in the MS CDEs;
- The MS CDEs 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 many 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.

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

#### Form Status Changes

##### New Forms:

- Physical Exam

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Social Status

History Data Source and Reliability

Vital Signs

The above forms were created using CDEs that were previously included on other forms.

### **Updated Forms:**

- Demographics
- Medical History
- Behavioral History
- Family History – Affected Relatives and Pedigree
- Reproductive and Hormonal History
- Pediatric Developmental History
- Relapse
- Diagnosis and Disease Characteristics
- Genetics

### **Removed Forms:**

None

### **Detailed Form Revisions:**

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

### **2 Multiple Sclerosis Revision History Table**

<b>CRF Module/ Guideline</b>	<b>Current Version</b>	<b>Previous Version</b>	<b>Change Classification</b>	<b>Change Type</b>	<b>Description of Change</b>
All	1.1	1.0	Minor	Modified CDEs	Nearly all CDE names and definitions were updated to achieve greater consistency across all NINDS CDEs and for clarity
Various	1.1	1.0	Minor	Deleted CDEs	The following types of CDEs were deleted: CDEs redundant with other CDEs; CDEs specifying unit; and CDEs specifying an "other, specify" response

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
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	Instructions were updated to include additional details.
Demographics	1.1	1.0	Minor	Modified Forms	Added footnote identifying certain CDEs as Core; relabeled Sex to Gender on form; rearranged CDE order; reworded zip code CDE.
Demographics	1.1	1.0	Minor	Deleted CDEs	Deleted City/Town CDE
Demographics	1.1	1.0	Minor	Modified Forms	Moved Marital or partner status, Education years number, Employment status, Job classification category, and Hand preference type to another form
Physical Exam	1.0	N/A	Minor	New Form	Created Physical Exam form using Hand preference type and General CDEs
Social Status	1.0	N/A	Minor	New Form	Created Social Status form with CDEs previously on Demographics form.
Social Status	1.0	N/A	Major	Modified CDEs	Modified Education years number, Employment status, and Job classification category permissible values
History Data Source and Reliability	1.0	N/A	Minor	New Form	Created History Data Source and Reliability form with CDEs previously on Medical History form

## Multiple Sclerosis CDE Revision History Document

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
History Data Source and Reliability	1.0	N/A	Minor	Modified Forms	Minor edits to wording on form
Behavioral History	1.1	1.0	Major	Modified CDEs	Updated CDEs on form to make consistent with General CDEs
Behavioral History	1.1	1.0	Minor	Deleted CDEs	Deleted Year started smoking and Year quit smoking
Behavioral History	1.1	1.0	Minor	New CDEs	Added Tobacco use duration
Medical History	1.1	1.0	Minor	Modified Forms	Edited name of form; added note regarding use of interview questions to document a complete medical history
Medical History	1.1	1.0	Major	New CDEs	Added CDEs to make form consistent with General CDEs
Medical History	1.1	1.0	Minor	Modified Forms	Moved Gestational age value and Birth weight value to this form from another form
Medical History	1.1	1.0	Minor	Modified Forms	Moved Data Source and Reliability elements to new form
Pediatric Developmental History	1.1	1.0	Minor	Modified Forms	Edited name of form; formatting changes
Pediatric Developmental History	1.1	1.0	Minor	Modified Forms	Moved Gestational age value, Birth weight value, Weight measurement, Height measurement, Head circumference measurement, Education years number to other forms



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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Pediatric Developmental History	1.1	1.0	Minor	Modified CDEs	Revised Breastfed indicator and Formula fed indicator permissible values
Pediatric Developmental History	1.1	1.0	Minor	New CDEs	Added Menstrual period received indicator and Education services type
Pediatric Developmental History	1.1	1.0	Minor	Deleted CDEs	Deleted Regular classroom indicator
Family History – Affected Relatives and Pedigree	1.1	1.0	Minor	Modified Forms	Renamed the form “Family History – Affected Relatives and Pedigree”; moved information on relation of relative to tables; other minor formatting changes
Family History – Affected Relatives and Pedigree	1.1	1.0	Minor	Modified CDEs	Revised Twin sibling type permissible values
Family History – Affected Relatives and Pedigree	1.1	1.0	Minor	Deleted CDEs	Deleted Twin gender type
Reproductive and Hormonal History	1.1	1.0	Minor	Modified Forms	Revised skip logic
Reproductive and Hormonal History	1.1	1.0	Minor	Modified CDEs	Modified Pregnancy outcome type permissible values

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Vital Signs	1.0	N/A	Minor	New Form	New CRF using General CDEs and several CDEs from Pediatric Elements form
Relapse	1.0	1.0	Minor	Modified CDEs	Remove Visit Date CDE; other minor changes
Diagnosis and Disease Characteristics	1.0	1.0	Minor	Modified CDEs	Modified Laterality type permissible values and changed Present/Absent permissible values to Yes/No for several CDEs
Diagnosis and Disease Characteristics	1.0	1.0	Minor	Modified Forms	Minor edits to wording on form
Genetics	1.1	1.0	Minor	Modified CDEs	Modified Family history medical condition relative type permissible values
Genetics	1.1	1.0	Minor	Modified Forms	Moved CDEs into table format