

Myasthenia Gravis CDE Revision History Document

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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

No changes.

March 2015 Revisions

- Classification changes to CDEs in MG per feedback from NMD Oversight Committee.

February 2015 Revisions

No changes.

January 2015 Revisions

- Posting of revised 508 compliant Start-Up and Highlight Summaries.
- Addition of Dr. Glen Nuckolls and removal of Dr. John Porter to the MG Acknowledgments page.

November 2014 Revisions

No changes.

September 2014 Revisions

No changes.

August 2014 Revisions

No changes.

July 2014 Revisions

No changes.

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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

Overview

There have been minor changes to the content and structure of the Myasthenia Gravis (MG) CDE materials in version 1.1 compared to version 1.0, including the following:

Form Status Changes

New Forms:

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

Updated Forms:

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

- Myasthenia Gravis Composite (MGC)

Removed Forms:

- None

Detailed Form Revisions:

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

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1 Myasthenia Gravis Revision History Table

CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Myasthenia Gravis Composite (MGC)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form
Short Form Health Survey- 36 (SF-36)	2.0	1.0	Major	Notice of Copyright	A Notice of Copyright was created for this form and will replace the existing form

September 2013 Revisions

Overview

The Myasthenia Gravis (MG) CDE Materials were previously listed under the outline for Neuromuscular Disease on the NINDS website. The NINDS website has recently expanded to support 4 new diseases and the Myasthenia Gravis CDE Materials have been removed from the Neuromuscular Disease Outline to create a new disease area featuring these materials. The materials listed in this disease area will be considered version 1.0.

Form Status Changes

A Start-up Resource Listing was added to the MG disease area to provide investigators with a set of CORE data elements to be used during a research study.

New Forms:

Modified Forms:

- Demographics – MG
- Social Status – MG
- Family History – MG
- Medical History – MG
- Prenatal and Perinatal History
- Surgical History
- Medical History of MG – MG
- Confirmatory Diagnostic Tests – MG

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- Physical Examination
- Polysomnography
- Vital Signs
- Biomarkers Sample Data Guidelines
- Biospecimen Collection Guidelines for Use
- Fat Aspirate Tissue Specimens
- Gene Table and Guidelines for Use
- Laboratory Tests and Tracking
- Laboratory Tests Recommendations Table and Guidelines for Use
- Muscle Biopsy and Autopsy Tissue
- Mutation Analysis
- Nerve Biopsy
- Skin Biopsies for Qualification of Intraepidermal Nerve Fibers
- Brain Magnetic Resonance Imaging (MRI)
- Cardiac Magnetic Resonance Imaging (MRI)
- Chest Imaging – MG
- Diffusion Tensor Imaging (DTI)
- Dual-Energy X-Ray Absorptiometry (DEXA)
- Magnetic Resonance Imaging (MRI)
- Magnetic Resonance Spectroscopy (MRS)
- Echocardiogram
- Electrocardiogram (ECG)
- Electrophysiology – MG
- Holter Examination
- Prior and Current Treatments for MG – MG

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- Thymectomy – MG
- Gastrointestinal Therapies
- Respiratory Interventions
- MG Clinical Outcomes Recommendations by Domain and Classification – MG
- MG Composite – MG
- MG Status – MG
- Cognitive Guidelines for Use
- Measures of Gas Exchange
- Pulmonary Assessment Master Outline and Guidelines for Use
- Pulmonary Function Testing
- Pediatric Cognitive Instrument Table
- Death Report

Removed Forms:

- NMD Clinical Outcome Recommendations by Domain and Classification

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
Demographics – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Social Status – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Family History – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Medical History – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Prenatal and Perinatal History	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Surgical History	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Medical History of MG – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Confirmatory Diagnostic Tests – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Physical Examination	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Polysomnography	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Vital Signs	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Biomarkers Sample Data Guidelines	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Biospecimen Collection Guidelines for Use	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Fat Aspirate Tissue Specimens	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Gene Table and Guidelines for Use	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Laboratory Tests and Tracking	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Laboratory Tests Recommendations Table and Guidelines for Use	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Muscle Biopsy and Autopsy Tissue	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Mutation Analysis	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Nerve Biopsy	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Skin Biopsies for Qualification of Intraepidermal Nerve Fibers	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Brain Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Cardiac Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Chest Imaging – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Diffusion Tensor Imaging (DTI)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Dual-Energy X-Ray Absorptiometry (DEXA)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Magnetic Resonance Imaging (MRI)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Magnetic Resonance Spectroscopy (MRS)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
Echocardiogram	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Electrocardiogram (ECG)	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Electrophysiology – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Holter Examination	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Prior and Current Treatments for MG – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Thymectomy – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Gastrointestinal Therapies	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Respiratory Interventions	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
MG Clinical Outcomes Recommendations by Domain and Classification – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis

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CRF Module/ Guideline	Current Version	Previous Version	Change Classification	Change Type	Description of Change
MG Composite – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
MG Status – MG	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Cognitive Guidelines for Use	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Measures of Gas Exchange	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Pulmonary Assessment Master Outline and Guidelines for Use	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Pulmonary Function Testing	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Pediatric Cognitive Instrument Table	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis
Death Report	1.0	N/A	Major	Modified Form	Forms were moved from Neuromuscular Disease to a new disease area for Myasthenia Gravis