

# Myasthenia Gravis CDE Revision History Document

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# **Myasthenia Gravis CDE Revision History Document**

## **August 2022 Revisions**

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

## **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.

# Myasthenia Gravis CDE Revision History Document

## 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

## **Myasthenia Gravis CDE Revision History Document**

- 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

## Myasthenia Gravis CDE Revision History Document

- 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.

**2 Myasthenia Gravis Revision History Table**

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

## Myasthenia Gravis CDE Revision History Document

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

## Myasthenia Gravis CDE Revision History Document

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



## Myasthenia Gravis CDE Revision History Document

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

## Myasthenia Gravis CDE Revision History Document

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

## Myasthenia Gravis CDE Revision History Document

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