**\***Date Medical History Taken: //20 m m dd yyyy

Does the participant/subject have a history of any medical problems/conditions in the following body systems**?**

[ ]  No (leave rest of form blank) [ ]  Yes

Enter all significant medical history items, including surgeries, EXCEPT the problem/condition that is the focus of this study. Use only one line per description.

\*Use BODY SYSTEM categories for medical history:

Constitutional symptoms (e.g., fever, weight loss)

Eyes

Ears, Nose, Mouth, Throat

Cardiovascular

Respiratory

Gastrointestinal

Genitourinary

Hepatobiliary

Musculoskeletal

Integumentary (skin and/or breast)

Neurological

Psychiatric

Endocrine

Hematologic/Lymphatic

Allergic/Immunologic

Hepatobilliary

Table for Entering Medical History Items Using Above List

| Body System\* | Medical History Term\*(one item per line) | Start Date\*(m m/dd/yyyy) | Ongoing?\* | End Date\*(m m/dd/yyyy) |
| --- | --- | --- | --- | --- |
| Cardiovascular | Example: Hypertension | 03/99/2009 | [x] Yes [ ] No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |
| Data to be entered by site | Data to be entered by site | //20 | [ ]  Yes [ ]  No | //20 |

The questions in the following table should be explicitly asked to ensure a complete medical history is documented for conditions commonly associated with Myasthenia Gravis.

| Associated Disease/Condition | Subject Affected? (Yes/No) | Type | Diagnosis Date (m m/dd/yyyy) |
| --- | --- | --- | --- |
| Thyroid Condition | [ ]  Yes [ ]  No | [ ]  Hypothroidism[ ]  Hyperthyroidism[ ]  Hashimoto’s | // |
| Diabetes mellitus | [ ]  Yes [ ]  No | [ ]  Type I[ ]  Type II | // |
| Rheumatoid Arthritis | [ ]  Yes [ ]  No | Intentionally left blank | // |
| Systemic Lupus Erythematosus (SLE) | [ ]  Yes [ ]  No | Intentionally left blank | // |
| Muscle Disease | [ ]  Yes [ ]  No | [ ]  Heridetary, specify:[ ]  Inflammatory, specify: | // |
| Epilepsy/Seizures | [ ]  Yes [ ]  No | Intentionally left blank | // |
| Cancer | [ ]  Yes [ ]  No | Type of cancer: | // |
| Other disease/condition, specify: | Intentionally left blank | Intentionally left blank | // |

\* Element is classified as Core

## General Instructions

Associated conditions data are collected to describe co-morbidities associated with Myasthenia Gravis. The form should focus on all other problems or conditions other than those related to the focus of the study.

Important note: All data elements on this CRF Module are classified as Core (i.e., strongly recommended for all Myasthenia Gravis clinical studies to collect). Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Date medical history taken -- Record the date (and time) the medical history was taken. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Does this participant/subject have…? If this question is answered NO then the rest of the form is blank. If the question is answered YES then the medical history for at least one body system should be recorded.
* Body system – Record the code number associated with the appropriate body system for each line of medical history. The numeric codes are provided for studies that will record the data on paper CRFs. In a database the body system can be used without the numeric codes.
* Condition/disease - Record one Medical History term per line. Surgeries in the medical history should also be recorded under this CDE.See the data dictionary for additional information on coding the condition using SNOMED CT.
* Start date –Record the date the medical condition/disease started. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Ongoing? – Check Yes or No to indicate if the medical condition/disease is still present.
* End date – If the condition is not ongoing, record the date (and time) the medical condition/disease stopped. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.