

15 May 2025

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Community Health Charities Member Agency MGFA code # 11240





High Impact Clinical Research and Scientific Pilot Projects in Myasthenia Gravis and Related Neuromuscular Junction Disorders

#### Overview

The Myasthenia Gravis Foundation of America (MGFA) requests submission of proposals to demonstrate proof-of-concept to support the feasibility of a paradigm shift, test a new research hypothesis, or otherwise advance the development of safe and effective treatments for MG. Proposals must include clear plans of investigation, well-defined deliverables, and metrics for determining the quality of those deliverables.

MGFA is committed to supporting research that will ultimately improve the lives of patients with myasthenia gravis and related neuromuscular junction disorders. The research committee has identified five broad research priorities of unmet need in the field that, when addressed, could substantially impact the understanding of the etiology or pathogenesis of disease, or advance the development of safe and effective treatments to end MG:

#### Biomarkers

- Early diagnosis
- Predictors of clinical outcome
- Predictors of response to immunosuppressive therapy
- Biomarkers for use in clinical trials

## Mechanisms of disease

- o Basic mechanisms of disease
- How loss of self-tolerance is sustained throughout the disease course

## Therapeutic strategies

- Development of new therapeutic targets
- Targeted therapies that prevent widespread immunosuppression and offtarget side effects
- Optimizing treatment strategies with existing therapies

#### Improving patient outcomes

- The patient perspective on their disease, its impact on their daily life, and treatment considerations that are most important to them
- Collateral effects of MG and its treatment, such as associated medical conditions, treatment-related side effects, and financial considerations
- Pediatric treatment strategies, safety concerns, and long-term outcome

Though this research agenda intends to guide researchers towards topics that are viewed as critical to the advancement of MG research and treatment, the

MGFA will accept proposals outside of these priority areas if the applicant demonstrates that work stemming from his or her proposal has the potential to impact the understanding or treatment of MG.

MGFA will fund highly meritorious projects with a maximum of \$110,000, over two years, of which no more than \$10,000 may be allocated to indirect costs. Funds will be expended over two years from the time of the award. Special funding requests and/or changes to the award period must be approved prior to submission of proposal through the Letter of Intent.

#### Instructions

Applicants are asked to submit a letter of intent (LOI) by June 13, 2025 using the forms provided in MGFA's grant portal, <u>ProposalCentral</u>. This form will be found by searching for Myasthenia Gravis Foundation of American under "Grant Opportunities." (Note: You must create an account and log in to access and submit all forms.) There, you will find additional documents and details regarding the application process. You will be informed by July 3, 2025, if you are invited to submit a full proposal.

The full application consists of:

- A five-page research proposal, which must be strictly formatted according to the NIH standard for applications: Specific Aims, Significance, Innovation to address how the research is novel and will push the boundaries of MG research or care, and an Approach section which includes preliminary data (if any), the experimental design, and the interpretation of expected outcomes. There is no limit to the reference section. A separate single page describing how the funds will benefit the MG investigation or treatment goals of the MGFA and also describe the plan for future support. For example, a copy of a funding agency review, which supports the need to obtain preliminary data, would be evidence of a specific plan for future support.
- o A separate Lay Summary of up to ½ a page in length or approximately 200 words.
- A detailed budget and budget justification in the NIH format. There are no specific budget restrictions, but all aspects of the budget must be clearly justified. If Principal Investigator salary support is requested, then a letter from a department chair or equivalent must accompany the application to assure that the PI is afforded protected research time for the project.
- Resubmission applications are required to submit an additional Introduction to Application. The Introduction must include a summary of substantial additions, deletions, and changes to the application. It must also include a response to weaknesses raised in the Summary Statement. The page limit for the Introduction may not exceed one page.

Applicants are required to include the following. Templated materials are available on the Proposal Central portal:

- Letter of Intent Form [1 pg]
- Cover Sheet [2 pg]
- Lay Summary [1/2 pg / 200 words]
- Research Proposal Form [5 pg]
- NIH Budget & Budget Justification [no page limit]
- Development of Future Support [1 pg]
- NIH Bio-sketch Form [5 pg]
- Institutional/Grants Agent Signature Required
- \*Letter from Department Chair if PI Salary Support Requested [1 pg]
- \*Introduction to Application page if Resubmission Application [1 pg]

All components should be submitted via MGFA's grants portal, <u>ProposalCentral</u>, no later than **August 15, 2025**. A preliminary review to ensure compliance with guidelines will be performed. Submissions that do not follow the required NIH formatting will not be reviewed. Proposals will be reviewed by a study section comprised of the MGFA research committee as well as ad hoc reviewers when required; NIH scoring scale and categories will be used. Funding notification is expected by **November 2025** and funds provided by **December 2025**.

Participation in MGFA key activities, such as presentations on funded work at the MGFA Scientific Session at the AANEM Annual Meeting and the MGFA National Conference are expected from award recipients. Recipients may also be asked for interviews on their project and its relevance to the MG Community for MGFA's lay-oriented website and/or newsletter at both the start and completion of the project.

# Eligibility

The RFA is open to established and new investigators. Applications will be accepted from U.S. and international principal investigators with faculty status. Applications are not open to forprofit or small business submissions.

## **Key Dates**

Activity	Date
Call for Proposals Opens	May 15, 2025
Letter of Intent Deadline	June 13, 2025
Notification of Invitation to Proceed with Application	July 3, 2025
Application Deadline	August 15, 2025
Funding notification	November 2025
Funding provided	December 2025
Progress Report / Final Study Report	To be determined; details stipulated in Notice of Award letter (typically at 1-year and at the end of the grant award period)

## **Questions?**

For inquiries related to\_research funded by the MGFA, High Impact Pilot Project funding, or other questions relevant to MGFA's role in funding MG research, please contact MGFA Vice President of Programs and Research Danielle M. Kerkovich, Ph.D. at <a href="mailto:dkerkovich@myasthenia.org">dkerkovich@myasthenia.org</a> or +1-202-812-6462.

For technical inquiries such as system access or site navigation related to ProposalCentral, please email pcsupport@altum.com or call 1-800-875-2562 (toll-free US and Canada) or +1-703-964.5840 (Direct Dial International).

More information about how to register and apply using ProposalCentral:

- How to Register as a ProposalCentral user
- How to Create an Application using ProposalCentral
- User FAQs.pdf (proposalcentral.com)