EXPLORE-MG2 Data and Biosample Sharing Policy

I. Introduction:

The goal of the Exploring Outcomes and Characteristics of Myasthenia Gravis 2 (EXPLORE-MG2) study is to prospectively characterize the natural history of MG through deep clinical phenotyping of largely neglected disease subgroups coupled with biospecimen collection for future studies of treatment-responsive biomarkers and other projects. This research material will be available to researchers and facilitate future research that will lead to a better understanding of the disease.

II. Purpose:

This policy documents the intent of MGNet to promote MG research and the process by which MGNet manages requests to access data and samples.

III. Scope:

This policy applies to requests for the use of clinical data and samples in the EXPLORE-MG2 biorepository.

IV. Definitions:

Central Laboratory: The central laboratory is located at the Duke Immune Profiling Core, Duke University Medical Center. Long-term storage of EXPLORE-MG2 samples will occur at the central laboratory. The central laboratory is available to conduct laboratory-based research and to provide specialized lab services and/or technical advice to support investigator studies as needed.

EXPLORE-MG2 catalog: Web-based system that will provide investigators with a searchable view of available biosamples. This catalog will be created and made available on the MGNet website, and will be maintained by the MGNet Administrative Center.

EXPLORE-MG2 coordinating center: The Duke Clinical Research Institute serves as the coordinating center and is overseen by the PI(s) of the EXPLORE-MG2 study. The coordinating center is responsible for the feasibility assessment and operational aspects needed to evaluate and complete data/sample requests for EXPLORE-MG2 projects. They are also responsible for coordinating sample shipments with requesting investigators/sites.

Steering committee (SC): The SC is composed of:

- The EXPLORE-MG2 study level PIs (RN, VJ)
- One member of the MGNet Statistical Core (GC or IA)
- One member of the MGNet Immunology Core (KO)
- Two site PIs from sites participating in EXPLORE-MG2 (TBD)

- One NIH representative (GN or TU)
- One representative from a MG patient advocacy group (TBD)

The EXPLORE-MG2 study level PIs are permanent members of the SC. Other members of the SC will serve two-year, renewable terms. The SC chair will be elected annually by the members of the SC. The outgoing SC Chair shall serve as the Vice-Chair to the incoming newly elected Chair. The SC will review all research proposals submitted by investigators for scientific validity, feasibility, ethics and appropriate funding. For all approved proposals, the SC will also review and approve authorship recommendations provided by the PI of the proposal. It is expected that sites contributing samples for a proposal will be recognized authors on all publications.

V. Policy:

The EXPLORE-MG2 biorepository encompasses biosamples stored at the central laboratory. Clinical data linked to the biosamples are stored in a REDCap database at the DMCC.

Requests for data and/or samples: Investigators interested in using EXPLORE-MG2 samples for research will submit a proposal request form (see Appendix) describing the study rationale, objectives, experimental design, analysis plan, timelines, investigators, number and type of samples required and funding source. A biosketch from the proposed PI will also be provided.

Review process: Proposals will be submitted to a designated MGNet administrator to verify completeness and for subsequent distribution. Completed requests will be reviewed by two members of the SC appointed by the SC Chair within two business weeks. A SC meeting will subsequently be convened for the SC reviewers to present the proposal to the SC with a recommendation of whether to support the proposal, ask for further information or decline. Following discussion, the SC will vote on the proposal with a simple majority needed to support a proposal. In the event of dissention regarding the merits of a proposal, the proposal may be escalated to review by the MGNet Executive Committee. SC proposal review meetings may occur either via a teleconference (preferred) or email. The review process should be completed within four weeks of submission of a complete sample request proposal. Review decisions will be shared with the requesting investigator by the SC Chair.

Priority will be given to proposals that advance knowledge in MG and benefit the MG patient community versus use of samples for experimental controls for work centered in other diseases. Novel and impactful projects will be prioritized over redundant studies.

Sample distribution: Documentation of IRB approval for the proposed project and an executed material/data transfer agreement must be in place prior to transfer of any samples or data. Following approval by the SC, samples will be distributed to the

requesting investigator for use. Since the samples will be shipped, MGNet cannot guarantee the quality of samples delivered to the requestor. Every effort will be made to ship samples in the best state possible. Requestors will be responsible for biosample selection, preparation and shipping costs. A schedule for these costs will be revised annually. Each sample will be matched with clinical phenotyping data requested in the approved study proposal (e.g. age, sex, onset age, age and MGFA status at time of specimen collection, thymectomy). All submitted proposals will be tracked on a Proposal Tracking form (see attachment).

Documentation: The SC will document all requests (PI name, title of proposal, submission date), the date of committee review, the committee members reviewing the request, the committee decision, date of communicating the outcome to the requesting investigators, and when a request was fulfilled (when applicable) on a proposal tracking form. Any resulting publications or other scientific output resulting from the proposal will also be tracked.

Obligations of investigators receiving biospecimens from MGNet:

- Experimental data will be shared with MGNet and made public via MGNet website (includes academic and industry investigators)
- MGNet and EXPLORE MG-2 investigators will be recognized on publications related to study of distributed specimens

VI. References:

- MGNet Publication Policy
- EXPLORE-MG2 Sample Request Form
- EXPLORE-MG2 Sample Rate Card
- EXPLORE-MG2 Proposal Tracking Form

VII. Review & Revision:

This policy will be reviewed at least every two years; however, more frequent review may occur as the scope of EXPLORE-MG2 changes.

VIII. History of Change:

Version	Rationale	Date
1.0	Original Document	14 SEP 2020
1.1	Revision 1	22 OCT 2022
1.2	Revision 2	28 NOV 2022
1.3	Revision 3	17 MAR 2023

APPENDIX A. Sample Request Form

Title of proposal	
Principal investigator information Send PI biosketch with this form	**Name:** **Position:** **Institution:** **Telephone #:** **Email:**
Co-Investigators and institution(s)	
Study rationale and background information	
Study objectives	
Study design	**Preliminary data and feasibility:** **Experimental approach:** **Name of analyzing lab:** **Scientific impact:**

Analysis plan and justification for sample size	**Analysis Plan:** **Sample size justification:**
Describe biosamples requested (e.g., number, antibody status, age, disease severity, concomitant meds, etc) *If only clinical data are needed, please describe the requested variables.*	**Justification for sample volume(s) requested:**
Funding Source (select one) Provide proof of funding with this sample request form	**Industry:** ☐ **Name of sponsor:** **Federal Grant:** ☐ **Name of funding agency and grant #:** **Patient organization/nonprofit:** ☐ **Name of organization:** **Other:** ☐ **Specify:**
Status of ethics review provide IRB approval notice with this sample request form	**Name of IRB:** **IRB number (if available):**
Study timelines	

Notices for approved proposals:

- Samples may be used only for the uses and in the laboratories noted in this request.
- A materials transfer agreement (MTA) and IRB/ethics committee approval notice are required prior to samples shipment.
- Research using MGNet samples and corresponding clinical information must be performed under approved IRB protocols and in accordance with HIPPA.

APPENDIX B. Proposal Tracking Form

PI Last Name	Proposal Title	Submission Date	SC Review Date	SC Review members	Decision (Y,N, WD, Other)	Outcome Notification Date	Date Request Fulfilled, IRB#, MTA	Comments (include publication references)
				Primary: Secondary: Other attendees:				
				Primary: Secondary: Other attendees:				
				Primary: Secondary: Other attendees:				
				Primary: Secondary: Other attendees:				

Abbreviations: N – No (rejected); PI – principal investigator; SC – steering committee; WD – withdraw; Y – Yes (approved)