

The Myositis Association Research Guidelines

(2020 funding cycle)

SECTION 1. INTRODUCTION

The Myositis Association (TMA) places a high priority on research into the cause, prevention, detection, treatment and cure of myositis. TMA administers research through the Research Fellowships and Grants Program as described in Section 5. These guidelines provide a framework for the funding and conduct of that research. Application of the guidelines will be under the direction of TMA's Board of Directors, Medical Advisory Board (MAB) and its Research Committee.

SECTION 2. WHAT IS MYOSITIS RESEARCH?

Myositis research includes:

1. Basic laboratory research into the cause, detection, treatment, prevention and cure of myositis.
2. Clinical and epidemiological research testing various diagnostic or therapeutic interventions.

SECTION 3. HOW IS MYOSITIS RESEARCH CARRIED OUT?

Research may be conducted in various types of institutions, in various settings, and by various levels of professionally trained individuals:

1. Post-doctoral trainees, young investigators and senior investigators may conduct research (see restrictions in award description Section 5.1).
2. Funded projects may be discrete or may be part of larger projects.
3. Investigators must work in accredited institutions that can provide space and support for the project. Faculty appointments must not be contingent upon receiving a TMA award.
4. Support of organizations that directly fund myositis research may be justified.

5. TMA may provide administrative support for the direction of research activities and the promotion and dissemination of information generated from research activities.

SECTION 4. GOVERNANCE

Spending on research is under the control of TMA's Board of Directors with consultation from the MAB and its Research Committee (Section 5.2).

Section 4.1. Medical Advisory Board

The MAB is a group of professional scientists and clinicians (holding an MD or PhD) from a variety of backgrounds with an interest in myositis research, selected to advise TMA's Board of Directors on all medical and scientific aspects of myositis. The MAB operates under its own bylaws and has a representative who serves on TMA's Board of Directors.

The duties and responsibilities of the MAB as they relate to research are to advise TMA's Board of Directors as the organization's research commitments are expanded.

SECTION 5. RESEARCH FELLOWSHIPS AND GRANTS PROGRAM

Section 5.1. Program Description

Research Fellowships and Grants are available to applicants holding an MD, PhD, or equivalent degree. At the discretion of the Board of Directors, special projects may be funded outside of the fellowship or grant mechanism.

Mentored Research Fellowships are designed to help promising junior investigators (MDs and PhDs) for a period of two years, subject to satisfactory progress, at the salary level approved by the participating institution, to a maximum received annually of \$50,000. Candidates should have completed residency or fellowship training or have received a PhD within the three years prior to commencing the Fellowship and be performing research under the supervision of an established mentor. Recipients must devote at least 50% of their time to research, but may include some study and clinical experience in allied fields. There should be limited supplementation of salary from outside sources.

A competitive candidate will be an early stage clinical or basic investigator that has demonstrated commitment to the field of myositis or related fields. The research environment, quality of research project, career development plan and mentor are all

equally weighted in the funding decision. Applicants must also convey a clear path to research independence.

As examples, applicants can apply at the level of 1) clinical/research fellow (post-residency training) with the award allowing them an opportunity to perform myositis research prior to an independent faculty position. 2) post-doctoral fellow with a clear commitment to myositis research and a path to an independent position. 3) Junior faculty within three years of their independent position as a means of freeing up clinical responsibilities to perform myositis research under the guidance of a mentor.

Pilot Project Grant Funding is designed to fund new and innovative research projects in the hope that they will attract funding from other sources (such as NIH). A competitive application will clearly delineate how this pilot funding will lead to future grant support. In addition, a competitive application will clearly distinguish itself from the investigator's existing research program. Any industry partnership must be clearly disclosed and a letter of support from the industry partner must be included. Pilot grants will be awarded for one or two years and up to a maximum of \$100,000 annually, subject to satisfactory progress.

TMA does not provide for salary of Principal Investigators. TMA provides funds for indirect or administrative costs within research awards, not to exceed 8 percent.

Section 5.2. Governance by the Research Committee

The MAB Research Committee is comprised of professional scientists and clinicians holding MD, PhD, or equivalent degrees, with knowledge of Myositis research. Its goals and responsibilities with respect to the Research Fellowships and Grants Program include:

1. Promoting and administering TMA's Research Grants program.
2. Reviewing Fellowship and Grant applications for basic and clinical research projects and recommending funding through the MAB chair to TMA Board of Directors.
3. Recommending 2nd year renewals based on progress reports.
4. Actively recruiting new researchers by encouraging the submission of grant and fellowship proposals.
5. Ensuring that recipients provide TMA with appropriate recognition in any published or oral material and provide regular reports to TMA.

6. Reviewing progress of awardees in order to recommend payments and renewals.

Section 5.3. Application Process

Only TMA application forms or computer-generated facsimiles of TMA forms containing the same information may be used. The proposal and other supporting documents shall be submitted electronically in a single PDF file and must be received by TMA no later than the submission deadline for applications stated in the research announcement. If the applicant does not receive an email confirming receipt of the application, it is the responsibility of the applicant to contact TMA to assure that the application has been received prior to the application deadline.

A Letter of Intent is required and must contain the following:

1. A one-page cover letter providing the title of the project and identification of any persons who might have a conflict of interest in reviewing the proposal (e.g. former and present collaborators, mentors, and/or competitors). The cover letter should also describe how this application meets the criteria for the level of funding requested:
 - **Pilot project** – evidence that the project is new and innovative and will lead to future grant support.
 - **Fellowship funding** – applicant must be within three years of completing training and be performing research under the supervision of an established mentor. Please identify the mentor.
2. A one-page description of the specific aims of the project.
3. A biosketch in NIH format (an example can be found on the TMA website)

Letters of Intent must be submitted in one PDF document and be received by midnight Eastern Time on the day of the submission deadline for Letters of Intent stated in the research announcement. Awards will be recommended by the Research Committee to the MAB and formally approved by TMA's Board of Directors. In unusual or extraordinary circumstances, TMA's Board of Directors may agree to have an application considered outside the ordinary established funding cycle.

Section 5.4. Eligibility

Anyone is eligible to apply for a grant or fellowship, regardless of whether they are currently being funded or are mentoring a fellow being funded by TMA. Any applicant who is a member of the MAB shall not participate in the MAB grant review process in

any capacity. Any applicant who is a member of the Research Committee shall not serve on the Committee during the funding cycle when the applicant's proposal is being considered.

Section 5.5. Research Fellowships and Grants Review

Evaluation will be on a competitive basis. The Research Committee will solicit input from the MAB to identify appropriate MAB reviewers for each application, following preliminary triage of the applications to deem those relevant and worthy of a full application. The intent is to have at least two MAB members review each application. Applications will be scored according to NIH rating standards. Proposals will be reviewed with respect to (1) relevance to the form of myositis specified and (2) the science. Additionally, fellowship applicants will also be scored based on the qualifications of the candidate, mentor, career plan, and institution. The Research Committee will meet in person, have each application presented by the assigned internal reviewer, and determine consensus ratings and rankings for the applications to then be presented to the MAB for its consideration. The MAB may receive presentations of each application by the assigned Research Committee internal reviewer. The MAB will then vote to approve or modify the ratings and rankings recommended by the Research Committee, with the final ratings and rankings to be presented to TMA's Board of Directors for a final funding decision.

Section 5.6. Reports and Payments

A progress report in lay terms, directed to the donors of the research fund ("Donor Report") must be submitted to TMA no later than one month after the first and second year of the investigation. The grants and contracts office of the awardee's university is required to provide an expenditure report within 30 days of the end of the grant period detailing how the TMA award was spent. The financial officer, or official to whom checks are mailed, must sign this report. TMA reserves the right to request copies of any or all documentation supporting outlays reported on the expenditure report. Any significant deviation from the project's direction, outlined in the applicant's funded proposal, or expected delay in beginning or concluding the project according to the proposed timeline, is to be reported to TMA's Executive Director in a timely fashion. Approval of second year funding for 2-year grants/fellowships is dependent upon satisfactory progress during the first year.

Award payments will be made in equal installments every 6 months during the funding period.

Section 5.7. Senior Investigator Conference

TMA may hold a Senior Investigator Conference where investigators conducting TMA-sponsored research projects are invited to attend and report on their findings.

SECTION 6. RESEARCH POLICIES

Section 6.1. Research Spending

TMA shall announce at the beginning of each funding cycle the amount of funding that is available for each disease-type of research.

Application for a grant should be made through an accredited medical school, university or research institute, which must agree to supply the clinical and/or laboratory facilities. For proposals involving participation of human subjects, the applicant must provide an Institutional Review Board approved consent form. If the IRB has not yet approved the study, a letter from the IRB acknowledging receipt of the consent request must be included and TMA must receive confirmation of the approval from the IRB prior to funding. Proposals involving participation of animal subjects must follow the process described above for human subjects, with references to “Institutional Review Board” replaced by “the institution’s animal care and use committee”. For proposals involving the use of drugs not approved by the FDA, evidence of an IND number from the DEA is also required prior to funding.

Section 6.2. Soliciting Volunteers for Research

Recruiting voluntary research subjects is an important function, but one which requires significant safeguards, in particular those having to do with patient confidentiality. In general, TMA when requested will work through TMA support groups, affiliates, and other volunteer groups to recruit potential research subjects. In recruiting volunteers, TMA will not turn over mailing lists to researchers. TMA will contact possible volunteers, inform them of the research, and supply potential research volunteers with a contact mechanism for the researcher.

Section 6.3. Proprietary Information

Any research proposal submitted for funding to TMA will remain the property of the applicant. TMA will distribute proposals to members of the MAB and Board of Directors for review and will keep proposals on file at TMA’s office.

All TMA funded proposals must contain a lay description (lay abstract) for use and publication as TMA sees fit. All other information from proposals will be kept confidential.

All published papers, abstracts, and oral presentations resulting from research performed as an awardee must acknowledge TMA, and TMA must be notified in a timely manner of the publication.

Section 6.4. Dissemination of Research Results

TMA shall publish periodic research updates in its newsletter (*The Outlook*) and on its website. TMA's update may include a publication list of papers resulting from TMA sponsored research.

SECTION 7. THE MYOSITIS ASSOCIATION STAFF

TMA's Executive Director will provide interaction between the Board of Directors, the MAB, its Research Committee and investigators. All management and administrative duties including issuance of award notices, release of funds, request for reports and program expansion will be under the direction of the Executive Director.

Visit our web site at www.myositis.org to learn more about available grants, to request more information, or to download an application form.