

# **The Myositis Association Research Guidelines**

## **SECTION 1. INTRODUCTION**

The Myositis Association (TMA) funds 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 (BOD), Medical Advisory Board (MAB) and the MAB's 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 are appropriate investigators for TMA grants (see restrictions in award description Section 5.1).
2. Funded projects may be stand alone 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.

## **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, PhD or other doctorate level degree) from a variety of backgrounds with an interest in myositis research and treatment. The MAB has been selected to advise TMA's Board of Directors on all medical and scientific aspects of the organization's activities. 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 implement the procedures to review grant applications and select those to be recommended for funding to TMA's Board of Directors. The BOD makes the final funding decisions.

## **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 maximum period of two years, at the salary level approved by the participating institution. The maximum amount that can be received annually is \$50,000 and funding for the second year is contingent on demonstrated progress in the first. 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 weighted in the funding decision. Applicants must also convey a clear path to research independence.

Examples of acceptable models are listed below. These are not exclusive and other approaches can be considered.

1. Clinical/research fellow (post-residency training) with the award allowing an opportunity to perform myositis research prior to an independent faculty position,
2. Post-doctoral fellow with a clear commitment to myositis research and path to an independent position,
3. Junior faculty within three years of their independent position to allow protected time 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 future funding from other sources (such as NIH). A competitive application will clearly delineate how this pilot funding will lead to future grant support and 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 of the total award.

## **Section 5.2. Governance by the Research Committee**

The Research Committee of the MAB 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 and selecting the strongest, most potentially impactful applications. The Committee recommends funding through the full MAB to the TMA Board of Directors for final decision making.
3. The Chair of the MAB reviews interim reports and recommends 2<sup>nd</sup> year renewals based on progress reports.
4. Acting to recruit new researchers by encouraging the submission of grant and fellowship proposals.

## **Section 5.3. Application Process**

The application process proceeds in two steps:

Step one -- Submission of a Letter of Intent (LOI) containing the following information:

1. One-page cover letter providing the title of the project and describing 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. One-page description of the specific aims of the project.
3. Biosketch in NIH format
4. Identification of any persons who might have a conflict of interest in reviewing the application (e.g. former and present collaborators, mentors, and/or competitors.)

Letters of Intent must be submitted in a single PDF document and be received by midnight Eastern Time on the day of the submission deadline stated in the research announcement. (If the applicant does not receive an email confirming receipt of the LOI, it is the responsibility of the applicant to contact TMA to assure that the LOI has been received prior to the application deadline.)

The LOI will be evaluated and the applicant will be notified whether they should proceed to completing the second step of the application process – the formal grant application.

#### Step two – Submission of the TMA Grant Application

TMA application forms can be found on the TMA website at the following location:  
<https://www.myositis.org/research/tma-grants-fellowships/research-funding-opportunities/>

Only application forms or computer-generated templates of TMA forms containing the same information may be used.

Applications must be submitted in a single PDF document and be received by midnight Eastern Time on the day of the submission deadline as 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.)

Other key points:

- 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 applications involving participation of human subjects, the applicant must provide an Institutional Review Board (IRB) 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.
- Applications 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 applications involving the use of drugs not approved by the FDA, evidence of an IND number is also required prior to funding.

#### **Section 5.4. Participation and Conflict of Interest**

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

Any member of the Research Committee who is considered conflicted due to institutional affiliation or potentially competitive research activities shall be recused from discussion of that particular application.

Any MAB member whose application is one of those recommended for funding by the Research Committee shall not participate in the research discussion at the MAB.

#### **Section 5.5. Research Fellowships and Grants Review**

Evaluation will be on a competitive basis. The Research Committee Chair will assign unconflicted MAB reviewers with the intent of having at least three reviews for each application.

The Research Committee will meet in person, if possible. Applications will be individually presented by an assigned MAB reviewer and discussed. The committee will determine consensus ratings and rankings to prioritize the applications as a recommendation for funding to the MAB. The MAB will then vote to approve or modify the ratings recommended by the Research Committee, and present those to TMA’s Board of Directors for a final funding decision.

#### **Section 5.6. Reports and Payments**

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

A narrative progress report (Interim report) is to be submitted to TMA no later than one month after the first year of the grant. Approval of second year funding for 2-year grants/fellowships is dependent upon satisfactory progress during the first year as outlined in the interim report.

Any significant deviation from the project's direction as outlined in the applicant's funded proposal, or 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.

The final payment will be released following receipt of the final narrative report at the conclusion of the project.

The grants and contracts office of the awardee's university is required to provide an expenditure report within 30 days of the final payment to TMA. The financial officer, or official to whom checks are mailed, must sign this report. TMA may request documentation of outlays reported on the expenditure report.

### **Section 5.7. Senior Investigator Conference**

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

## **SECTION 6. RESEARCH POLICIES**

### **Section 6.1. 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, when requested, TMA 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 potential subjects and inform them about the research opportunity, allowing them to contact the investigator should they have interest in learning more.

### **Section 6.2. 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 and provided with a copy.

### **Section 6.3. 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 ROLE**

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](http://www.myositis.org) to learn more about available grants, to request more information, or to download an application form.*