



## INSTRUCTIONS FOR COMPLETION OF THE DEVELOPMENT GRANT APPLICATION

### Introduction

In preparing your grant application, please read and follow these instructions carefully. Incomplete or improperly prepared applications will not be reviewed. An application will be considered incomplete if: (1) it is not prepared and submitted according to instructions; or (2) the information it contains is not sufficient to permit an adequate review.

To facilitate proper review of your application please remain succinct and limit the sections of your application describing your “Specific Aims”, “Background” and “Experimental Plan” to a maximum total of **seven (7) pages** INCLUDING FIGURES AND LEGENDS with 0.5 margins. Applications must be submitted using 11pt font only.

The Applicant (PI) and Sponsor (Mentor) are responsible for the scientific and technical direction of the project.

### Deadline for Receipt of Completed Application

The application must be **RECEIVED on or before** the deadline date given. Once the deadline has passed, the submit button will no longer be available.

### General Submission Guidelines

- ❖ Development Grant applications are **limited to one application per lab per application cycle.**
- ❖ Applications and ALL supporting documents MUST be submitted in English.
- ❖ Request support in U.S. dollars (\$) only. Awards are \$60,000 per year including indirect costs (maximum of 10%).
- ❖ Avoid abbreviations except for those in common use such as DNA, ATP, CK, and so forth.
- ❖ Appendix material is limited to one (1) unpublished manuscript and unlimited preprints and manuscripts accepted for press but NOT YET PUBLISHED and MUST be uploaded to the application with the acceptance letter/correspondence. **DO NOT ATTACH MANUSCRIPTS, ABSTRACTS, OR REPRINTS ALREADY PUBLISHED.** These attachments will be deleted from your application.
- ❖ A resubmission MUST be accompanied by a **Resubmission Statement** responding to the previous reviewers’ concerns.
- ❖ A **Signed Cover Sheet** will be populated as you complete your application sections. Once you have completed your entire application you will go to Section 17 (Print) and click on “Print Signature Pages.” You will then need to obtain an institutional official’s signature **and** your mentor’s signature. You will sign the form where indicated and upload to your application.

## Principal Investigator

The Principal Investigator is the one person responsible for the scientific and technical direction of the project. An application may have only one Principal Investigator. The Principal Investigator must be the author of the application.

If a **co-investigator** and/or **collaborator(s)** are involved with the proposed project, a letter of collaboration and a biosketch for each **MUST** be uploaded to the application.

## Sponsor (Mentor)

The Sponsor (Mentor) is the person whose lab the PI will be working in. The Sponsor (Mentor) must agree to help facilitate the project and PI in all manners to accomplish the aims of the project.

## SECTION 1

### Project Title

Whenever possible, the title should include the name of the neuromuscular disease or class of neuromuscular disease to which the research is most related. (MDA reserves the right to edit grant titles for clarity.)

### Resubmission

If you have marked the application as a resubmission, please put the date of the previous submission. In a case where it is the 2<sup>nd</sup> resubmission of a grant, please indicate the most recent submission prior to the current application.

An applicant may resubmit their original application with revisions up to two (2) times. However, an applicant who is resubmitting an application may not be more than six (6) years from their terminal degree.

At the bottom of this page, your previous application(s) should appear. Please click on the previous proposal for which you are resubmitting.

A resubmission application will be required to upload a "Resubmission Statement." The Resubmission Statement should address the previous reviewer's concerns any changes you have made to the current application. The Resubmission Statement **must not exceed one (1) page in 11 pt font with 0.5 margins.**

## SECTION 2

### Download Templates and Instructions

This section contains ALL templates that are required to complete or which might be necessary for the full submission of your application.

You **MUST** use the “**Research Plan**” template provided in this section for submission. This part of your application is **required**, limited to seven (7) pages in an **11 pt font with 0.5 margins**.

The Biosketch template provided should be used for the Principal Investigator. You will also need to upload a Biosketch for the Sponsor (Mentor) and each Co-PI, Collaborator and Consultant who will be responsible for the execution of this project. Each Biosketch should clearly identify all papers in all fields published during the past three (3) years and a list of all grants held within the past three (3) years, specifying funding sources. Please identify films, tape recordings and monographs on which you may have collaborated. Each Biosketch is limited to a **maximum of four (4) pages**.

The Facilities Available for Research is a **required** section of the application but is not limited to a maximum number of pages but **must be in 11 pt font with 0.5 margins**. Please list ALL facilities available for conducting the proposed research project. Include laboratory space, clinical facilities, animal facilities, computer facilities, office space, clerical staff and major equipment available. Identify by name and address any facilities that are not part of the sponsoring institution and describe the arrangements made for using those off-site facilities.

The Budget Justification is a **required** attachment and should be completed by fully justifying all expenses listed on the main Detailed Budget page.

References for Literature Cited is a **required** section of the application. There are no page limits but **must be in 11 font with 0.5 margins**. Make every attempt to be judicious in compiling a relevant reference list. It need not be exhaustive.

**Note: Subcontracts are not permitted on Development Grant awards.**

## **SECTION 3**

### **Enable Other Users to Access this Proposal**

This section is used specifically for providing access rights to other people whom you may wish to have access to your application. You may choose their access as “View” or “Edit.” If you give someone “Edit” ability they can upload documents or add attachments in your absence.

If you mark an individual as “Auto Notify” this means each time an email is sent to you through proposalCENTRAL, that person will automatically receive a copy of the email.

## **SECTION 4**

### **Applicant/PI**

This section of the application asks for the Principal Investigator’s information. All fields that are marked with asterisk (\*) are required fields. If you already have a professional profile within proposalCENTRAL, these fields will be automatically populated and filled in. Please review them carefully to confirm the information is correct.

## Conflict Of Interest Disclosure

Any potential conflict of interest the Principal Investigator(s) or collaborator(s) may have relating to the project must be revealed. Such conflict would include, but may not be limited to, having a proprietary interest that may be affected by the outcome of a research project. It is expected that MDA grantees will observe the highest ethical standards in the conduct of research. Please attach a one-page explanation if a conflict of interest exists.

## SECTION 5

### Institution and Contacts

This section contains the information of the “Lead Institution.” This page defaults to the institution of the Principal Investigator. If the institution is incorrect, you may click on the “Change Institution” button and search for the correct institution. The asterisks (\*) denote required fields. Please make sure that all information on this page is correct, including the IRS EIN number. The IRS EIN number should be 9 digits in the following format XX-XXXXXXX. Do NOT include letters or additional separators. You will need to upload a copy of your institution’s W-9 form before submitting the application.

The W-9 Form should be available to you through your Grants and Contracts or Sponsored Programs Office.

**NOTE:** If you are applying from a **non-U.S.** institution/university and your institution/university does not have an EIN number, you will need to type in **N/A** in the space provided.

Your University/Institution may already have contacts listed under their profile. Contacts that are required on all grants are marked with an asterisk (\*) and cannot be removed. These contacts are generally institutional officials, financial officers or grant and contract personnel. However, if you need to add one, you may do so by entering their email information in the space provided and clicking the “Add” button.

You will also need to add your Dean, Department Chairperson and the Institution’s Public Relations contact.

## SECTION 6

### Key Personnel

ALL personnel working, collaborating, over-seeing or coordinating on the project **MUST** be listed in this section. This section should also include all Co-PIs and Collaborators. You will need to insert their email address in the space provided and click “Add.” Complete all required fields and click “Save” when completed. This person will now appear in the “Key Personnel” window.

## SECTION 7

### Letters of Reference

**Three (3)** letters of reference are **required** for each applicant – one (1) from the Mentor/Sponsor, and two (2) additional references from other Professors/Colleagues. **Only 3 letters of reference are allowed.**

Once you have input the email address of the person you are requesting a letter of reference from an email is generated to that person with specific instructions on how to provide the letter of reference for you. These letters are blind letters and not sent to you for uploading. It is up to the applicant to make sure the letters are uploaded prior to the Validation stage.

### **Content of Sponsor/Mentor Letter**

The letter from the Sponsor/Mentor must include the items below in addition to an evaluation of the candidate. The Sponsor/Mentor letter should be limited to 4 pages maximum. Sponsors/Mentors will be prompted to upload their document by an email from proposalCentral. The Sponsor/Mentor letter must be signed and accompany the application in order to be considered for this program.

#### **1. Research Support Available**

In a table, list all current and pending research and training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates and amount of the award. If the mentor's research support will end prior to the end of the proposed training period, the mentor should provide a contingency plan for how the applicant's research will be supported. The role of the mentor in the integrated research and development plans should be described.

#### **2. Mentor's Training History**

Give the total number of postdoctoral individuals previously mentored. Select up to five that are representative, and, for those five, provide information on time spent in the lab, their present employing organizations and position titles or occupations.

#### **3. Applicant's Qualifications and Potential for an Independent Research Career**

Describe how the applicant is suited for this research training opportunity based on his/her academic record and research experience, including how the individual research training plan and your own expertise as the mentor will help this researcher establish an independent research career.

#### **4. Institutional Commitment**

Describe the institutional title will the applicant hold at the time the award would be expected to be made. Please clarify the institutional qualifications for this title and its relationship to faculty status. Is there institutional commitment of a faculty position during the award period?

### **Content of Reference Letters from other than the Sponsor/Mentor**

These letters must be submitted by professors or colleagues in the field of research who can best evaluate the scientific interests and qualifications of the applicant. These recommendation letters must be signed and accompany the application in order to be considered for this program. There are no exceptions.

## **SECTION 8**

### **Patent Information**

If you have filed for or obtained Patents please complete the information in this section. Please use the date format of MO/DY/YEAR. If you have not filed or obtained a Patent you may leave this section blank.

## **SECTION 9**

### **Lay Summary and Abstract**

Please provide a succinct and non-technical summary of your proposed project in non-scientific terms that would be understood by a general audience. Since this summary will be public information, do NOT include any proprietary or confidential information in this section. Do NOT summarize past accomplishments or cite literature in this section.

The Lay Summary section is limited to 1,500 characters, including spaces. Information entered in this section must be text only. Scientific notations, special characters, special fonts and other rich-text formatting (i.e. bold, italics, underline) cannot be saved or displayed. Do NOT insert carriage returns at the end of each line. Type continuously until completed or starting a new paragraph.

If you “cut and paste” in this section, please double check that there are no additional carriage returns before submitting the application.

The Abstract section should be a succinct summary in scientific terms that would be understood by a technical audience. Since this summary may be public information, do not include any proprietary or confidential information.

In concise terms state: (1) the long term objectives; (2) the specific aims; (3) the primary methodology and principal organism, tissue, or preparation being used; (4) the relationship of the project to neuromuscular disease.

Do **NOT** summarize past accomplishments or cite literature in this section. Limit the Abstract summary to 3,000 characters or less, including spaces. Information entered in this field must be text only: scientific notations, special characters, special fonts, and other rich-text formatting (e.g. bold, italics, underline) cannot be saved or displayed. Do NOT insert carriage returns at the end of each line. Type continuously until completed or starting a new paragraph.

If you “cut and paste” in this section, please double check that there are no additional carriage returns before submitting the application.

### **Impact Statement**

Please state how this project will promote major advancement in the understanding of neuromuscular disease, accelerate treatments and cures or optimize patient care. This statement will play a major role in the review of your application and its importance to MDA’s mission. Please limit your statement to 1000 characters or less.

## Research Category

At the bottom of this section you will see a listing of the main categories under the MDA umbrella of neuromuscular diseases. You may choose one category or multiple categories that apply. Under the general category you will find the disease specific categories. Please choose only one Primary Disease Code. Under the Secondary Disease Codes you can choose one disease or multiple diseases. Please note that the one(s) you have chosen will appear to the right of the boxes.

Please choose these categories carefully as they will be used to help facilitate the selection of scientific peer reviewers.

## SECTION 10

### Budget Period Detail

You will need to enter the Start Date and End Date of each Budget Period. To change to a new Budget Period, click on the buttons at the top of the page for "Period 1," "Period 2," or "Period 3." You will need to complete each section of the Detailed Budget for each year of support for which you are requesting funds.

The Budget Summary (Section 11) will auto complete itself once you have completed the Detailed Budget.

**Personnel** must be listed by name, role, and percentage effort devoted to project but should be listed as \$0 under the Requested Salary column. The Salary category for a Development Grant is limited to the **Principal Investigator ONLY**. Requested salaries are **NOT** to be used to replace salaries or partial salaries that are already assured by institutional or other funds. The Principle Investigator's specific role(s) in the proposed research must be described under "Proposed Budget Justification."

The "Institutional Base Salary" should be the Principle Investigator's **total** base salary and "Fringe Benefits" listed should be the proportionate percentage of the Principle Investigator's benefit cost.

**Equipment**, whether capital or not, must be listed in this section. Along with a full justification, identify the manufacturer and model number under budget justification section. This category is limited to a maximum of \$3,000 per year. Computer hardware limited to a **maximum of \$3,000 per grant**. Support for computer equipment will be limited to one (1) laptop per grant. Any request for lap tops or other computer equipment must be fully justified on the Budget Justification page of the application.

**Supplies** must be listed by sub-category: glassware, chemicals, reagents, radioisotopes, animals, and so forth. If animals are to be used in your research, state how many are to be used, their unit purchase price and their unit care cost.

**Travel** to attend foreign or domestic scientific or medical meetings to present the results of MDA-supported research is permitted. Also, funds for travel required in conducting the specific aims of the research project may be requested. All travel must be fully justified in the proposed budget justification; however, **MUST NOT** exceed **\$1,000** in any given year and is restricted to the Principal Investigator.

**Other** expenses may include items such as publication costs, computer use fees, equipment maintenance and office supplies. Office supplies may **NOT** exceed **\$600** in any given year. The need for each item must be justified in the budget justification section.

**Indirect Costs** are limited to a **maximum of 10%** of all direct costs.

**Subcontracts are NOT permitted on Development Grants.**

**Unauthorized Expenses**. The following expenses are **not** permitted under MDA's research program:

- ❖ Salary or fringe benefits for the Sponsor (Mentor), collaborating investigators, co-investigators or lab personnel;
- ❖ Salaries, travel and/or housing related to sabbatical leaves;
- ❖ Salaries for administrative, secretarial and/or clerical staff;
- ❖ Life and Disability insurance fees;
- ❖ Purchase or rental of office equipment; (i.e., furniture, filing cabinets, and copy machines);
- ❖ Expenses normally covered by the indirect cost of the Principal Investigator's institution, i.e. general liability insurance and general auto insurance;
- ❖ Fees for tuition, registration or other fees relating to academic studies;
- ❖ Membership dues, subscriptions, books or journals; and/or
- ❖ Expenses for or related to moving from one institution to another.

## **SECTION 11**

Section 11 (Budget Summary) will automatically complete itself once you have completed the Detailed Budget section.

## **SECTION 12**

### **Other Support**

**ALL** sources of current and pending research support - including other MDA projects - must be identified in this section for the Principal Investigator and Sponsor (Mentor) only. This includes all sources – Federal, non-federal, commercial or institutional. Prizes or gifts do not need to be included.

Please upload the current budget or proposed budget for all Supplemental or Alternate funding sources for this project in Section 14 of your application.

## **SECTION 13**

### **Organization Assurances**

If your application requests support for research involving human subjects, tissues or materials, then this section **MUST** be completed. A copy of the IRB/FDA approval **MUST** be uploaded to your application. If your IRB or FDA approvals are “pending”, please indicate this by clicking the “Pending”

button. In cases where the IRB/FDA approvals are pending, you must upload a copy of the approval once you have obtained it from the appropriate governing board. An approval must be on file with MDA before funds may be forwarded for the project if funded.

MDA-funded projects **MUST** be in compliance with all policies, rules, and regulations governing clinical trials, including those of the federal regulatory agencies, the respective university and institution, and MDA. MDA must be advised about any amendments to the original research protocol (including the patient consent form) occurring prior to the commencement of or during the course of the research project.

If your application requests support for research involving experimental drugs or devices, this section **MUST** be completed. If your FDA approval is pending, please indicate this by clicking on the “Pending” button. An approval must be on file with MDA before funds may be forwarded for the project if funded.

If your application requests support for research involving vertebrate animals or materials derived there from, this section **MUST** be completed. If your Animal Care and Use Committee approval is pending, please indicate this by clicking the “Pending” button. An approval must be on file with MDA before funds may be forwarded for the project if funded.

Continue down the list of the assurances, marking them either “Yes” or “No.” Click on the “Save” button in the corner to save any changes you may have.

## **SECTION 14**

### **Research Plan and Supporting Attachments**

#### **SPECIFIC AIMS, RATIONALE AND SIGNIFICANCE, BACKGROUND AND PLAN**

**You must use the “Research Plan” template settings for the body of this section. You may have up to 7 pages in 11 pt font. DO NOT exceed seven (7) pages including FIGURES AND LEGENDS with a 0.5 margin. Your application will not be forwarded for review if the page limit is exceeded.**

MDA has adopted NIH’s recent guidelines for enhancing reproducibility through rigor and transparency and reviewers will assess whether these areas have been appropriately addressed by the applicant.

Give the specific aims of the project, prioritized chronologically, and an estimate of the time you expect will be necessary to complete each aim. State the rationale for the project and explain its significance, i.e., how the anticipated results will help solve important problems in the field. This section should clearly provide the reader with succinct information on the research you are proposing, why it is important and how it will advance the neuromuscular disease research field.

Summarize the key results and major conclusions from published, in preparation and/or unpublished studies that specifically relate to your proposed project. Applicants should describe the general strengths and weaknesses of the prior research being cited to support the application. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources. For example, basing one's proposed research on previous publications that lacked statistical power, were not blinded, lacked detail on the sex of animals or

authentication of cell lines would be considered a weakness of the application if it does not identify these weaknesses and propose ways to improve going forward. Likewise, conclusions drawn from prior research that used a small sample size may not adequately support the next phase of research, such as moving to a higher species of animals or to humans.

Describe the experimental design and any novel laboratory procedures required to accomplish the specific aims of the proposed project. For a new methodology state its advantage over existing methodologies. Applicants should describe how they will achieve robust and unbiased results when describing the experimental design and proposed methods. Sample sizes should be clearly delineated and justified using power analyses. Sex as a biological variable should be factored into research designs in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. Succinctly state the potential difficulties and limitations of the proposed procedures in achieving the specific aims of the project. Discuss how data will be analyzed and interpreted. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be taken for their protection.

## **APPLICANT STATEMENT**

**You must use the “Applicant Statement” template settings for the body of this section. You may have up to 6 pages in 11 pt font. DO NOT exceed six (6) pages with a 0.5 margin. Your application will not be forwarded for review if the page limit is exceeded.**

### **1. Applicant’s Background and Goals for Training Period**

#### **A. Previous Research Experiences**

Summarize your research experiences in chronologic order including doctoral dissertation, post-doctoral research, and others, if applicable, including the areas studied and the conclusions drawn. Do not list academic courses.

#### **B. Training Goals and Pathway to Independence**

Describe your overall training goals during the duration of this award. Explain how the proposed award will enable the attainment of these goals specifically identifying the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. Describe the specific training plan that you and your mentor have developed together that will enable the attainment of these goals. The training plan should be individualized for you, keeping in mind your strengths and any gaps in needed skills, and should be designed to enhance research training and professional development. The training plan for a post-doc in their second year may vary from the training plan for a post-doc in their fifth year. Include descriptions of specific items such as classes, seminars, opportunities for interaction with other groups and scientists, and development of professional skills such as grant writing, public speaking and lab management. Discuss how the proposed additional training will facilitate your transition to an independent research position including how the proposed research project will help you to develop an independent scientific program.

#### **C. Activities planned under this award**

Describe, by year, the activities (research, teaching, clinic etc.) you will be involved in during the proposed award and the estimate of percentage of time devoted to each activity; the percentage should total 100 for each year. Make sure to also include any planned activities relating to professional development and securing an independent research position.

## 2. Respective Contributions

Describe the collaborative process between you and your mentor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research.

## 3. Description of Institutional Environment and Commitment to Training

You must document a strong, well-established research program related to your area of interest, including the names of key faculty members relevant to your proposed developmental plan. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars and presentations, and other relevant activities.

## APPENDIX

Appendix material is **LIMITED TO** manuscripts or pre-prints **ACCEPTED** for publication, but **not yet** published. Please provide the communication of acceptance along with the manuscript or preprint. You may also attach one (1) unpublished manuscript not yet accepted. Uploaded items that have been published WILL BE DELETED. **W-9 FORM**

You will need to upload a W-9 Form for your University or Institution. If you are with a non-US University of Institution, please upload the blank form to fulfill the “required” attachments for the Validation process. You do not need to fill out the form if you are a non-US institution.

## SECTION 15

### Validate

**AFTER** you have validated the document you **MUST click “SUBMIT”** for the application to be submitted. Validating the document **DOES NOT** submit the application to MDA. Proceed to Section 17 for Submitting the application.

### **IMPORTANT NOTE**

One copy of your completed application should be filed with the business office of the sponsoring institution to alert them to your pending request for MDA support.