INSTRUCTIONS FOR COMPLETION OF THE RESEARCH 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 Preliminary Data" and "Experimental Plan" to a maximum total of **seven (7)** pages including FIGURES and LEGENDS**.** Applications must be submitted using **11pt font only.** This section of the application is found under the "Research Plan."

All times referenced in the application process and through proposalCENTRAL are given in **Eastern Time**.

Deadline for Receipt of Completed Application

A Letter of Intent is required by **December 15** for the January 30 application deadline and by **June 15** for the July 15 application deadline. The completed application **must** be submitted through **proposalCENTRAL** by **January 30** for a grant to begin the following **August 1**, or **July 15** for a grant to begin the following **February 1**.

The application must be **RECEIVED on or before** the deadline date. Once the deadline has passed, the submit button will no longer be available. You may view the deadline at the top of each section of your application.

General Submission Guidelines

- Applications and **ALL** supporting documents MUST be submitted in English. This includes your IACUC Approvals, IRB Approvals and Biohazardous Use Certificates.
- Request support in **U.S. dollars ($) only.**
- 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- Appendix material is limited to one (1) unpublished manuscript and unlimited preprints and manuscripts accepted for press but NOT YET PUBLISHED and MUST be uploaded to the application with the acceptance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. The statement is limited to a **maximum of one (1) page**.
- A fully executed Signed Cover Page must be attached. Please see instruction under **Section 13**.

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.

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

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.)

Early Stage Investigator

An **Early Stage Investigator**, is a *new investigator* who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant.

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 2nd resubmission of a grant, please indicate the most *recent* submission prior to the current application.

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 and any changes you have made to the current application. The Resubmission Statement must not exceed one (1) page.

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. **DO NOT** change the margins which are 0.5 on all sides.

The Biosketch template provided should be used for the Principal Investigator. You will also need to upload a Biosketch for each Co-PI, Collaborator, Consultant and Post-Doctoral Associate 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. A Biosketch is not needed for graduate students, technicians or coordinators.

The Facilities Available for Research Template is a required section of the application but is not limited to a maximum number of pages. Please use 11 pt Font and all margins must be 0.5. 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 template is a required section of the application. Please use 11 pt Font for this section and 0.5 margins. There are no page limits for this section. Make every attempt to be judicious in compiling a relevant reference list. It need not be exhaustive.

A Subcontract Detail Budget is provided in the event that you will have a subcontract listed on the Detailed Budget. Each subcontracting institution should have their own SubContract Detail Budget attached. Indirect costs are not permitted on the subcontract budget page. The indirect costs will be fully included on the main Detail Budget page to the Lead Institution. All indirect costs are limited to a maximum of ten (10) percent of the direct costs.

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.

SECTION 6

Key Personnel

ALL personnel working, collaborating, over-seeing or coordinating on the project MUST be listed in this section. This should also include all Co-PIs, Collaborators and Subcontract PIs. 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

Patent Information

If you have filed for or obtained a patent please complete the information in this section. Please use the date format of MO/DY/YEAR. You will need to upload your Patent Disclosure in the Appendix section of the application. If you have not filed or obtained a Patent you may leave this section blank.

SECTION 8

Lay Summary and Scientific Abstract

Please provide a succinct and non-technical lay 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 Scientific 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 Scientific 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. Under the general category you will find the disease-specific categories. You may choose multiple categories under this section. 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 9

Detailed Budget

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 10) will auto complete itself once you have completed the Detailed Budget.

Personnel must be listed by name, role, and percentage effort devoted to project. The Principal Investigator's salary is permitted, equivalent to the ratio of effort up to 25% but not more than $15,000, plus a proportionate ratio of fringe benefits. 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. Computer equipment is limited to $5,000 per grant. Laptop purchases are limited to one (1) per grant and must be fully justified on the Budget Justification page.

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 personnel listed on the Budget in the Personnel Cost category.

Subcontract(s) must be listed in this section of the budget. A separate "Sub Contract Detailed Budget" must be submitted for each subcontract. A template for the Sub Contract Detailed Budget is provided in the Supporting Attachments section (Section 13). The subcontract budgets may **NOT** include indirect costs as they are absorbed through the main budget "indirect costs." If fees for consultants are requested, their names and institutional affiliations **must** also be given.

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.

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

- Salary or fringe benefits for collaborating Investigators, co-Investigators or consultants;
- 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, General Auto Insurance;
- Fees for tuition, registration or other fees relating to academic studies;
- Fees for or related to obtaining visas or citizenship status;
- Membership dues, subscriptions, books or journals; and/or
- Expenses for or related to moving from one institution to another.

SECTION 10

Section 10 (Budget Summary) will automatically complete itself once you have completed the Detailed Budget section.

SECTION 11

Other Support

ALL sources of current and pending research support - including other MDA projects - must be identified in this section for the Principal Investigator 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 13 of your application.

SECTION 12

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 13

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 INCLUDING FIGURES AND LEGENDS. **DO NOT exceed seven (7) pages in an 11 pt font with 0.5 margins.** 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.

SIGNED COVER SHEET

The cover sheet is auto populated as you complete the application sections. You will need to go to item 15 (Print) and click on the "Print Signature Page." You will need to obtain an Institutional Official's signature as well as signing the page yourself. You will then upload the document in section 12 of your application. If you do not upload this page with signatures your application will **not** be accepted for review.

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 14

PI Data Sheet

This part of your profile is not mandatory. MDA uses this strictly for association statistics and does not print or advertise this information.

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.

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. Hardcopies are not to be sent to MDA.