

## INSTRUCTIONS FOR COMPLETION OF THE MDA IDEA AWARD GRANT APPLICATION



### Introduction

A great idea can come from anywhere or anyone at any time! With this in mind, the MDA is requesting applications for the MDA Idea Award Program which will seek bold, innovative research ideas that can have an impact in the field of neuromuscular disease. The idea should be supported by a strong scientific premise and include a feasible experimental plan.

Awards will be \$25,000 for one year of support. Funds can only be used for supplies and reagents. See Section 9 for the full list of Allowable costs.

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.

### Application Deadline

The application deadline is **April 16, 2021**. The application must be completed and submitted through proposalCENTRAL.

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

### Eligibility Requirements

To be eligible to apply for the MDA Idea Award, an applicant must:

1. Hold a Doctor of Medicine (M.D.), Doctor of Philosophy (Ph.D.), Doctor of Science (D.Sc.) or equivalent degree (i.e. D.O.);
2. Be a professional or faculty member (Professor, Associate Professor or Assistant Professor) at an appropriate educational, medical or research institution;
3. Be qualified to conduct and mentor a program of original research within his or her own laboratory;
4. Assume both administrative and financial responsibility for the grant; and
5. Have access to institutional resources necessary to conduct the proposed research project.

### Application Submission Requirements

- ❖ Applications and ALL supporting documents **MUST** be submitted in English. This includes IACUC Approvals, IRB Approvals and Biohazardous Use Certificates.
- ❖ Proposed project costs may only be requested in **U.S. Dollars (USD)**.
- ❖ Avoid abbreviations wherever possible.
- ❖ Appendix material is limited to one (1) unpublished manuscript and unlimited preprints and manuscripts accepted for press but **NOT YET PUBLISHED** and **MUST** be uploaded to the application with the acceptance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.

## Review Criteria

- **Impact:** What is the potential for the proposed study to advance the field? If successful, is this work likely to lead to subsequent grant proposals?
- **Innovation:** Does the application propose a novel and unique approach to study neuromuscular disease? Does the proposed idea seek to challenge current research paradigms?
- **Research Strategy:** Is the experimental plan appropriate to test the proposed idea? Is there a reasonable rationale for the study? Will the proposed experiment(s) lead to clear results that can validate the viability of the idea?

## 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 Collaboration on institutional letterhead explaining the role of the project partner is required.

## SECTION 1

### Title Page

Please enter a title that accurately and concisely captures the proposed project. Please also indicate Early Stage Investigator and Resubmission status.

## SECTION 2

### Required Application Templates and Instructions

#### Research Plan

You MUST use the “**Research Plan**” template provided in this section for submission. To facilitate proper review of your application please remain succinct and limit the application describing your Background/Rationale, Specific Aim(s), and Experimental Plan to a maximum total of **two (2)** pages in a size 11 font. Preliminary data are not required or expected for this application. **DO NOT** change the margins which are 0.5 on all sides.

#### Biosketch

A biosketch template is provided and may be used for the Principal Investigator. MDA will accept an NIH formatted biosketch in lieu of the template provided. 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. A biosketch is not needed for graduate students, technicians or coordinators.

#### Facilities

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 size 11 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.

#### Budget Justification

The Budget Justification is a required attachment and must explain why proposed costs are necessary to complete the proposed project.

## References for Literature

The References for Literature Cited template is a required section of the application. Please use size 11 font for this section and 0.5 margins. There are no page limits for this section.

## 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. Additionally, please link your ORCID ID to your proposalCENTRAL account as instructed on this page.

### Conflict of Interest Disclosure

Any potential conflict of interest the Principal Investigator(s) or collaborator(s) may have relating to the project must be disclosed. 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

### Payment Information/Institution Contacts

This section contains the information of the applicant. This page defaults to the institution of the Principal Investigator. If the institution is incorrect, 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 and ACH payment information. The IRS EIN number should be 9 digits in the following format **XX-XXXXXXX**. Do NOT include letters or additional separators. Please upload a copy of your institution’s W-9 form before submitting the application.

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

**NOTE:** Applicants from a non-U.S. institution/university without an EIN number, will enter in N/A in the space provided. If your institution/university has a W-8BEN, please attach it in place of a W-9. If your institution does not have a W-8BEN, please upload a blank document in order to pass the validation stage.

The applicant 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. To add a contact, enter their email address in the space provided and click the “Add” button.

It is also necessary to add the institution’s Dean, Department Chairperson, Technology Transfer contact and a Public Relations contact.

## SECTION 6

### Key Personnel

**ALL** personnel working, collaborating, overseeing or coordinating on the project **MUST** be listed in this section. This should also include all Co-PIs and Collaborators. 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 the applicant has filed for or obtained a patent, please complete the information in this section. Please use the date format of M/D/Y. Upload the Patent Disclosure in the Appendix section of the application. Please leave this section blank if a Patent has not been filed or obtained.

## SECTION 8

### Lay Summary and Abstract

Please provide a succinct and non-technical **Lay Summary** of the 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.

The **Abstract** 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.

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.

### 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 this statement to 1000 characters or less.

## Research Category/Disease Code

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 (1) 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

### Budget Period Detail

Enter the Start Date and End Date of the Budget Period at the top of the screen. This program is limited to a maximum of one budget period. Complete the Supplies section of the Detailed Budget with the appropriate breakdown of proposed costs.

### Allowable Costs

**Supplies:** There is no maximum cost for supplies. The total request should include all supplies that will be purchased for this project but may not include "Other" expenses such as shipping, printing or office supplies. You do not need to group costs by the type of supplies. You may enter a total amount for Consumables.

**Unallowable Costs.** The following costs are **not** permitted:

- ❖ Salaries for any personnel including the PI;
- ❖ Salaries for administrative, secretarial and/or clerical staff;
- ❖ Costs related to travel or meeting registration fees;
- ❖ Costs related to a sub-contract;
- ❖ Costs related to publication costs, computer use fees, equipment maintenance, shipping or office supplies;
- ❖ Life and Disability insurance fees;
- ❖ Purchase or rental of office equipment; (i.e., furniture, filing cabinets, and copy machines);
- ❖ Costs 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;

- ❖ Costs for or related to moving from one institution to another; and/or
- ❖ Indirect Costs.

## SECTION 10

### Budget Summary

This will be auto-completed once you have completed the Budget Period Detail page.

## 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 Specific Aims and current budget or proposed budget for all alternate funding sources for this project as Appendix Materials.**

## SECTION 12

### Organization Assurances

If the applicant 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 with the application. If the IRB or FDA approvals are “pending”, please indicate this by clicking the “Pending” button. In cases where the IRB/FDA approvals are pending, a copy of the approval must be uploaded once it is obtained from the appropriate governing board. An approval must be on file with MDA before funds can be authorized 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 notified 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 the applicant requests support for research involving experimental drugs or devices, this section **MUST** be completed. If an FDA approval is pending, please indicate this by clicking on the “Pending” button. An approval must be on file with MDA before funds can be authorized for the project, if funded.

If the applicant requests support for research involving vertebrate animals or materials derived there from, this section **MUST** be completed. If 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 can be authorized 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 all changes.

## SECTION 13

### Research Plan and Supporting Attachments

## **Background/Rationale, Specific Aims, and Experimental Plan**

You must use the “Research Plan” template settings for the body of this section. You may have up to **2** pages in size 11 font. **DO NOT exceed two (2) pages in a size 11 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.

Summarize the key results and major conclusions from published, in preparation and/or unpublished studies that specifically relate to your proposed project and explain how they support your scientific premise. 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.

Give the specific aims of the project and an estimate of the time you expect will be necessary to complete them. Describe the experimental design and any novel laboratory procedures required to accomplish the specific aims of the proposed project. 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.

## **SECTION 14**

### **PI Data Sheet**

This section is voluntary and will not be used as part of the review process.

## **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. Please make sure that the application is now marked as submitted.

## **SECTION 16**

### **Required E-Signatures**

The applicant/PI will type their name in the space provided and click Sign to comply with stated assurances. Following the e-signature of the PI, the applicant’s Signing Official must type their name and click Sign to comply with stated assurances. It is also possible to save your application to PDF before submitting to MDA.

## **SECTION 17**

### **Submit**

To submit your proposal, click the Submit button on this page. You will be unable to submit if you have not provided all the required information. Any missing information will be listed on the screen. If your submission is successful, you will receive a confirmation message on the screen and a confirmation email from pcsupport@altum.com will be sent to the applicant.

**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.