INSTRUCTIONS FOR COMPLETION OF
THE DEVELOPMENT GRANT APPLICATION

Introduction

The purpose of Development Grants is to expand the number of scientists conducting meritorious neuromuscular disease research from among investigators who may be part of a team in the laboratory of a senior investigator under whose guidance the researcher will be given flexibility to work independently or as part of a collaborative effort.

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.

Letter of Intent (LOI) and Application Deadlines

A Letter of Intent (LOI) is required by **March 15, 2021** for the **April 16, 2021** application deadline. The LOI and application must be completed and submitted through proposalCENTRAL.

The LOI and application must be **RECEIVED** <u>on or before</u> the deadline dates. Once the deadlines have passed, the submit button will no longer be available. All deadlines are located at the top of each section of your LOI and application.

Eligibility Requirements

MDA will consider an application for a Development Grant from a candidate who may be a member of a research team in the laboratory of an independent investigator (Principal Investigator) under whose guidance the applicant will be given flexibility to conduct a neuromuscular disease research project.

To be eligible for a Development Grant, 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 member of a research team at an appropriate institution;
3. Be qualified to conduct a program of original research under the supervision of an independent investigator;
4. Have an acceptable research plan for a **specific disease** in MDA's program;
5. Have access to institutional resources necessary to conduct the proposed research project;
6. Have a **minimum of eighteen (18) months** of post-degree research laboratory training at the time of application;
7. Be no more than 60 months (5 years) from receiving their Ph.D. or D.Sc.; or no more than 96 months (8 years) from receiving their M.D., D.O. or M.D., Ph.D. Please contact MDA to discuss your eligibility if you have questions.
8. Not have been funded under the Development Grant program in the past.

Proposals from applicants outside the United States will be considered for projects of highest priority to MDA and when, in addition to the applicant's having met the requirements noted above, the applicant's country of residence may not have adequate sources of financial support for biomedical research.

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. M.D., D.O. and M.D., Ph.D. applicants, may not be more than 9 years from their terminal degree.

Application Submission Requirements

❖ Development Grant applications are **limited to one application per lab per application cycle.**

❖ 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)**.

❖ Applications will be accepted for no more than $70,000 per year for 3 years including a maximum 10% indirect cost rate with a 7/1/2021 – 6/30/2024 proposed award period.

❖ Avoid abbreviations where 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.

❖ A resubmission MUST be accompanied by a **Resubmission Statement** responding to the previous reviewers' concerns.

❖ A **Cover Sheet with E-Signature** 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 in one of the blank spaces. You will sign the form where indicated and upload to your application.

Review Process

To ensure support of meritorious neuromuscular disease research, applications are peer-reviewed to assess their scientific merit and to evaluate their relevance to MDA's goals. MDA's Board of Directors has the sole authority to award development grants.

Applicant (Principal Investigator)

The Applicant (PI) and Sponsor (Mentor) are 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.

Sponsor (Mentor)

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

SECTION 1

Title Page

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 2nd 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.

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 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 in a size 11 font. **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.

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.

Resubmission Statement (if applicable)

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 size 11 font with 0.5 margins.**

Applicant Statement

See Section 14 for instructions regarding completing the Applicant Statement

Budget Justification

The Budget Justification is a required attachment and must explain why proposed costs are necessary to complete the proposed project. **Sub-contracts are not permitted as part of Development Grant applications.**

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) 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. 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 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.

<u>**Content of Sponsor/Mentor Letter**</u>

The letter from the Sponsor/Mentor must include the items below in addition to an evaluation of the candidate. The Sponsor/Mentor letter is 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.

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 the applicant will hold at the expected start date of the proposed project. 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?

5. **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 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 9

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 your 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 10

Budget Period Detail

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". Complete each section of the Detailed Budget for each year of support for which funds are requested.

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

Allowable Costs

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**. The Principal Investigator's specific role(s) in the proposed research must be described under "Proposed Budget Justification."

The "Institutional Base Salary" should be the Principal Investigator's **total** base salary and "Fringe Benefits" listed should be the proportionate percentage of the Principal 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 is limited to a **maximum of $3,000 per grant**. **Laptop purchases are limited to one (1) per grant and must be fully justified on the Budget Justification page.**

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 expenses by the type of supplies. You may enter a total amount for Consumables.

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 $1,500** in any given year and is restricted to personnel <u>listed</u> on the Budget in the Personnel Cost category.

Other expenses may include items such as publication costs, computer use fees, equipment maintenance, shipping 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. If fees for consultants are requested, their names and institutional affiliations **must** also be given.

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

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

- ❖ 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.

- ❖ **Sub-contracts are not permitted for any part of the project.**

SECTION 11

Budget Summary

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

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

SECTION 13

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 14

Research Plan and Supporting Attachments

Specific Aims, Rationale and Significance, Background and Experimental Plan

You must use the "Research Plan" template settings for the body of this section. You may have up to 7 pages in a size 11 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 a size 11 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 the proposed project. Explain how the project will enable the attainment of these goals specifically identifying the skills, theories, conceptual approaches, etc. to be learned or enhanced during the project period. 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 project will help you to develop an independent scientific program.

   C. **Activities Planned for the Proposed Project**
      Describe, by year, the activities (research, teaching, clinic etc.) you will be involved in during the proposed project period and the estimated 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.

SECTION 15

PI Data Sheet

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

SECTION 16

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 your application is now marked as submitted.

SECTION 17

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 mentor and the applicant's Signing Official must type their names and click Sign to comply with stated assurances. It is also possible to save your application to PDF before submitting to MDA.

SECTION 18

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.

<u>**IMPORTANT NOTE**</u>

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.