



INSTRUCTIONS FOR COMPLETION OF THE RESEARCH INFRASTRUCTURE GRANT APPLICATION

1. Introduction

In preparing your grant application, please read and follow these instructions carefully. Incomplete or improperly prepared applications will not be reviewed nor funded. 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 the proper review of your application please be succinct; limit your application to 7 pages; and it must be in a standard size 11 pt font.

The required signatures should be obtained after completing the application.

The required "Cover Page" will auto populate as you complete the full application. You will need to click on Item 16 – Print to obtain the cover page for signatures.

2. Deadline for Receipt of Completed Application

The application must be received on or before the deadline date given in proposalCENTRAL.

3. Submission Guidelines

- * Use only English language in the application.
- * Request support in U.S. currency only.
- * Avoid abbreviations except for those in common use such as DNA, ATP, CK, and so forth.
- * The application must be typed single-spaced on the application form and its continuation pages.
- * A resubmission must be accompanied by a letter responding to the previous review concerns.

Section One: Title Page

1. **Project Title** – The project title was carried forward from your Letter of Intent. Whenever possible, the title should include the name of the neuromuscular disease or class of neuromuscular disease to which the research is most related, and describe what type of infrastructure is proposed. (MDA reserves the right to edit grant titles for clarity.). Please limit the title to 60 characters.
2. **Resubmissions:** 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 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 “Proposal Narrative” template provided in this section for submission. This part of your application is required, limited to seven (7) pages in a 11 pt font including figures and legends. Margins must be set at 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.

References for Literature Cited template is a required section of the application. There are no page limits or font limitations for this template. 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 Main Budget. Each subcontracting institution should have its own Subcontract Detail Budget attached. Overhead is not permitted on the subcontract budget page. The overhead will be fully included on the main Detail Budget page to the Lead Institution. All overhead is 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. The Principal Investigator MUST be the same person that submitted the Letter of Intent. 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 that the information is correct.

1. **Principal Investigator** - The Principal Investigator is the one person responsible for the scientific and technical direction of the project.
 - 1a. If a co-investigator and/or collaborators are involved with the proposed project, a letter of support and a curriculum vitae for each must accompany the application.

NOTE: The Principal Investigator must sign and date the application and obtain the signature of the appropriate institutional official before submitting online.

2. **Principal Investigator Address** - Give the complete mailing address for the office or lab where the Principal Investigator will be conducting the proposed research. All correspondence sent by MDA to the Principal Investigator will be sent to the address listed here.

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 Sub-Contract 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: Letters of Community Support

Letters of community support from members of the neuromuscular disease research community who are not listed as personnel, consultants or contract agencies on the current project stating their need for and support of this infrastructure project must accompany your application. These letters will be blind letters through proposalCENTRAL. You will need to enter the person’s name and email address for which you are requesting the support letter. You must have a minimum of 10 letters but not more than 20. Applications lacking letters of support from the community are considered incomplete and will not pass the validation check.

Section 8: 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.

1. 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.

2. 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 include: (1) A short description of the proposed infrastructure; (2) rationale for developing the proposed infrastructure.

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.

3. 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.

4. 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. You can choose one primary disease code and multiple secondary disease codes. 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 Summary

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 Budget for each year of support for which you are requesting funds.

Amount must be in US currency.

Authorized expenses include:

1. Principal investigator's salaries are permitted to an equivalent ratio of effort up to a maximum of 25% but not to exceed a total of \$15,000 plus a proportionate ratio of fringe benefits per year. Requested salaries are not to be used to replace salaries or partial salaries that are already assured by institutional or other funds. The co-investigator(s) must be listed as well as their % effort devoted to the project. However, salary support should be listed as \$0.
2. Other scientists, Technicians', research assistants', post-doctoral fellows', and graduate student salaries and fringe benefits at levels appropriate to the institution;
3. Equipment and supply expenses necessary to fulfill the project's specific aims. Unless otherwise stipulated at the time of the award, equipment purchased solely with MDA funds belongs to and is considered the property of the Academic Principal Investigator or company to whom the grant was awarded.

3a. Office supplies (i.e. pencils, notebooks, etc.) are limited to a maximum of \$600 per year.

3b. Computer hardware (i.e., PC's, printers, monitors, etc.) limited to a maximum of \$5,000 per grant. Support for computer equipment will be limited to one (1) laptop computer per grant. Any request for computers must be fully justified on the Budget Justification page of the application.

4. Travel expenses:

- a. Must be directly related to the implementation of the research and/or expressly and solely for the purpose of reporting the results of MDA-supported research at suitable scientific or medical meetings;
- b. Are limited to \$1,000 maximum per year;

5. Costs associated with advertisement of infrastructure availability (Web site, brochure);

6. Costs associated with making the proposed tool, technique or service available to others for research (e.g. production, database maintenance, animal maintenance, shipping, record-keeping)

7. Indirect costs not to exceed 10% of direct costs or the percentage rate on the approved budget.

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

1. Salaries, travel and/or housing related to sabbatical leaves;
2. Salaries for secretarial and/or clerical staff;
3. Purchase or rental of office equipment; (i.e., typewriters, word processors, furniture, filing cabinets, and copy machines);
4. Life and Disability insurance fees;
5. Expenses normally covered by the indirect cost of the Principal Investigator's institution i.e. General Liability Insurance and General Auto Insurance;;
6. Fees for tuition, registration or other fees relating to academic studies;
7. Membership dues, subscriptions, books or journals; and/or
8. Expenses for or related to moving from one institution to another.

Note: The role(s) and % effort of the Principal Investigator, co-investigator(s) and additional personnel must be clearly stated in this section.

Section 10: 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 infrastructure project. If supplemental funding from another source overlaps substantially with the project described in this application, please differentiate the aims that would be funded from each source.

Section 11: Organization Assurances

If your application requests support for infrastructure 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 infrastructure 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 infrastructure 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 12: Proposal Narrative and Supporting Attachments

This section includes the rationale for the proposed infrastructure, the description of the infrastructure and the facilities to conduct the research. This section should consist of no more than 7 pages.

Rationale:

Describe the rationale for the proposed Infrastructure project (tool, technique or service). Specifically address significance to the field of neuromuscular disease research and the demonstrated need by other investigators (refer to included letters of support).

Description:

Describe the proposed infrastructure (tool, technique or service) with attention to:

1. How the infrastructure will be developed, including a time-line and reasoning behind specific choices
2. How the infrastructure will be maintained financially (i.e. plans for securing future funding, self-sustaining fees, or phase out plans) and physically (staff, contracts, time and space commitments)
3. How the infrastructure will be distributed to the research community; include a specific and realistic plan for making the resource available to other investigators

Make use of diagrams charts and graphs when necessary.

Facilities:

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. Include statement on whether Institutional guidelines for the use and care of animals in research exist at the sponsoring Institution and whether your proposed studies fall under those guidelines for the off-site facility as well.

Appendix:

Graphs, diagrams, tables and charts, and manuscripts pertinent to the proposed research may be submitted as appendix material or incorporated in the application. Appendix material may include manuscripts or pre-prints accepted for publication, but not yet published.

Justification of Proposed Budget:

The Budget Justification is a required section and should be completed by fully justifying all expenses listed on the main Detailed Budget page. Justify the funds being requested for each item in the budget. Describe in this section the relationship of each item in your proposed budget to all other sources of support for that item.

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 or 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 13: 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 14: 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.

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.