



Fighting Forty Neuromuscular Diseases

Muscular Dystrophy Association, Inc.
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INFRASTRUCTURE GRANT POLICY

Infrastructure grants awarded by the Muscular Dystrophy Association, Inc. ("MDA") are governed by the policy set forth herein.

MDA supports research aimed at developing treatments for the muscular dystrophies and related diseases of the neuromuscular system. These are the muscular dystrophies (among which are Duchenne and Becker); motor neuron diseases (including ALS and SMA); the peripheral nerve disorders (CMT and Friedreich's ataxia); inflammatory myopathies; disorders of the neuromuscular junction; metabolic diseases of muscle as well as other myopathies.

The Infrastructure Grant is part of the Research Program, which has the mission of identifying and overcoming the inherent regulatory, cultural, financial and logistical barriers to bringing to market new therapeutic drugs or biologics for neuromuscular disease.

*Terms of this policy are subject to revision
or alteration at any time*

SECTION A

RESEARCH INFRASTRUCTURE GRANT

I. PURPOSE

The Infrastructure Grant is designed to fund the development of infrastructure—tools, techniques or services—that will be of use to the neuromuscular disease research community for the purpose of therapy development. Although the need for the proposed infrastructure can be presented in the context of a specific research project or projects, the grant will ultimately be evaluated on the need for the infrastructure by the community at large, and on the applicant's specific plan for making this resource available to the community. Collaboration and compatibility of the proposal with relevant existing infrastructure is encouraged.

Examples of acceptable infrastructure projects include, but are not limited to, development of databases and registries, core facilities (e.g., vector production, muscle imaging, drug screening), microarray chips, animal model resources, tissue repositories, and components of clinical research networks.

II. ELIGIBILITY

Those eligible to apply for an MDA Infrastructure Grant must:

1. Be a professional or faculty member at an appropriate educational, medical or research institution and be qualified to conduct and supervise a program of original research;
2. Have access to institutional resources necessary to conduct the proposed infrastructure project; and
3. Hold a Doctor of Medicine, Doctor of Philosophy, Doctor of Science or equivalent degree.

Proposals from applicants outside the United States will be considered only for projects of highest priority to MDA and with the understanding that the proposed infrastructure will be relevant and available to investigators in the United States; and when, in addition to the applicant's having met the eligibility requirements noted above, one or more of the following conditions exist:

1. The applicant's country of residence has inadequate sources of financial support for biomedical research;
2. Collaboration with an MDA-supported U.S. investigator is required to conduct the research; or
3. An invitation to submit an application has been extended by MDA.

III. AWARD REQUIREMENTS

1. Proposed infrastructure must be made available to the research community according to the plan outlined in the grant application.
2. Status reports at designated annual time periods or as otherwise specified or requested.
3. Submission of appropriate institutional/federal regulatory requirement approvals and renewals.

IV. DURATION OF GRANTS

Research infrastructure grant awards are for one, two or three years. Payments for years two and three are contingent upon the availability of funds, submission of respective status reports and Report of Expenditures satisfactory to MDA and confirmation that appropriate Institutional and Regulatory approvals are current and on file at the institution and MDA.

V. REVIEW CRITERIA

Infrastructure grants will be reviewed based on the following:

Recognized community need for proposed infrastructure: Rationale and supporting letter(s) from potential users

Feasibility: Description of resource and detail of its development and maintenance; evidence of effectiveness; superiority over existing similar resources

Compatibility with Existing Infrastructure: If applicable, is there compatibility with pre-existing data formats, protocols, or record-keeping?

Access Plan: Plan for disbursement, sharing, and collaborations; ease of access, breadth of access, and cost of access

Local Support: Commitment from a university, institution or other funding agency to support the project (e.g. commitment of space, staff, other resources)

Cost Effectiveness: proposed infrastructure development cost is reasonable in the face of benefit to the research community; vendor contracts are appropriate and cost-effective

Principal Investigator: General excellence; experience with proposed infrastructure subject

VI. GRANT PAYMENT

Checks are made payable to the Principal Investigator's institution and are issued twice per year. The institution's financial officer should establish an account from which research expenses may be paid under the terms of the approved award. The amount authorized by MDA for institutional overhead may be disbursed as the institution deems appropriate providing that such institutional overhead relating to the Principal Investigator of the MDA-funded project is fully covered.

VII. AUTHORIZED EXPENSES

When MDA deems them justified by the project, the expenses identified below are permitted under the Infrastructure Grant:

1. Salary and fringe benefits:
 - a. 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.
 - b. Technicians', research assistants', post-doctoral fellows', and other qualified staff salaries and fringe benefits at levels appropriate to the institution;
 - c. Requested salaries are not to be used to replace salaries or partial salaries that are already assured by institutional or other funds.

2. Equipment and supply expenses necessary to fulfill the project's goals. Unless otherwise stipulated at the time of the award, equipment purchased solely with MDA funds belongs to and is considered the property of the Principal Investigator to whom the grant was awarded.
3. Travel expenses:
 - a. Directly related to the implementation of the proposed project;
 - b. Expressly and solely for the purpose of describing the new MDA-supported resource at appropriate venues (i.e., scientific or medical meetings)
 - c. 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

VIII. UNAUTHORIZED EXPENSES

The following expenses are not permitted under the MDA Infrastructure grants program:

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

VIII. CHANGE IN STATUS

4. CANCELLATION OF GRANT BY MDA

MDA has the option of canceling an award at anytime with notice for any of the following reasons:

1. If within ninety (90) days from the scheduled funding start date or the established deadline date for receipt of required reports, MDA has not received the applicable institutional supporting documentation (i.e., copy of IRB, IACUC approval/renewal letters); MDA status reports; or other documentation as defined by MDA Infrastructure Grants Policy.
2. Availability of Association resources is limited to the extent that continuation of funding of Infrastructure grants must necessarily be placed on temporary or indefinite hold.

3. For any violation of the guidelines governing MDA's Infrastructure grants program as defined by the Research Infrastructure Grant Policy.

XV. PATENT AND LICENSING POLICY INFORMATION

Grants awarded through MDA's Research Program are subject to the Association's Patent and Licensing Policy (see page 7).

XVII. CURRICULUM VITAE

Curriculum vitae of all key staff, collaborators, etc. who will be participating in the execution of the infrastructure project with an M.D., Ph.D. or equivalent, must be provided to MDA with the grant application. When a project is underway, MDA's Research Department must be informed immediately in writing of any change in key personnel participating in the project, the reason(s) for such a change, and be provided the curriculum vitae of any additional or replacement personnel.

RESEARCH REPORTS AND PUBLICATIONS

I. REPORT OF EXPENDITURES

The financial officer must, within twelve weeks of the conclusion of each funding year of the grant, upload the completed Report of Expenditures form to proposalCENTRAL and mail a check in the amount of all uncommitted and unexpended funds plus any unexpended accrued interest. When unexpended funds are not returned with the Report of Expenditures, the Report of Expenditures will be considered unacceptable and will be returned to the financial officer. In such cases, MDA will expect the financial officer to remit payment in full within four (4) weeks.

II. REPORT OF STATUS

Status reports must be submitted at least eight (8) weeks prior to the expiration date of year one (and two if support continues). A final report must be submitted no later than four (4) weeks following the grant termination date. MDA may require additional status reports at any time during an award period as a condition of continuing the award.

III. ACKNOWLEDGEMENTS, PUBLICATIONS AND NEWS RELEASES

MDA expects timely publication of the results of all research projects it supports and requires that every such publication - whether in peer-reviewed journals, meeting abstract formats, or in review articles or similar publications - contain the following statement or its equivalent: "*Supported by MDA.*"

Funds to support MDA's research program come primarily from donations from private citizens. It is essential to the growth and maintenance of MDA and its research program that these donors be kept fully informed of the research progress their contributions make possible. Individuals and families affected by the neuromuscular diseases covered under its programs must also be kept fully informed of research progress. For these purposes MDA often issues press releases on newsworthy research developments and produces various publications for the public that report research activities. Such a press release or report may be issued on the occasion of the publication of an article in a professional journal or a presentation at a scientific or medical meeting.

To avoid misinterpretation of research results or the raising of false hopes about a possible treatment or cure for diseases covered under MDA programs, the Association requires the cooperation of the Principal Investigator in providing MDA with advance prepublication copies of all articles and abstracts reporting the results of MDA-supported research which MDA shall keep confidential. MDA also requires the cooperation of its Principal Investigators in participating in interviews as MDA may deem necessary. This cooperation will enable MDA to prepare press releases or other reports MDA issues on the research it supports.

MDA Infrastructure grantees must notify all end users of the infrastructure that such resources are "Supported by MDA," and that end users are expected to acknowledge MDA's support in all publications and presentations as described above. Whenever possible, MDA Infrastructure grantees should provide advance prepublication copies of all articles and abstracts resulting from the use of MDA-supported infrastructure resources.

HUMAN AND/OR ANIMAL SUBJECTS/TISSUES

I. RESEARCH PROTOCOL

When human subjects, tissues and/or materials are to be used in a research project, it is the responsibility of the Principal Investigator and the institution to ensure that the institution has the following on file and uploaded to their proposalCENTRAL file:

1. A complete copy of the research protocol approved by the Institution's Human Subjects Review Board and a copy of that Board's current approval notice;
2. A copy of the Board's approved patient informed consent form(s) to be used.

A copy of the Board's current approval notice and a copy of the Board's approved patient informed consent form must be submitted with the application and upon each annual renewal.

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 participant consent form) occurring prior to the commencement of or during the course of the research project.

II. FOOD AND DRUG ADMINISTRATION

When experimental drugs and/or experimental medical devices are to be administered to patients, the materials required in the "Research Protocol" section "E" of this document are necessary. In addition, it is the responsibility of the Principal Investigator and the institution to ensure that the institution has the following on file and uploaded to their proposalCENTRAL file

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1. A complete copy of the Investigational New Drug (IND) and/or Investigational Device Exemption (IDE) application approved by the Federal Food and Drug Administration (FDA) and a copy of the FDA's approval notice; and
2. Copies of all correspondence during the application and award periods between the FDA and the MDA Principal Investigator pertaining to the experimental drug(s) and/or device study.

III. PATIENT CHARGES

MDA requires that patients participating in experimental drug and/or device studies not be charged directly for any research procedures included under the project's approved protocol. Patients must be fully advised about their responsibility for ancillary costs relating to participation in a research project -- travel, lodging, food, etc.

IV. ANIMAL RESEARCH

MDA investigators should use animals and animal tissues for research purposes only when reasonable and practical alternatives do not exist. When attainment of the specific aims of a project requires the use of animals and/or animal tissues, a detailed justification must be included in the research grant application submitted to MDA. The justification shall include statements confirming that institutional guidelines:

1. Are at least as protective as those of the National Institutes of Health;
2. Conform to all applicable laws and regulations;
3. Meet prevailing community standards for responsible scientific research;
4. Apply throughout the project to ensure the humane treatment of any animals involved in the project.

It is the responsibility of the institution to ensure that no MDA funds will be released for research involving humans and/or animals until the required documentation described above is on file with the appropriate official at the institution as well as MDA.

V. CONFLICT OF INTEREST

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 Principal Investigators will observe the highest ethical standards in the conduct of research.

IV. SUBCONTRACTS

MDA's Research Infrastructure Grants Program includes support for multi-center studies. While the Association will consider reviewing separate grants for each institution participating in a multi-center study, it is recommended that one institution submit the application for the group and, in turn, subcontract with the collaborators.

In connection with a subcontract, the contractor (principal investigator) submitting the core grant will administer and account for all expenses of the collaborating investigators and their respective institutions. This includes indirect costs. All such costs should be accounted for in the core grant. Each of the participating investigators will be independently responsible for the respective institutional documentation required of compliance with policies, rules and regulations governing animal use and clinical trials. MDA will require that such documentation be submitted for the institution of the principal investigator submitting the core grant application prior to funding and will request that copies of the appropriate documentation be provided MDA from the collaborating institutions. The documentation should be forwarded to MDA with a copy of each subcontract agreement.

PATENTS AND LICENSING POLICY OF MUSCULAR DYSTROPHY ASSOCIATION, INC.

All grants by the MUSCULAR DYSTROPHY ASSOCIATION, INC. ("MDA") are subject to MDA's Policy on Patents and Licensing. By accepting an MDA award for a research project, the Principal Investigator or other personnel contributing to and working on the Project, as well as the Institution(s) with which they are affiliated, agree to be bound by the terms and conditions of MDA's Patents and Licensing Policy.

MDA understands that patents and licensing agreements may be sought on inventions resulting from research by the grant recipient supported in whole or in part by funds furnished by MDA; that such inventions should be administered so that they are introduced into public use as soon as practicable; and that such result will be achieved through granting permission to patent and license such inventions. Accordingly, it adopts the following policy:

1. An invention (hereinafter "MDA invention") resulting from the support in whole or in part to the grant recipient of funds awarded by MDA shall be reported to MDA promptly in writing. The inventions hereinafter contemplated shall include those made by employees or agents of the Institution or Investigator and third parties under the control of Institution or Investigator.
2. If the university or other research institution or an individual investigator(s) associated therewith ("Institution" or "Investigator") which is the recipient of financial support for the work leading to the MDA invention, has an established patent and licensing policy and procedure for procuring and administering inventions which are known to and accepted by MDA, or has an agreement with another organization, including agencies or departments of the U.S. Government relating to the MDA invention due to joint support, MDA will defer to that policy or agreement on the following terms:
 - a. With respect to any MDA invention, the Institution or Investigator shall have the right to file a patent application thereon, and if it wishes to do so, shall file such a patent application within a reasonable time and notify MDA thereof in writing. If MDA has not received such notification and believes that a patent filing is necessary in order to protect valuable rights in the MDA invention, it may notify the Institution or Investigator in writing of its intent to file a patent application, and if the Institution or Investigator does not thereafter, within such reasonable time as may be necessary to avoid loss of rights, file a patent application and notify MDA in writing thereof, or notifies MDA in writing that it has decided not to file a patent application, MDA, to the extent legally permissible, shall have the right to file a patent application thereon, and Institution or Investigator shall reasonably cooperate, at MDA's expense, in making such filing, and in conveying title thereto (and of all corresponding foreign and international patent rights and priorities) to MDA.
 - b. The Institution or Investigator will notify MDA in writing of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend a reexamination or opposition proceeding on a patent, in any country, not less than thirty days before the expiration of response period required by the relevant patent office. The Institution or Investigator will convey to MDA, upon written request, title to any such patent application or patent.
 - c. The Institution or Investigator will make the invention available for commercial licensing upon reasonable terms and conditions.
 - d. From the monies, if any, received from licensing the invention, MDA and the Institution or Investigator and all other parties shall share on terms mutually agreed upon by the Institution or Investigator and MDA, such terms to be determined prior to any licensing or commercial exploitation of the invention, on terms that reasonably reflect the proportion of funding that MDA has provided for the specific research project through grants and awards.
 - e. In the event that it obtains a patent, license arrangement or other commercial exploitation of an MDA invention, the Institution or Investigator shall promptly notify MDA in writing thereof, and, no less frequently than annually, make periodic reports to MDA with respect to the utilization of the invention and account for any income received by it by reason of exploitation of the invention.
 - f. The Institution or Investigator or its licensee will use commercially reasonable efforts to make MDA inventions available for the public benefit within a reasonable period of time. MDA shall have the right to notify Institution or Investigator in writing that it believes there has been an unreasonable delay in making the MDA invention available for the public benefit, and unless within sixty (60) days thereafter Institution, Investigator or its licensee demonstrate to MDA's reasonable satisfaction that appropriate efforts are being made, MDA has the right, notwithstanding any exclusivity provisions of any license granted by Institution or Investigator, to grant a license with respect thereto to a party designated by MDA on such terms as are reasonable in the circumstances.
 - g. MDA shall have a perpetual, nonexclusive, nontransferable, irrevocable, fully paid, royalty-free and sublicensable right and license thereunder to practice for noncommercial research purposes only, all MDA inventions and patents filed or issued thereon of which Institution or Investigator retains ownership of in accordance with this Section 2.
 - h. Any licenses or transfers of any patent applications, patents, know-how or other rights in an MDA invention shall be subject to the rights of MDA under this Patents and Licensing Policy.
3. If the Institution or Investigator has no patent or licensing policy and procedure for administering inventions, MDA shall have the right to determine the disposition of the invention rights in any such case.