

RESEARCH DEVELOPMENT GRANTS POLICY

Research 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.

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

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SECTION A

PROGRAMS AND APPLICATIONS

I. TYPE AND PURPOSE OF RESEARCH GRANTS

PRIMARY RESEARCH: To advance areas of scientific and medical knowledge that could improve understanding of the causes of neuromuscular diseases or assist in developing strategies for their diagnosis and treatment.

RESEARCH DEVELOPMENT: 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.

SPECIAL RESEARCH: To encourage scientific meetings for researchers to exchange ideas and to establish collaborations.

II. APPLICATION PROCEDURE

APPLICATIONS ARE NOT PROVIDED TO INSTITUTIONS FOR GENERAL DISTRIBUTION. Grant applications are made available to qualified applicants only. An application may be submitted and accepted at MDA's sole discretion and is based on the nature of the research proposed and the qualifications of the applicant. In order to receive an application, a Letter of Intent must be completed and submitted through proposalCENTRAL for review.

III. DEADLINE DATES

1. The Letter of Intent (LOI) is due **December 15** for a grant to begin the following August 1, or **June 15** for a grant to begin the following February 1.
2. The completed application must be submitted through proposalCENTRAL by **January 15** for a grant to begin the following August 1, or **July 15** for a grant to begin the following February 1.

Should a deadline fall on a weekend or US holiday, it will be extended to the next business day.

IV. APPLICATION REVIEW

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 research grants.

V. PATENT AND LICENSING POLICY INFORMATION

Grants awarded through MDA's Research Program are subject to the Association's Patent Policy. By accepting a grant offered through MDA's Research Program, the Principal Investigator, all personnel contributing to and working on the respective project, as well as the institution with which they are affiliated, agree to be bound by the terms and conditions of MDA's most recent policy on patents and licensing as described on page 5.

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.

SECTION B

RESEARCH DEVELOPMENT GRANT PROGRAM

Research Development Grants are awarded to directly support the research outlined in the original application submitted to the Association.

I. ELIGIBILITY FOR RESEARCH DEVELOPMENT GRANTS

MDA will consider an application for a research 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 a Principal 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; and
6. Have a minimum of eighteen (18) months of post-degree research laboratory training at the time of application but no more than five (5) years (60 months).
7. 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.

II. DURATION OF GRANTS

Research development grant awards are for one, two or three years at a maximum level of \$60,000 per year as of July 1, 2008. Grants awarded prior to July 1, 2008 are awarded at a maximum level of \$45,000 per year. Payments for years two and three are contingent upon the availability of research funds, submission of respective progress 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. (See Section D)

III. DELAY IN ACTIVATION

The activation of a research development grant by the Principal Investigator may not be delayed. A Principal Investigator who is unable to begin his or her grant on its designated start date must relinquish the award and reapply.

All Institutional and Regulatory approvals must be submitted, approved and distributed to appropriate offices, including MDA prior to the release of funds.

IV. GRANT PAYMENT

Checks are made payable to the Principal Investigator's institution and are issued quarterly, providing all contingencies are met at that time. 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. MDA has the right to withhold or cancel payments for non-compliance of Policies.

V. AUTHORIZED EXPENSES

The following expenses are, when MDA deems them justified by the research, permitted under the MDA research development grants program:

1. Salary and fringe benefits;
 - a. Development Grants are limited to salary for the Principal Investigator only.
2. 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 Principal Investigator to whom the grant was awarded;
 - a. Development Grant equipment is limited to \$3,000 in any given year.
 - b. Office supplies (i.e., pencils, notebooks, etc.) are limited to a maximum of \$600 per year.
3. 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;
 - c. Are limited to the Principal Investigator.
4. Costs associated with publication of the research;
5. Costs associated with making the products of the research (i.e., cell lines, DNA, protein and other biological substances) available to others for research;
6. Indirect costs not to exceed 10% of direct costs or the percentage rate on the approved budget.

VI. UNAUTHORIZED EXPENSES

The following expenses are not permitted under the MDA's research development grant program:

1. Salary or fringe benefits for anyone other than the Principal Investigator;
2. Salaries, travel and/or housing related to sabbatical leaves;
3. Life and Disability insurance fees;
4. Purchase or rental of office equipment; (i.e., 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 related to academic studies;
7. Membership dues, subscriptions, books, journals or online subscriptions/access; and/or
8. Expenses for or related to moving from one institution to another.
9. Subcontract(s) for any part of an award.

VII. SUPPORT FROM OTHER SOURCES

1. ALTERNATE FUNDING

A Principal Investigator may not apply for, use or accept MDA funds for a research project or part of a project already supported for the SAME PURPOSE either by MDA or by funds from another public or private source. Accordingly, full disclosure of all funds for research support available to the Principal Investigator from private, governmental and institutional sources, including MDA, is required. Such disclosure must be made in the research grant application. If funds from other sources become available to the Principal Investigator during the review or tenure of an MDA grant, then, the Principal Investigator must so inform MDA's Research Department in writing. MDA will then make a decision about the allocation of its research award.

2. SUPPLEMENTAL FUNDING

Financial support for clearly different aspects of one project or parts of a project from separate funding sources is permitted under MDA grants. Such supplementary funding must be disclosed, fully, to MDA as part of the research grant application or at the time such funding is received.

IX. BUDGET REVISIONS

MDA requires the submission of a revised budget when the grant awarded is less than originally requested. The revised budget must reallocate the amount awarded for items requested in the original budget - except for any items specifically described in the award letter that must be deleted from the budget. A revised budget must be completed and saved in the applicant's proposalCENTRAL file within four (4) weeks of the date of the Notice of Award posted in the applicant's account.

Subsequent to budget approval the Principal Investigator must submit a written request to MDA's Research Department for authorization to reallocate funds for the following reasons:

- a) Reallocation totals more than fifteen percent (15%) of the current annual budget;
- b) Change approved equipment purchases;
- c) Add a budget category not previously approved by MDA.

Such requests must include the amount of the reallocation and a detailed justification. Requests for budget revisions will be accepted up to the last three (3) months of the full funding period of the award. MDA does not permit budget revisions from an approved category to a non-approved category without a written request and full justification. In addition, MDA does not permit budget revisions exceeding twenty five percent (25%) of the total approved annual budget. Reallocations are permitted only during the current funding year.

X. UNEXPENDED FUNDS

If funds are not completely expended at the end of a support year, they must be returned to the Association within twelve (12) weeks of the support period. If a second or third year of funding of support still exists, a carry forward of funds may be requested. Carry over of unexpended funds is limited to a maximum of ten (10) percent of the award for that budget year. Such a request must be submitted in writing no later than four (4) weeks after the termination date of that year of support. The request must state the amount that remains unexpended and how those funds will be used in the following year. All category maximums remain in effect.

XI. EXPENDITURES BEYOND GRANT EXPIRATION DATE

Expenditures may not be committed against a grant after its expiration date except when authorized in writing by MDA's Research Department. As well, a deficit balance at the end of a support year, may NOT be carried forward into a new funding year.

XII. NO COST EXTENSION

Under exceptional circumstances, a project may be extended for a period of either three (3) or six (6) months beyond the grant's original expiration date. The Principal investigator must request such an extension in writing stating the funds remaining and a detailed justification for the extension satisfactory to MDA. The request must be made no later than four (4) weeks **BEFORE** the termination date of the award. The originally approved budget remains in effect throughout the extension period including all category maximums.

VIII. CHANGE IN STATUS

MDA Development Grants are not transferable to another Principal Investigator. Should a Development Grant recipient become an independent faculty member or professional member during their support period, they are permitted to retain the funding of the Development Grant. If a grant recipient then applies for a Research Grant and is funded, he/she will need to relinquish the remaining funds on the Development Grant in order to retain the Research Grant award.

1. MOVE TO NEW INSTITUTION

Continued use of funds by a Principal Investigator who changes institutions requires prior written authorization from MDA. The Principal Investigator must write to the MDA Research Department requesting such authorization at least eight (8) weeks before the effective date of change in institution. The letter must include:

- a. Effective date - month/day/year - of change in institution;
- b. Complete address of the new institution. The new mailing address of the Principal Investigator should also be included if it differs from that of the new institution;
- c. Statement of the adequacy of the new institution's facilities.
- d. Statement from Principal Investigator's new mentor at the institution, accepting the Principal Investigator and the responsibility of the award.

When continuation of a grant and/or a transfer of funds to a new institution are authorized, a new application cover sheet signed by the Principal Investigator's new institution is required. Instructions for transfer of funds between institutions will be provided by MDA's Research Department.

Upon a transfer of a grant, unexpended grant funds plus unexpended accrued interest, if any, must be returned to MDA and a final Report of Expenditures be submitted within eight (8) weeks of the transfer date.

When a transfer is not authorized, the grant is terminated and all unexpended funds plus unexpended accrued interest, if any, must be returned to MDA accompanied by a Report of Expenditures within eight (8) weeks of the termination of that award.

2. CANCELLATION OF GRANT

If, for any reason, the recipient of a grant must relinquish the award, the Principal Investigator should promptly so notify MDA's Research Department in writing. The notification should state the effective date of cancellation of the grant. Unexpended grant funds plus unexpended accrued interest, if any, must be returned to MDA accompanied by a final Report of Expenditures within eight (8) weeks of the cancellation date.

MDA reserves the right to cancel a grant if circumstances render the individual on whose behalf the award was made unfit, unqualified and/or unable to perform under the terms and conditions of this Research Grants Policy. Such circumstances include, but are not limited to, abandonment of the project, loss of license, conviction of a crime, or withdrawal of insurance or other material institutional protections.

3. 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 required supporting documentation, i.e. copy of IRB, FDA, IACUC approval letters; IND confirmation; copy of informed/consent form(s); progress report; or other documentation as defined by MDA Research Grants Policy.
2. Availability of Association resources are limited to the extent that continuation of funding of research grants must necessarily be placed on temporary or indefinite hold.
3. For any violation of the guidelines governing MDA's research grants program as defined by the Association's Research Grants Policy.

IX. CURRICULUM VITAE/BIOSKETCH

Curriculum vitas of the investigator, advisors, co-investigators and collaborators who will be participating in the execution of the research project 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 personnel participating in the project, the reason(s) for such a change, and be provided the curriculum vitae or biosketch of any additional or replacement personnel.

SECTION C

RESEARCH REPORTS AND PUBLICATIONS

The protocol cited in the original application to the Muscular Dystrophy Association is the protocol that is being funded unless otherwise notified in writing by MDA's Research Department Staff. Any amendments or adjustments to the original protocol by the Principal Investigator MUST be reported in the Project Status Report under the "Protocol Amendments" section. MDA must be IMMEDIATELY notified of ALL substantive changes to the protocol.

I. REPORT OF EXPENDITURES

A Report of Expenditures form is available for upload to the financial officer of the Principal Investigator's institution. The financial officer of the institution must, within twelve weeks of the conclusion of each funding year of the grant, upload the completed form to MDA and mail a check in the amount of all uncommitted

and unexpended funds plus any unexpended accrued interest. When unexpended funds are not returned within sixty days of the receipt of the Report of Expenditures, the Report of Expenditures will be considered unacceptable and will be returned to the financial officer of the awarded institution. In such cases, MDA will expect the financial officer to remit payment in full within four (4) weeks.

In certain circumstances, MDA may withhold the unexpended funds balance from a continuing year or new grant to the Principal Investigator if necessary.

Upon a cancellation or transfer of a grant, unexpended grant funds plus unexpended accrued interest, if any, must be returned to MDA and a Report of Expenditures must be submitted within eight (8) weeks of the cancellation/transfer date.

II. REPORT OF PROGRESS

Progress reports must be submitted at least eight (8) weeks prior to the expiration dates 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 progress reports at any time during an award period as a condition of continuing the award.

III. PUBLICATIONS, SCIENTIFIC PRESENTATIONS AND NEWS RELEASES

MDA's Research Department expects timely publication of the results of all research projects it supports and requires that every such publication or presentation - whether in peer-reviewed journals, meeting abstract formats, platforms, poster presentations 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 as well as individuals and families affected by the neuromuscular diseases covered under its programs 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's Research Department 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.

SECTION D

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

:

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 require 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 MDA funds will not 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.



MUSCULAR DYSTROPHY ASSOCIATION

3300 E. Sunrise Drive, Tucson, AZ 85718-3208

<http://www.mda.org>

R. Rodney Howell, M.D., Chairman of the Board - GERALD C. WEINBERG, President & CEO

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