



Muscular Dystrophy Association, Inc.
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RESEARCH INFRASTRUCTURE GRANTS POLICY

Research Infrastructure grants awarded by the Muscular Dystrophy Association, Inc. ("MDA") is 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 Research Infrastructure Grant is part of MDA's Translational 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

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SECTION A

I. TYPE AND PURPOSE OF INFRASTRUCTURE GRANTS

MDA's Research Infrastructure Grant is designed to fund the development of 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, core facilities (e.g., vector production, muscle imaging, drug screening), microarray chips, animal model resources, tissue repositories, and components of clinical research networks.

II. AWARD REQUIREMENTS

1. Proposed infrastructure must be made available to the research community according to the plan outlined in the grant application
2. Progress reports and reports of expenditures must be provided at designated time periods, usually annually.
3. Provision of records of appropriate institutional/federal regulatory requirements

III. APPLICATION PROCEDURE

APPLICATIONS ARE NOT PROVIDED TO INSTITUTIONS FOR GENERAL DISTRIBUTION.

Applications are accepted from 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 MDA's online grants management system, proposalCENTRAL[®] for review.

IV. DEADLINE DATES

1. The Letter of Intent (LOI) may be submitted at any time, and will be evaluated for approval by MDA and its advisors.
2. The completed application must be submitted through proposalCENTRAL[®].

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

V. 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 all grants. The main criteria for approval of Infrastructure Grants are:

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, 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

V. PATENT AND LICENSING POLICY INFORMATION

Grants are subject to the Association's Patent Policy. By accepting a grant offered through MDA's Translational 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 in Exhibit 1.

SECTION B

I. ELIGIBILITY FOR INFRASTRUCTURE GRANTS

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 research 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.

II. DURATION OF GRANTS

Research Infrastructure grant awards are for up to three years. Payments are contingent upon the availability of research funds, submission of 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)

Renewal for infrastructure grants may be available. Renewal for a period of time between one and three years may be authorized following a satisfactory evaluation of the final progress report and if funds are available.

III. DELAY IN ACTIVATION

The activation of an Infrastructure 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. SUBCONTRACTS

MDA's Translational Research Grants Program includes support for approved subcontracts. It is expected that the recipient will manage collaborations with outside companies or academic investigators through a subcontract mechanism, with the understanding that MDA's Translational Research Grants Policy allows the payment of no more than 10% overhead to academic and institutional research organizations. In connection with a subcontract, the contractor (Infrastructure Grant recipient) submitting the core grant will administer and account for all expenses of collaborators. This includes indirect costs. Appropriate documentation related to regulations governing animal and human subject use will be required from each subcontracted entity where relevant. The PI submitting the core grant application will be responsible for assembling and submitting to MDA such documentation along with a copy of each subcontract agreement prior to funding.

V. GRANT PAYMENT

Checks are made payable to the Principal Investigator's institution and are issued quarterly. 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. The final quarterly payment will be held until all final reports have been received.

VI. AUTHORIZED EXPENSES

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

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.
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.

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.

VII. UNAUTHORIZED EXPENSES

The following expenses are not permitted under the MDA research grants 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. Expenses normally covered by the indirect cost of the Principal Investigator's institution, ie General Liability Insurance, Auto Insurance etc;
5. Fees for tuition, registration or other fees relating to academic studies;
6. Membership dues, subscriptions, books or journals; and/or
7. Expenses for or related to moving from one institution to another.

VIII. 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 applicant 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. Corporate entities are expected to provide matching funds to support the project, and allocate the budget accordingly.

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 deliverables section of the applicant's online grant. 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. totals more than fifteen percent (15%) of the current annual budget,
- b. reappointing personnel
- c. changing approved equipment purchases
- d. adding 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. Under exceptional circumstances, a carry forward of funds may be requested. Carryover 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. The originally approved budget remains in effect throughout the extension period including all category maximums.

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, inclusive of all category maximums.

XIII. CHANGE IN STATUS

The continued use of grant funds following any major change in status of the Principal Investigator requires prior written authorization from MDA. As described below, such changes include but are not limited to prolonged absence, change in institution or withdrawal from the project.

1. PROLONGED ABSENCE

In general, a prolonged hiatus of an infrastructure grant will not be approved. Instead, continued use of funds by or reassignment of a project to another qualified investigator during a prolonged absence of the Principal Investigator (excluding institutionally authorized vacation) is preferred, but requires prior written MDA authorization. The Principal Investigator must write to the MDA Research Department requesting such authorization at least six (6) weeks before the starting date of the period of absence. The request must contain an explanation of the reasons for the absence and details about the arrangements made for conducting the research project during the absence. The letter must include the following:

- a. Inclusive dates of absence;
- b. Reason(s) for absence;
- c. Name, address, telephone number, and curriculum vitae of the investigator who has agreed to be responsible for the scientific conduct of the research project;
- d. Proposed method and frequency of communication between the Principal Investigator and the investigator-in-charge;
- e. Signature of the investigator referred to in item "c" above confirming that he or she is familiar with all aspects of the project and accepts full responsibility for the conduct of the research during the absence of the Principal Investigator.

When a request for continued use of grant funds during a prolonged absence of the Principal Investigator 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 date of termination.

2. MOVE TO A 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. Titles and periods of support of all MDA grants affected by the change in institution;
- c. 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;
- d. Statement of the adequacy of the new institution's facilities for conducting the research projects identified in item "b" above.

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.

3. WITHDRAWAL FROM PROJECT

When a Principal Investigator withdraws from a project, his/her grant terminates 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 withdrawal from the project.

Under exceptional circumstances, a grant may be continued under a new Principal Investigator at the same institution. In such cases, the Principal Investigator must write to MDA's Research Department requesting authorization for such a continuation at least eight (8) weeks before the effective date of withdrawal from the project. The following documentation must be provided:

- a. Effective date - month/day/year - of the change in Principal Investigator;
- b. Updated progress report on the project;
- c. Name, address and curriculum vitae of the proposed new Principal Investigator.

The proposed new Principal Investigator must, in a separate letter, indicate to MDA his/her familiarity with the specific aims of the project and agree to accept responsibility for all scientific and administrative aspects of the grant and also provide a statement about the availability of equipment, personnel, etc., necessary to conduct the research.

4. 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 Infrastructure 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.

5. CANCELLATION OF GRANT BY MDA

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

- a. 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 Infrastructure Grants Policy.
- b. 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.
- c. For any violation of the guidelines governing MDA's research grants program as defined by the Association's Infrastructure Grants Policy.

XIV. CURRICULUM VITAE/BIOSKETCH

Curriculum vitae of all investigators, advisors, co-investigators and post-doctoral fellows 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

I. REPORT OF EXPENDITURES

A Report of Expenditures form is available for upload, through proposalCENTRAL, to the financial officer of the Principal Investigator's institution. The financial officer must, within twelve weeks of the conclusion of each funding year of the grant, return the completed form to MDA with 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 PROGRESS

Progress reports must be submitted at least eight (8) weeks prior to the expiration dates of year one (and years two and three 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 as established by the time line for accomplishing project milestones.

III. 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.

All MDA Translational Research Grants are subject at minimum to the terms of MDA's Translational Research Grants Communications and Confidentiality Policy (Exhibit 2)

SECTION D

HUMAN AND 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:

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 approved patient informed consent form(s) to be used.

A copy of the Board's current approval notice and a copy of the corresponding IRB approved patient informed consent form(s) must be submitted to MDA with the application and upon 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 "D" 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, as well as on file with the MDA Research Department:

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. It is required that the principal investigator provide copies of documentation for animal research to MDA's Research Department when applicable.

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.

Exhibit 1:

PATENTS AND LICENSING POLICY OF MUSCULAR DYSTROPHY ASSOCIATION, INC. Revised 6-2013

All grants and awards by the MUSCULAR DYSTROPHY ASSOCIATION, INC. ("MDA") are subject to MDA's Policy on Patents and Licensing, as it may be revised from time to time (MDA's Patents Policy). By accepting an MDA grant or 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, (the Grant Recipients) agree to be bound by the terms and conditions of MDA's Patents Policy, which is incorporated into and made a part of such grants and awards.

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 support in whole or in part to the Grant Recipient awarded by MDA shall be reported to MDA promptly in writing, before publication of the MDA Invention. Such reporting shall include the particulars of any invention disclosure and patent filing on an MDA Invention, and shall be updated at least annually during the term of the grant and for at least two years thereafter. MDA Inventions shall include those made by employees or agents of the Grant Recipient and third parties under the Grant Recipient's control.
2. If (a) the Grant Recipient is a university or other research institution ("Institution") with an established intellectual property policy including a procedure for procuring and administering inventions, or has an agreement with another organization, or is subject to regulation or restriction from agencies or departments of the U.S. Government, (b) that Grant Recipient policy or procedure, or agreement, or regulation or restriction, is inconsistent in part with this MDA Patent Policy; (c) the Grant Recipient discloses such inconsistency to MDA, and (d) MDA accepts such inconsistency, then (e) this Patents Policy will be subject to that policy or procedure or agreement or regulation or restriction to the extent of such inconsistency as disclosed and accepted.
3. If the Grant Recipient has an intellectual property policy, the following terms apply:
 - a. With respect to any MDA invention, the Grant Recipient 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 Grant Recipient in writing of its intent to file a patent application, and if the Grant Recipient 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 Grant Recipient 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 Grant Recipient 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 Grant Recipient will make the invention available for commercial licensing upon reasonable terms and conditions.
 - d. From the monies, if any, received from licensing an MDA Invention, MDA and the Grant Recipient shall share on terms mutually agreed upon by the Grant Recipient 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. Absent an agreement to the contrary, MDA shall receive 25% of such monies, after deduction of patent prosecution expenses.
 - e. In the event that it obtains a patent, license arrangement or other commercial exploitation of an MDA invention, the Grant Recipient 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 MDA Invention and account for any income received by it by reason of exploitation of the MDA Invention. MDA may, upon request, review Grant Recipient licenses pertaining to an MDA Invention, on a confidential basis.
 - f. The Grant Recipient or its licensee will use commercially reasonable efforts to make MDA Inventions available for the public benefit within a reasonable period of time, and shall provide annual reports describing such efforts. MDA shall have the right to notify Grant Recipient 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 Grant Recipient 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 Grant Recipient, to grant a license with respect thereto to a party designated by MDA on such terms as are reasonable in the circumstances. Any dispute under this paragraph will be escalated to a discussion between the Grant Recipient's director of patent licensing and MDA's Vice President for Research.
 - g. MDA shall have a perpetual, worldwide, 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 Grant Recipient retains ownership in accordance with this Section 2.
 - h. Grant Recipients shall provide that 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 Policy.
4. If the Grant Recipient has no patent or licensing policy and procedure for administering inventions, MDA shall have the right to determine the disposition of MDA Inventions, in MDA's complete discretion, and Grant Recipient shall assign, and hereby does assign to MDA all right, title and interest in such MDA Inventions.
5. Failure or delay by MDA in exercising any rights provided herein or by law shall not be deemed a waiver of any rights.

Exhibit 2

Translational Research Grants Communications and Confidentiality Policy

By accepting an MDA award for a research project, the company Principal Investigator or other personnel contributing to and working on the Project, as well as the Institution(s) or companies with which they collaborate, agree to be bound by the terms and conditions of MDA's Translational Research Grant Communications and Confidentiality Policy as they relate to the project for which the grant has been awarded. MDA in turn agrees to abide by the same provisions described in this policy. Additional provisions may be negotiated during the period before the recipient company formally accepts the MDA award. MUSCULAR DYSTROPHY ASSOCIATION, INC. ("MDA") understands that information is sensitive and its release can be harmful to certain entities, and that proprietary information needs to remain confidential and protected. In turn, the recipient company or institution recognizes that dissemination of information about MDA funded research projects is important to the Muscular Dystrophy Association and the families that it serves. Such information is critical to ensuring the continued financial support of the Association by the public. If the recipient company or institution has an established confidentiality agreement that is known to and accepted by MDA, MDA may choose to accept, in addition, those terms of that policy or agreement that do not violate or supersede those of MDA's Translational Research Grant Communications and Confidentiality Policy.

Policy Terms:

1. MDA retains the right to make public the title and amount of all funded projects, as well as a brief lay summary. All other project-related information, including the substance of the grant application, any resulting progress reports, or other written or oral communications is considered confidential and will not be released to other than MDA staff without specific, written permission from the recipient company or institution. Recipient companies/ institutions should designate one representative (project information officer) to oversee and authorize release of project-related information.
2. It is understood that MDA and the recipient company or institution will make every effort to coordinate publicity related to work funded by MDA, and that MDA will respect confidentiality agreements and proprietary information about this work. All press releases or other information designated for public release that is related to the awarded project, whether generated by MDA or the recipient company, must be reviewed and approved by both the recipient company and MDA. Company-generated press releases and journal publications should include a reference to the support received by the Muscular Dystrophy Association and its role in the research project. Conversely, press releases and other public media generated by MDA will acknowledge the recipient company or institution by name.
3. Any and all project-related outcomes, achievements must be reported to MDA as specified in the grant paperwork as part of milestone and progress reports.
4. Copies of any papers resulting from an MDA research award must be sent to the MDA Research Department upon acceptance for publication, even if the publication date is several months away, or if there is no publication date known. Journal embargoes will not be violated.
5. Failure to adhere to this policy will result in termination of project support.