



MDA RESEARCH DEPARTMENT GRANTS POLICY

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

*Terms of the policy herein are subject to revision
or alteration at any time.*

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|---|-----------|
| SECTION A: GENERAL INFORMATION | 3 |
| I. PURPOSE OF MDA’S RESEARCH DEPARTMENT GRANT PROGRAMS..... | 3 |
| II. APPLICATION PROCEDURE | 3 |
| III. APPLICATION REVIEW | 3 |
| IV. NOTICE OF INTENT TO FUND | 3 |
| V. PATENT AND LICENSING POLICY | 3 |
| SECTION B: RESEARCH DEPARTMENT GRANTS PROGRAM..... | 5 |
| I. DURATION OF GRANTS | 5 |
| II. DELAY IN ACTIVATION | 5 |
| III. SUB-CONTRACTS | 5 |
| IV. GRANT PAYMENTS..... | 6 |
| V. GOOD STANDING POLICY | 6 |
| VII. AUTHORIZED COSTS | 7 |
| VIII. UNAUTHORIZED COSTS | 7 |
| IX. DIRECT COSTS VS INDIRECT COSTS..... | 7 |
| X. SUPPORT FROM OTHER SOURCES..... | 7 |
| XI. BUDGET REVISIONS | 8 |
| XII. UNEXPENDED FUNDS, CARRY FORWARD, AND NO COST EXTENSION | 8 |
| XIII. CHANGE IN STATUS | 8 |
| XIV. BIOSKETCH REQUIREMENTS..... | 11 |
| XV. RIGHT TO AUDIT | 11 |
| SECTION C: RESEARCH REPORTS AND PUBLICATIONS..... | 11 |
| I. REPORT OF EXPENDITURES | 11 |
| II. MODULAR BUDGET REPORTING..... | 11 |
| III. GRANT STATUS REPORT | 12 |
| IV. INVENTION/PATENT REPORTING | 12 |
| V. PUBLICATIONS, SCIENTIFIC PRESENTATIONS AND NEWS RELEASES | 12 |
| VI. PUBLIC ACCESS POLICY..... | 12 |
| VII. PROGRAM ASSESSMENT..... | 13 |
| SECTION D: HUMAN AND/OR ANIMAL SUBJECTS/TISSUES..... | 13 |
| I. RESEARCH PROTOCOL | 13 |
| II. FOOD AND DRUG ADMINISTRATION | 13 |
| III. PATIENT CHARGES | 14 |
| IV. ANIMAL RESEARCH | 14 |
| V. CONFLICT OF INTEREST | 14 |

SECTION A: GENERAL INFORMATION

I. PURPOSE OF MDA’S RESEARCH DEPARTMENT GRANT PROGRAMS

MDA provides support for research throughout the pipeline of drug development from discovery research through clinical trials to advance areas of scientific and medical knowledge that could improve understanding of the causes of neuromuscular diseases, assist in developing strategies for their diagnosis and treatment, or support promising clinical trials.

II. APPLICATION PROCEDURE

Applications are accepted through ProposalCentral from eligible applicants only in accordance with the Application Requirements provided for each grant mechanism which detail specific items such as: application deadlines, eligibility requirements, allowable costs, etc. Applications are accepted at MDA's sole discretion and are based on the nature of the proposed research and the qualifications of the applicant.

For technical inquiries such as system access or site navigation related to ProposalCentral, please send an email to pcsupport@altum.com or call 1-800-875-2562 (Toll-free US and Canada) or +1-703-964.5840 (Direct Dial International). For additional help, see the [ProposalCENTRAL FAQ](#).

III. 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 mission and Research Department scientific priorities. MDA's Board of Directors has the sole authority to award research department grants.

IV. NOTICE OF INTENT TO FUND

Following peer review, MDA will inform applicants that have been recommended for funding in the intent to fund letter. This notification will consist of a non-binding letter through ProposalCentral stating that the application was favorably reviewed through one of MDA's Research Advisory Committees or by ad hoc review and was placed in a "pre-award" status pending approval from MDA's Board of Directors.

V. PATENT AND LICENSING POLICY

Grants will not be awarded to institutions who do not comply with MDA's Patent and Licensing Policy. By accepting a grant through MDA's Research Department, the Principal Investigator (PI), all personnel contributing to and working on the funded project, as well as the institution with which they are affiliated, agree to be bound by the terms and conditions of MDA's patents and licensing policy as described below.

PATENTS AND LICENSING POLICY OF MUSCULAR DYSTROPHY ASSOCIATION, INC.

(Revised 10/2022)

All grants and awards by the MUSCULAR DYSTROPHY ASSOCIATION, INC. ("MDA") are subject to this Patents and Licensing Policy, as it may be revised from time to time ("MDA Patents Policy"). By accepting an MDA grant or award for a research project, the principal investigator, other personnel contributing to and working on the research project, and the university or other research institution(s) with which they are affiliated (collectively, the specific principal investigator, other personnel, and the relevant institution(s), "Grant Recipient") agree to be bound by the terms and conditions of this MDA Patents Policy, which is incorporated into and made a part of any such grant or award.

MDA understands that patents and licensing agreements may be sought on inventions resulting from research by Grant Recipient and funded in whole or in part by funds furnished by MDA. MDA desires that such inventions should be administered so that they are introduced into public use as soon as practicable and recognizes that this may be achieved through granting permission to patent and license such inventions. Accordingly, MDA adopts, and Grant Recipient accepts any grant or award subject to, the following policy:

1. An invention resulting from funding, in whole or in part, to Grant Recipient awarded by MDA (hereinafter "MDA Invention"), shall be reported to MDA within two (2) months of its realization. The report shall include the particulars of such realization, including the approximate time of realization and the relevant MDA award number(s). Grant Recipient shall report to MDA within two (2) years of the initial disclosure to MDA whether it has elected to pursue a patent covering such MDA Invention. If Grant Recipient elects, at any time, to file a patent application covering an MDA Invention, it will, within two (2) months of filing, report to MDA the patent numbers, date of filing and the relevant MDA award number(s).
2. If Grant Recipient chooses not to pursue a patent covering an MDA Invention after the disclosure of such invention, or, if within two (2) years of the disclosure being made known to MDA, MDA has not received notification of Grant Recipient's decision not to pursue a patent, and MDA desires to have a patent filed covering such MDA Invention, then MDA may notify Grant Recipient in writing of such desire and Grant Recipient shall either file a patent application covering such MDA Invention within thirty (30) days of such notice or shall, and hereby does, assign its entire right, title and interest, in and to such MDA Invention (including all intellectual property rights globally) to MDA upon the expiration of such thirty (30) day period.
3. If Grant Recipient starts a patent application and then decides not to continue the prosecution of such application, pay maintenance fees, or defend a reexamination or opposition proceeding on a patent, in any country, Grant Recipient will notify MDA in writing of this decision not less than thirty (30) days before the expiration of response period required by the relevant patent office. Grant Recipient will convey to MDA, upon written request, title to any such patent application or patent.
4. Grant Recipient will make the MDA Invention(s) available to the public, including through commercial licensing upon reasonable terms and conditions or direct access. From the monies (including equity), if any, received from licensing or direct commercializing of an MDA Invention, MDA and Grant Recipient shall share on terms mutually agreed upon in writing by Grant Recipient and MDA, prior to any licensing or direct commercializing of the MDA Invention; provided, that (i) such terms will reflect the proportion of funding that MDA has provided for the specific research project that gave rise to such MDA Invention through grants and awards, and (ii) if Grant Recipient and MDA cannot agree on such terms within ninety (90) days of initiating discussions with respect thereto (or Grant Recipient grants rights in contravention of this Section 4 without first agreeing with MDA), then MDA shall receive twenty-five percent (25%) of all upfront, milestone, royalty and other compensation received from a licensee or from the direct commercialization of the MDA Invention (exclusive of compensation that reimburses Grant Recipient for actual costs incurred maintaining patents covering such MDA Invention). Payments shall be made to MDA within thirty (30) days of receipt by Grant Recipient of any payments from a licensee or from direct commercialization. If Grant Recipient receives monies in the form of an equity share or other non-cash property, Grant Recipient shall ensure that MDA receives its proper share of such property, or the value thereof, at the time such non-cash consideration is converted into cash by Grant Recipient.
5. If Grant Recipient enters a license arrangement or other commercial relationship related to the exploitation of an MDA Invention, then Grant Recipient shall promptly notify MDA in writing thereof, including providing a copy of the agreement(s) governing such license arrangement or other commercial relationship, and make periodic reports to MDA (no less frequently than annually and as requested by MDA from time-to-time), 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. Grant Recipient shall provide MDA with any amendments to any such license arrangements or other commercial relationships.
6. Grant Recipient or its licensee will use commercially reasonable efforts to make the MDA Invention(s) available for the public benefit as soon as practicable. MDA shall have the right to notify Grant Recipient in writing if it believes there has been an unreasonable delay in making the MDA Invention(s) available for the public benefit, and, unless within sixty (60) days thereafter Grant Recipient or its licensee demonstrates that fifty thousand dollars (\$50,000) (or more) has been spent annually, since gaining access to such MDA Invention(s), in developing such MDA Invention(s), any exclusive rights granted to a licensee shall become non-exclusive and the license granted to MDA under Section 7 of this MDA Patents Policy shall become unlimited in

scope and freely sublicensable (through multiple tiers).

7. MDA shall have a perpetual, worldwide, nonexclusive, nontransferable, irrevocable, fully paid, royalty-free and sublicensable (through multiple tiers) right and license thereunder to practice for non-commercial research, educational, and/or patient treatment purposes only, all MDA Inventions, including under any patents filed or issued thereon; provided, that any such sublicensing shall be limited to academic and/or medical institutions or non-profit organizations (or service providers working on behalf of MDA or any of the foregoing) and solely for non-commercial research, educational, and/or patient treatment purposes.
8. Grant Recipient shall ensure that any licenses or transfers of any patent applications, patents, know-how or other rights in any MDA Invention shall be (i) subject to this MDA Patents Policy, (ii) obligated to indemnify and hold harmless MDA, and its trustees, officers, employees, and agents, against any claims, liabilities, and other costs (including attorneys' fees) based on or arising out of the exploitation any MDA Invention and MDA shall be an intended third party beneficiary of such indemnification, and (iii) obligated to conduct all activities relating to any MDA Invention in compliance with all applicable laws, regulations, and rules.
9. Failure or delay by MDA in exercising any rights provided herein or by law shall not be deemed a waiver of any rights. This MDA Patents Policy is enacted subject to New York law and is intended to be interpreted and enforced in accordance with New York law. This MDA Patents Policy is intended to survive and to continue to control with respect to any MDA Invention notwithstanding the expiration or exhaustion of any underlying grant or award agreement.

SECTION B: RESEARCH DEPARTMENT GRANTS PROGRAM

I. DURATION OF GRANTS

Research grants are awarded for one, two or three years in duration in accordance with the policies herein and the terms and conditions of the Notice of Award.

II. DELAY IN ACTIVATION

The activation of a research grant by the principal investigator (PI) may not be delayed. If the PI is unable to begin the grant on the start date designated in the Notice of Award, the PI must relinquish the award by notifying MDA in writing prior to the start date. In extreme situations, a delayed start date may be requested by contacting the assigned MDA grant manager detailing the reason for the delay. Such requests will be reviewed and approved by MDA, at its sole discretion.

III. SUB-CONTRACTS

If authorized in MDA's grant application requirements, research grants can include support for collaborative, multi-center research if the support is necessary to complete a portion of the project. While MDA will consider reviewing separate projects for each participating applicant in collaborative, multi-center research projects, it is strongly recommended that one institution submit the application for the group and, in turn, sub-contract with qualified collaborators.

In connection with a sub-contract, the MDA-funded PI must administer and account for all expenses of collaborating investigators and their respective institutions. All such costs, including indirect costs, must be accounted for by the MDA-funded PI. Each of the sub-contracted investigators must report to the MDA-funded PI and be independently responsible for the institutional documentation required to comply with policies, rules and regulations governing animal use and clinical trials. All subcontracted costs, approved as part of the MDA grant, must be substantiated with the submission of a report of expenditures on the form required by MDA and the signature of the PI at the

subcontracted institution(s). Indirect costs are not permitted as part of subcontracted expenses since they are already accounted for in the indirect cost calculation by the MDA-funded PI's institution.

IV. GRANT PAYMENTS

Automatic Clearinghouse (ACH) payment transfers are processed in accordance with the signed Notice of Award and the payment schedule detailed in the Proposal Central grant file, provided all required deliverables are submitted and approved at that time. If a check payment is processed, it is made payable to the PI's institution only. The institution's financial officer should establish an account from which grant expenses may be paid under the terms and conditions of the awarded grant. The amount authorized by MDA for institutional indirect cost may be disbursed as the institution deems appropriate.

All grant payments are contingent upon the availability of grant funds, approval of required research progress and grant expenditure reports, and confirmation that required Institutional and Regulatory approvals are current and on file at the funded institution and MDA.

All contingencies and project deliverables stated in the Notice of Award including, Institutional and Regulatory approvals, must be submitted by the grantee by the stated deadline and approved by MDA, prior to the release of grant funds.

Should a delinquent deliverable cause a payment to be delayed, the delinquency shall be subject to MDA's Good Standing policy.

MDA will make every attempt to replace a missing or lost payment. However, the missing or lost payment must be brought to the attention of MDA Research Department staff by sending an email to grants@mdausa.org or by emailing the assigned grant manager within six (6) months of the issue date on the original payment or a reissuance of the payment will not be authorized.

MDA has the right to withhold or cancel grant payments for non-compliance of the policies herein and the grantee shall be subject to MDA's Good Standing policy. The final grant payment will be held until required financial and/ or research progress reports as well as any other reports and regulatory documentation required by MDA are submitted, reviewed, and approved.

V. GOOD STANDING POLICY

Principal Investigators, Co-Principal Investigators, and the applicant or grantee institution must maintain compliance with the following to remain in Good Standing with MDA. Applicants or grantees deemed Not In Good Standing are not eligible to reapply for funding until MDA determines they have met all conditions to regain good standing as stated below for current or previously funded grantees:

- Timely Reporting:
 - Good Standing:
 - Financial and/ or research progress reports, regulatory documentation, as well as other project deliverables agreed to by MDA and the grantee are submitted by the assigned deadline and approved.
 - All unspent funds returned to MDA by the assigned deadline.
 - Not In Good Standing:
 - Financial and/ or research progress reports, regulatory documentation, as well as other project deliverables agreed to by MDA and the grantee were not submitted by the deadline or were not approved.
 - Unspent funds were not returned to MDA by the assigned deadline.

- Regaining Good Standing:
 - Good Standing:
 - Applicant or grantee is approved to submit a proposal for future funding cycles.
 - Not In Good Standing:
 - Applicant or grantee is not approved to submit a proposal for future funding cycles.

The following steps will be implemented before MDA assigns the designation: Not in Good Standing:

- 1) Warning emails from grant manager describing delinquency issue(s) at thirty (30) days and sixty (60) days overdue.
- 2) If delinquency issue(s) is not resolved within ninety (90) days of the due date agreed to in the Notice of Award, grant is assigned the designation Not in Good Standing with written notice to grantee.
- 3) If delinquency is not resolved within thirty (30) days of MDA's designation of Not in Good Standing, MDA sends written notice of intention to terminate the grant early.
- 4) If delinquency is not resolved within ten (10) days following MDA's notice of intent to terminate project, MDA sends notice terminating grant in accordance with Change in Status/ Cancellation of Grant by MDA policy.

VII. AUTHORIZED COSTS

All authorized costs are detailed in the application requirements for the relevant MDA grant mechanism. All project costs will be reviewed and approved according to the guidance provided in the application requirements and when MDA deems them justified at its sole discretion.

VIII. UNAUTHORIZED COSTS

All unauthorized costs are detailed in the application requirements of the relevant MDA grant mechanism. All project costs will be reviewed according to the guidance provided in such application requirements.

IX. DIRECT COSTS VS INDIRECT COSTS

Direct costs can be specifically identified in the awarded grant to achieve progress on approved research aims. Indirect costs are associated with general infrastructure of the institution or department supporting the progress of approved research aims. For example, administrative support, building use, maintenance and operations, library fees, insurance and depreciation are considered indirect costs and are not permitted as a direct cost in the awarded grant. Indirect cost guidance is detailed in the application requirements of the relevant MDA grant mechanism and must not exceed a maximum of 10% of direct costs.

X. SUPPORT FROM OTHER SOURCES

A PI may not apply for, use, or accept MDA grant funds for a research project or part of a research 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 PI from private, governmental, and institutional sources, including MDA, is required. Such disclosure must be made in the submitted grant application and as part of annual research progress status reports. If funds from other sources become available to the applicant during the review process or to the grantee during the award period of an MDA grant, then the PI must inform MDA's Research Department in writing. MDA will then review the disclosure and inform the applicant or grantee about the financial allocation and/ or award status of the application at its sole discretion.

XI. BUDGET REVISIONS

(This section is not applicable to awarded grants with modular budgets. Refer to section C: Research Reports and Publications for more information about modular budgets)

MDA requires submission of a revised budget when the amount awarded by MDA 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 Notice of Award that must be deleted from the budget. A revised budget must be completed in the applicant's ProposalCentral file within four (4) weeks of the date of the Notice of Award posted in the applicant's grant file.

If the Principal Investigator wishes to reallocate funds within the budget after MDA has approved the budget, and the proposed revision totals more than 25% of the current annual budget, the Principal Investigator must submit a written request for the reallocation by contacting their assigned grant manager for authorization. Such requests must include the amount of the reallocation by budget category and a detailed justification explaining how the requested revision will affect approved research aims. 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 budget category to a non-approved category without a written request and full justification for review. Reallocations are permitted only during the current funding year.

XII. UNEXPENDED FUNDS, CARRY FORWARD, AND NO COST EXTENSION

If grant funds are not completely expended by the termination date of the grant, the remaining balance must be returned to the MDA within four (4) weeks of the grant termination date. A carry forward of unexpended funds must be requested or the amount of unexpended funds on the submitted expense report will be deducted from any pending grant payments. Carry forward requests are limited to a maximum of ten (10) percent of the awarded funds for that budget year. However, with a reasonable justification, more than (10) percent of unexpended funds can be requested. 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.

(This section is not applicable to awarded grants with modular budgets. Refer to section C: Research Reports and Publications for more information about modular budgets.)

A No Cost Extension (NCE) changes the termination date of the grant without providing additional funding. Expenditures may not be committed against a grant prior to the start date or subsequent to its termination date except when authorized in writing by MDA's Research Department.

Under exceptional circumstances, a grant may be extended beyond its termination date for a period of either three (3) or six (6) months if there is a project delay or for another justified reason, at the sole discretion of MDA. The PI must request an extension in writing by completing the No Cost Extension Request form provided by MDA and it must be uploaded in the ProposalCentral grant file no later than four (4) weeks BEFORE the grant termination date to be reviewed by MDA staff. If approved, 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 PI 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.

Leave of Absence

Under certain circumstances, PI(s) or Co-PI(s) may be unavailable to work on approved project aims for a defined period of time. If the absence is less than 12 weeks and is due to a life event such as, maternity or paternity leave, hospitalization or family emergency, prior written notification is not required.

An absence for 12 weeks or more is considered a prolonged absence and continued use of grant funds by or reassignment of a grant to another qualified PI requires prior written MDA authorization. The PI must provide written notification to the MDA Research Department requesting a prolonged absence authorization at least six (6) weeks before the start date of the period of absence when possible. The request must contain an explanation for the absence and detail the strategy for conducting the awarded research grant's approved aims during the absence. The letter, on institutional letterhead, must include the following:

1. Dates of absence,
2. Reason(s) for absence,
3. Name, address, telephone number, and biosketch of the substitute investigator who has agreed to be responsible for the scientific conduct of the research grant's approved aims,
4. Proposed communication strategy between the PI and the substitute PI assigned during the absence,
5. Signature of the substitute investigator confirming their familiarity with all aspects of the awarded grant and acceptance of full responsibility for the conduct of the research grant's approved aims during the absence of the PI.

When a request for continued use of grant funds during a prolonged absence of the PI is not authorized, the grant is terminated and all unexpended funds, if any, must be returned to MDA accompanied by a Report of Expenditures within eight (8) weeks of the date of termination.

Move to New Institution

Continued use of grant funds by a PI who changes institutions requires prior written authorization from MDA. The PI must notify MDA's Research Department requesting authorization in writing by submitting a Request for Transfer to New Institution form at least eight (8) weeks before the effective date of the change in institution. The completed form must include:

1. Effective date - month/day/year - of change in institution,
2. Project titles and periods of support of all MDA grants affected by the change in institution,
3. Complete address of the new institution and the new mailing address of the PI if it differs from the new institution,
4. Statement of Adequate Facilities of the new institution's facilities for conducting the awarded research project(s).

Instructions for transfer of funds between institutions will be provided by MDA's Research Department.

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

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

Withdrawal from Project

When a PI withdraws from a project, the grant terminates and all unexpended funds, 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 PI at the same institution. In such cases, the PI must notify MDA's Research Department in writing 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:

1. Effective date - month/day/year - of the change in PI,
2. Updated research progress report for the awarded grant,
3. Name, address and biosketch of the proposed new PI.

The proposed new PI must, in a separate letter, provide an explanation to MDA regarding their familiarity with the specific approved aims of the project and agree to accept responsibility for all scientific and administrative aspects of the awarded grant with a statement regarding the adequacy of the facilities necessary to conduct the research project.

Cancellation of Grant by Grantee

If, for any reason, the PI must cancel the awarded grant, the PI shall promptly notify MDA's Research Department in writing. The written notification on institutional letterhead must include:

1. the reason for the cancellation
2. the effective date of cancellation of the grant
3. the MDA grant number and project title
4. the name and signature of the PI
5. the name, title, and signature of the institutional official

Unexpended funds, 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 an awarded grant if circumstances render the individual on whose behalf the awarded grant was made is deemed unfit, unqualified, and/or is unable to perform under the terms and conditions of the policy herein and the Notice of Award. Such circumstances include, but are not limited to, abandonment of the project, loss of license, conviction of a crime, lack of employment by a qualified institution, or withdrawal of insurance or other material institutional protections.

Cancellation of Grant by MDA

MDA has the option of canceling its notice of intent to fund or an awarded grant at any time with notice for any of the following reasons:

1. If within ninety (90) days from the start date designated in the Notice of Award (NOA) or the assigned deadline date for submission of required reports MDA has not received the signed NOA, or required supporting documentation, i.e., copy of IRB, FDA, IACUC approval letters; IND confirmation; progress report; expenditure report or other documentation as defined by the policy herein.
2. Availability of MDA 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 policy herein.

XIV. BIOSKETCH REQUIREMENTS

A biosketch for all principal investigators, advisors, co-investigators, and post-doctoral fellows who will be participating in the performance of the research project must be provided to MDA with the grant application, in accordance with requirements set forth in the relevant MDA grant application requirements. When a grant is active, 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 biosketch of any additional or replacement personnel.

XV. RIGHT TO AUDIT

MDA requires grantees to maintain accurate and complete records of grant fund expenditures for a period of five (5) years from the termination date of the awarded grant and agrees that MDA may conduct an audit of such records during usual business hours upon prior reasonable notice by MDA.

SECTION C: RESEARCH REPORTS AND PUBLICATIONS

The research (plan) protocol cited in the original application approved by MDA is the protocol that is being funded, unless otherwise notified in writing by MDA's Research Department. Any amendments or adjustments to the original protocol by the PI **MUST** be reported in the Project Status Report under the "Protocol Amendments" section.

MDA must be IMMEDIATELY notified of ALL substantive changes to the research plan.

I. REPORT OF EXPENDITURES

The financial officer of the institution must, within four (4) weeks of the end of a project period/ funding year or the termination of the grant, complete the corresponding expenses column within the ProposalCentral grant file and mail a check or process an ACH payment in the amount of all unexpended funds. When possible, MDA will first deduct the amount of unexpended funds from unpaid scheduled grant payments, and then request any remaining balance from the grantee. If remaining unexpended funds are not returned within sixty (60) days of MDAs request, the grantee shall be subject to MDA's Good Standing Policy (located in the Good Standing Policy section).

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

A deficit balance may not be carried forward to a new funding period.

Once the final Report of Expenditures has been submitted, MDA will not accept revisions to the submitted final report.

II. MODULAR BUDGET REPORTING

The financial officer of the awarded PIs' institution must, within four (4) weeks of each funding year, complete the corresponding Modular Budget Justification section within the ProposalCentral grant file, which serves as the Report of Expenditures for grant awards with modular budgets. PIs have the discretion to determine how to allocate and account for costs related to modular awards within their institutional accounting system. Institutions are required to ensure that all costs charged to MDA awards are in accordance with applicable cost principles per the MDA Research Department Grant application requirements. Following the termination date of the grant, the institution must mail a check or process an ACH payment in the amount of all unexpended funds.

Upon a cancellation or transfer of a grant, unexpended funds, if any, must be returned to MDA and a Modular Budget Justification must be submitted within eight (8) weeks of the cancellation/transfer date.

A deficit balance may not be carried forward to a new funding period.

Once the final Modular Budget Justification has been submitted, MDA will not accept revisions to the submitted report.

III. GRANT STATUS REPORT

Grant progress status reports must be submitted at least four (4) weeks prior to the expiration dates of each approved funding year. 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 a project year as a condition of continuing the awarded grant.

IV. INVENTION/PATENT REPORTING

The patent report submitted to MDA should be the initial copy of the Institution's Invention disclosure form (and any subsequent versions that have substantive changes or additional information) which details any Inventions that may have been disclosed to an Awardee Institution. The report should be submitted to MDA within sixty (60) days of the date the Invention is disclosed and prior to any public disclosure.

V. 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, and poster presentations or in review articles or similar publications - contain an acknowledgement in the following or similar language that includes the award Digital Object Identifier (DOI), "This publication is based on research supported by the MDA Award (Insert your DOI number from ProposalCentral here)."

Grant 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, are 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 when the publication of an article in a professional journal or a presentation at a scientific or medical meeting occurs.

To avoid misinterpretation of research results or the raising of false hopes about a possible treatment or cure for diseases covered under MDA programs, MDA requires the cooperation of the PI in providing MDA's Research Department with advance pre-publication copies of all articles and abstracts reporting the results of MDA-supported research, which MDA shall keep confidential. MDA also requires the cooperation of PIs 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.

VI. PUBLIC ACCESS POLICY

Public Access Policy Requirement (awards beginning January 1, 2022) MDA requires that all journal articles resulting from MDA funding be made freely available in PubMed Central within twelve (12) months of publication. It will be the responsibility of the author to ensure this occurs.

VII. PROGRAM ASSESSMENT

Principal Investigators are required to participate in follow-up assessments of their scientific and professional progress as a condition of the awarded grant. For a period of five (5) years after the grant termination date and in response to the requests from MDA, the PI will annually inform MDA of their professional status, research support, patents, publications, etc. for MDA to assess the effectiveness and impact of grant funds. The final assessment will occur five (5) years after the grant termination date. This provision shall survive expiration or early termination of the awarded grant.

SECTION D: HUMAN AND/OR ANIMAL SUBJECTS/TISSUES

I. RESEARCH PROTOCOL

MDA is not responsible for the conduct of research grant activities by grantees and grantee institutions. However, MDA requires assurances that the grantee will implement the necessary and customary safeguards when using human subjects, human tissues/materials, biohazardous materials and/or animals in connection with a research grant.

All research grantees must comply with any applicable laws and regulations in connection with their research grants, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Grantees shall provide MDA with information evidencing compliance with any procedures required by a government agency with respect to the research grant.

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

1. A current copy of the approval by the Institution's Human Subjects Review Board (IRB).

Awarded grants 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 in writing about any amendments to the original research protocol 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 requirements in the Research Protocol section 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 grant 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).
2. Copies of all correspondence during the application and award periods between the FDA and the MDA-funded PI 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 grant'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 animals are to be used in a research project, it is the responsibility of the grantee and the institution to ensure that an Institutional Animal Care and Use Committee (IACUC) protocol (or national equivalent) for all planned procedures are approved and uploaded to their ProposalCentral grant file. Additionally, the use of animals and/or animal tissues will require a detailed justification 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 grant.

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 herein 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 with the submitted grant application or awarded grant must be disclosed to MDA. Such a 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-funded Principal Investigators will observe the highest ethical standards in the conduct of research.

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