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HUMAN CLINICAL TRIAL GRANT 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
GENERAL INFORMATION

I. PURPOSE OF HUMAN CLINICAL TRIAL GRANT

To complete clinical trials and clinical studies in aid of development of therapeutic interventions for neuromuscular diseases.

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) 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®.

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 4.

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.

SECTION B
HUMAN CLINICAL TRIAL GRANTS PROGRAM

Human Clinical Trial Grants are awarded to directly support the trial/study outlined in the original application submitted to the Association.

I. ELIGIBILITY FOR HUMAN CLINICAL TRIAL GRANTS

To be eligible to apply for a Human Clinical Trial 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 qualified to conduct and mentor a program of original clinical research;
3. Assume both administrative and financial responsibility for the grant; and
4. Have access to institutional resources necessary to conduct the proposed research project.

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.

NOTE: To apply for a Human Clinical Trial Grant, you must be an independent investigator, i.e., not a trainee, not a post-doctoral fellow, not a research assistant, not a research associate and not under the supervision of another person (Principal Investigator/Independent Investigator) who is directing the research.

II. DURATION OF GRANTS

Human Clinical Trial awards are for one, two or three years, with an optional 8 month planning period. Payments are contingent upon the availability of research funds, submission of respective milestone 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 Sections D & E).

III. DELAY IN ACTIVATION

The activation of a Human Clinical Trial grant by the Principal Investigator may be delayed with a full justification submitted in writing.

All Institutional and Regulatory approvals must be submitted, approved and distributed to appropriate offices, including MDA prior to the release of funds, except when a planning period for obtaining regulatory approvals has been awarded.

IV. SUBCONTRACTS

MDA's Human Clinical Trial Grants Program includes support for multi-center studies. It is recommended that one institution submit the application for the group and, in turn, subcontract with the collaborating institutions.

In connection with a subcontract, the contractor (principal investigator) submitting the core grant will administer and account for all expenses of the collaborating investigators and their respective institutions. This includes indirect costs. All such costs should be accounted for in the core grant. Each of the participating investigators will be independently responsible for the respective institutional documentation required of compliance with policies, rules

and regulations governing clinical trials. MDA will require that such documentation be submitted for the institution of the principal investigator submitting the core grant application prior to funding and will request that copies of the appropriate documentation be provided to MDA from the collaborating institutions. The documentation should be uploaded to proposalCENTRAL® with a copy of each subcontract agreement.

V. GRANT PAYMENT

Checks are made payable to the Principal Investigator's institution and are issued after demonstrating completion of each milestone 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.

VI. AUTHORIZED EXPENSES

When MDA deems them justified by the trial/study, the expenses identified below are permitted under the MDA Human Clinical Trials grants program:

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. Study Coordinators, Nurses, Statisticians etc. 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 Principal Investigator to whom the grant was awarded.

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

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

4. Travel expenses:

    a. Are limited to Personnel listed on the MDA project.

    b. Must be directly related to the implementation of the trial and/or expressly and solely for the purpose of reporting the results of MDA-supported trial at suitable scientific or medical meetings;

    c. Are limited to $1,000 maximum per year;

    d. Site visit travel solely to support travel of investigators between sites to facilitate the trial is limited to $5,000 per year.

5. Costs associated with publication of the research;

6. During the planning period, the budget may not exceed $50,000. The funds provided for the planning period are restricted for the purpose of obtaining institutional approvals, consent form(s) and subcontracts.

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 Human Clinical Trial Grants program:

1. Salary or fringe benefits for collaborating Investigators, co-Investigators or consultants;
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 relating to academic studies;
7. Membership dues, subscriptions, books or journals; and/or
8. Expenses for or related to moving from one institution to another.

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 Human Clinical Trial 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.

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 Human Clinical Trial 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 uploaded in the applicant's proposalCENTRAL® file within four (4) weeks of the date of the formal Notice of Award.

X. UNEXPENDED FUNDS

If funds are not completely expended at the end of a support period, they must be returned to the Association within twelve (12) weeks of the support period. Carry forward of funds may be requested if additional support periods exist on the award. Carryover of unexpended funds must be requested in writing no later than four (4) weeks after the termination date of a support period. 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 six (6) or twelve (12) 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

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) 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 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 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 research 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 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.

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:

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, 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.

XIV. CURRICULUM VITAE/BIOSKETCH

Curriculum vitas 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 D
RESEARCH REPORTS AND PUBLICATIONS

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 period 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 support period or new grant to the PI 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. MILESTONE REPORTS

Milestone reports must be submitted when the trial reaches the agreed upon milestones, and updates must be supplied to MDA on request if milestones are significantly delayed. A final report must be submitted no later than

four (4) weeks following the grant termination date. MDA may require additional milestone 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, and 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 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 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 E
HUMAN 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.

IV. 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.