



Muscular Dystrophy Association, Inc.  
www.mda.org

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# MDA CLINICAL RESEARCH NETWORK GRANTS POLICY

MDA Clinical Research Network 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.*

UPDATED FEBRUARY 17th, 2017

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

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## **SECTION A**

### **PROGRAM AND APPLICATION**

#### ***I. PURPOSE OF CLINICAL RESEARCH NETWORK GRANTS***

MDA Clinical Research Network Grants will be awarded to select MDA clinics to form a research network. The purpose of the network is to promote and accelerate clinical research for one of the diseases covered by MDA's program (<https://www.mda.org/disease/list>). The specific goals of the network are to: 1] develop and conduct clinical studies aimed at optimizing and standardizing medical management; 2] to develop and standardize outcome measures for the clinical studies and trials; 3] to facilitate the testing of new therapies through clinical trials; and 4] to coordinate activities which enhance communication and collaboration among MDA clinics. The program is intended to help support the infrastructure necessary to conduct such studies in an efficient manner through the activities of the network.

#### ***II. APPLICATION PROCEDURE***

APPLICATIONS ARE NOT PROVIDED TO INSTITUTIONS FOR GENERAL DISTRIBUTION. Grant applications are made available to qualified applicants only (see Section B for eligibility requirements). An application may be submitted and accepted at MDA's sole discretion and is based on the potential contributions to the clinical research network. In order to receive an application, a letter of intent (LOI) must be completed and submitted to MDA through proposalCENTRAL for review.

#### ***III. DEADLINE DATES***

1. The LOI is not open to the general public for submission. A deadline date will be given upon discussion with MDA staff.
2. The completed application must be submitted through proposalCENTRAL by the due date given at the time of the LOI acceptance.

#### ***IV. APPLICATION REVIEW***

To ensure support of meritorious clinical research centers, applications are peer-reviewed to evaluate the clinic's experience and personnel, as well as institutional resources available to permit the center to participate, effectively, as part of MDA's Clinical Research Network. MDA's Board of Directors has the sole authority to award research grants.

#### ***V. PATENT AND LICENSING POLICY INFORMATION***

Grants awarded through MDA's Clinical Research Network Grant Program are subject to the Association's Patent Policy. By accepting a grant offered through MDA's Clinical Research Network Grant 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**

### **CLINICAL RESEARCH NETWORK GRANT PROGRAM**

MDA Clinical Research Network Grants are awarded to help support the infrastructure necessary to participate in activities of the network. Grantees will be expected to actively participate in network meetings, including periodic face-to-face and teleconference meetings, to participate in network research projects, and to promote and enhance communication with MDA clinics in their geographic region, and

#### ***I. ELIGIBILITY FOR CLINICAL RESEARCH NETWORK GRANTS***

To be eligible to apply for an MDA research grant, an applicant must:

1. Hold a Doctor of Medicine (M.D.) or equivalent degree (i.e. D.O.);
2. Be a permanent member of a MDA clinic team. If the PI is not a named MDA clinic director, a letter of support from the clinic director(s) is required.
3. Be qualified to conduct clinical research within his or her institution;
4. See or have access to a minimum of 100 individuals with a disease covered in MDA's program (<https://www.mda.org/disease/list>) each year;
5. Be experienced in clinical research in for a disease covered in MDA's program;
6. Have or employ adequate personnel to allow active participation in network activities;
7. Assume both administrative and financial responsibility for the grant; and
8. Have the ability to obtain funding for research projects conducted through the network.

#### ***II. DURATION OF GRANTS***

Grants to MDA Clinical Research Centers will total \$60,00 per center per year. Grants will be awarded for a 3 year period but will be renewed annually. Payment for subsequent years is contingent upon availability of funds, submission of respective progress reports and reports of expenditures (ROEs) 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 research grant by the Principal Investigator may not be delayed. A Principal Investigator who is unable to begin his or her grant on its designated start date must relinquish the award and reapply.

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

#### ***IV. GRANT PAYMENT***

Checks are made payable to the Principal Investigator's institution and are issued quarterly providing all contingencies are met at that time. The institution's financial officer should establish an account from which authorized expenses may be paid under the terms of the approved award. Indirect costs for MDA Clinical Research Network Grants are allowed a maximum of \$6,000 per year to the Primary Institution only. MDA has the right to withhold or cancel payments for non-compliance of Policies.

## **V. AUTHORIZED EXPENSES**

When MDA deems them justified by the research, the expenses identified below are permitted under the MDA research 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. Complete or partial salaries for key Clinical Research Center team members, such as clinical coordinators and clinical evaluators, as detailed in the center's proposed budget;
3. Equipment and supply expenses necessary to support network activities. 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 grant. Support for computer equipment will be limited to one (1) laptop per grant. Any request for a laptop computer must be fully justified on the Budget Justification page of the application.
4. Travel expenses:
  - a. Must be directly related to the conduct of network activities or 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 publication of the research;
6. Other costs detailed in the center's proposed budget and approved by MDA;

## **VI. UNAUTHORIZED EXPENSES**

The following expenses are not permitted under the MDA research 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. Salaries for administrative, secretarial and/or clerical staff;
4. Life and Disability insurance fees;
5. Purchase or rental of office equipment; (i.e., furniture, filing cabinets, and copy machines);
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.
9. Indirect costs over the \$6,000 limit to the lead institution only.

## **VII. DIRECT COSTS VS INDIRECT COSTS**

Direct costs are those costs that can be specifically identified with the funded project. Indirect costs are those costs that are associated with general infrastructure support of the institution or department. For example, administrative support, building use, maintenance and operations, library fees, insurance and depreciation would all be indirect costs and cannot be charged as a direct cost of the funded project.

## **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.

### **2. SUPPLEMENTAL FUNDING**

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

## **IX. BUDGET REVISIONS**

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

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

- a) 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**

It is expected that funds will be expended during the grant year in which they are disbursed. 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 MDA may consider carryover of funds for a period of three or six months beyond the termination date of that year of support. Carry-over of unexpended funds is limited to a maximum of ten (10) percent of the award for that budget year. Such a request must be submitted in writing no later than four (4) weeks after the termination date of that year of support. The request must state the amount that remains unexpended and how those funds will be used in the following year. All category maximums remain in effect.

## **XI. EXPENDITURES BEYOND GRANT EXPIRATION DATE**

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

When a Principal Investigator moves to a new institution, 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 change in in Principal Investigator;
- b. Updated progress report on activities supported by the grant;
- 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 clinical research network grant and also provide a statement about the availability of equipment, personnel, etc., necessary to continue network activities. When continuation of a grant is authorized, a new application cover sheet signed by the new Principal Investigator and institutional official is required.

When continuation of the grant under a new 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 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 clinical research network grant and also provide a statement about the availability of equipment, personnel, etc., necessary to continue network activities.

#### 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 anytime with notice for any of the following reasons:

1. If within ninety (90) days from the scheduled funding start date or the established deadline date for receipt of required reports, MDA has not received the required supporting documentation, i.e. copy of IRB, FDA, approval letters; IND confirmation; copy of informed/consent form(s); progress report; or other documentation as required to conduct network activities or as defined by MDA Clinical Research Network 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 personnel who will be participating in the execution of the network activities must be provided to MDA with the grant application.

#### ***XV. CHANGE IN PERSONNEL***

When a project is underway, MDA's Research Department must be informed immediately in writing of any change in personnel participating in the project, and 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 through proposalCENTRAL for upload to the financial officer of the Principal Investigator's institution. The institutional financial officer overseeing administration of the MDA Clinical Research Network grant must, within twelve weeks of the conclusion of each funding year of the grant, upload the completed form to MDA and mail a check in the amount of all uncommitted and unexpended funds plus any unexpended accrued interest. When unexpended funds are not returned within sixty days of the receipt of the Report of Expenditures, the Report of Expenditures will be considered unacceptable and will be returned to the financial officer of the awarded institution. In such cases, MDA will expect the financial officer to remit payment in full within four (4) weeks. In certain circumstances, MDA may withhold the unexpended funds balance from a continuing year or new grant to the PI if necessary.

In addition to the Lead Institution uploading an annual Report of Expenditures each sub-contract institute must also upload an annual Report of Expenditures.

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

## **II. REPORT OF PROGRESS**

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

## **III. PUBLICATIONS, SCIENTIFIC PRESENTATIONS AND NEWS RELEASES**

MDA's Research Department expects timely publication of the results of all research projects it supports and requires that every such publication or presentation - whether in peer-reviewed journals, meeting abstract formats, platforms, 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 studies and clinical trials including those of the federal regulatory agencies, the respective university and institution and MDA. MDA must be advised about any amendments to the original research protocol (including the participant consent form) occurring prior to the commencement of or during the course of the research project.

## **II. FOOD AND DRUG ADMINISTRATION**

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

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

## **III. PATIENT CHARGES**

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

## **IV. 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.

CRNG 02/17/2017