

# **Clinical Research Training Grant (CR-TG) Policy Manual**

## **I. PURPOSE**

The CR-TG is designed to provide promising young clinicians the research training opportunities needed to become productive clinical investigators in neuromuscular disease research. This training opportunity is intended to be compatible with the requirements of a traditional clinical fellowship in neuromuscular disease and any forthcoming requirements for certification in neuromuscular disease. Trainees will be expected to design their own educational plans and to participate, under the supervision of a mentor, in the development and/or coordination of a clinical research project. At minimum, trainees should gain experience in the basic epidemiological methods of clinical research, ethical and legal issues, and the principles involved in monitoring patient-oriented research, including regulatory requirements and quality assurance. Recipients are also encouraged to acquire knowledge of and exposure to research technologies, large dataset management, bioinformatics and other research tools, as well as to develop the communication and collaboration skills necessary for successful investigator development. Clinical Research Training Grants will be awarded annually to no more than two qualified Recipients for the amount of \$90,000 per year for two years.

## **II. ELIGIBILITY**

Those eligible to apply for an MDA Clinical Research Training Grant must:

1. Hold a Doctor of Medicine or Doctor of Osteopathy degree and be licensed to practice medicine in the state in which the grant will be given;
2. Be board eligible or board certified in neurology, child neurology or physical medicine and rehabilitation at the time of the award. Clinicians who have been in a practice focused on neuromuscular diseases for not more than 5 years are also eligible to submit an application;
3. Be a professional member at an appropriate educational, medical or research institution within the United States;
4. Be a U.S. or Canadian citizen, resident alien, or nonresident alien with a valid employment authorization;
5. Have an identified mentor with adequate resources to facilitate completion of the training grant; mentor must hold doctorate of Medicine or Osteopathy and should have appropriate experience in clinical or translational research in the area of neuromuscular disease.

## **III. AWARD REQUIREMENTS**

Applicants must:

1. Complete a core selection of coursework on clinical research in the first year of the grant. Coursework should include, but does not have to be limited to
  - biostatistics
  - epidemiology
  - ethics/responsible conduct of research
  - study design/clinical trials design
  - use of human subjects
  - scientific writing/grantsmanship, and
  - good clinical practice

2. Participate in the design and conduct of a mentored clinical research project on human neuromuscular disease in year two;
3. Over the course of the two-year fellowship, participate in the equivalent of at least 6 months full-time patient care (including inpatient and outpatient care);
4. Dedicate 100% of full-time professional effort (the applicant's department chair or program director must provide a letter of support confirming protected time);
5. Produce brief progress reports at the end of six (6) and eighteen (18) months of training documenting the recipient's progress in his or her training program;
6. Produce a detailed progress report at the end of year one, to include proof of successful completion of coursework, a detailed clinical research project plan, mentor letter, and report of expenditures. The trainee and mentor should each include information about the trainee's future plans, particularly relating to his or her transition to an independent clinical researcher;
7. Produce a final report, due at the end of year two, which includes a project update, a mentor letter/review and an exit interview;
6. Agree to tracking of his or her career development for at least five (5) years beyond completion of the clinical research training grant.

#### **IV. DURATION OF GRANTS**

Clinical Research Training Grant awards are for two years. Payment for year two is contingent upon satisfactory completion of required coursework, approval of the planned clinical research project, availability of research funds, submission of applicable institutional requirements for human subject protection and animal care, and the receipt of a satisfactory mentor letter.

#### **V. REVIEW CRITERIA**

Quality of Applicant: Applicant should demonstrate a commitment to clinical research in neuromuscular disease and a track record of general excellence. The applicant will be asked to provide a statement outlining, briefly, the proposed curriculum and research project, his or her future career plans related to clinical research in neuromuscular disease, and how the training grant experience will help to facilitate the achievement of these career goals. The mentor must submit a statement of support addressing the applicant's qualifications and ability to complete the grant requirements. A co-mentor, if any, will also be asked to provide a letter of support. Two additional letters of support, from persons familiar with the applicant's training and qualifications, are also required.

Quality of Mentor and Environment: Reviewers should consider the adequacy and nature of the research conducted by the mentor, the mentor's ability to expose the recipient to clinical research principles as described in the purpose of this award, and the ability of the mentor's institution to provide resources and support necessary for completion of the grant requirements. The mentor will be asked to provide a statement describing how he/she will participate in the training of the applicant.

Educational Training Plan: The plan must be developed by the applicant and should list specific educational goals consistent with the purpose of the grant and explain how the goals will be achieved. The plan should also contain a detailed section describing how requirements for core coursework will be met in the first year of the award. The plan should also briefly outline a clinical research project to be conducted in year two, describing the rationale for the project and the resources available to support it (note: applicants are not expected to have detailed project plans at the time of application for this grant). Recipients who indicate that, simultaneously, they will be seeking

certification in neuromuscular disease should include the elements required for certification in the educational plan.

## VI. GRANT PAYMENT

Checks are made payable to the Recipient's institution and are issued quarterly, based on completion of required activities. The institution's financial officer should establish an account from which expenses may be paid under the terms of the approved award.

All coursework must be approved in advance of enrollment. Reports of expenditures will be required at the end of year one before funding is released for year two.

## VII. AUTHORIZED EXPENSES

The maximum award amount is \$90,000 per year. When MDA deems them justified, the expenses identified below are permitted under the MDA CR-TG program:

1. Recipient's salary is permitted up to a *maximum* of 100% but not to exceed a total of \$85,000, inclusive of fringe benefits. A 100% effort is required.
2. Of the funds remaining after salary and fringe benefits are subtracted, up to \$10,000 can be used to pay for the following expenses:
  - a. Fees for tuition, registration or other expenses relating to coursework needed to fulfill the requirements of the grant (not limited).
  - b. Purchase of computer hardware (i.e., laptop) and/or software, limited to a total maximum of \$1,500.
  - c. Travel expenses:
    1. Travel and accommodations directly related to course completion (not limited).
    2. Travel and accommodations directly related to clinical research project (not limited).
    3. Travel and accommodations for the purpose of reporting the results of MDA-supported research at suitable scientific or medical meetings (limited to an annual maximum of \$1000).

**Note:** All unexpended funds must be returned to MDA upon completion of the grant.

## VIII. UNAUTHORIZED EXPENSES

The following expenses are not permitted under the MDA research grants program:

1. Salary or fringe benefits for mentor;
2. Salaries, travel and/or housing related to sabbatical leaves;
3. Salaries for secretarial and/or clerical staff;

4. Purchase or rental of office equipment; (i.e., typewriters, word processors, furniture, filing cabinets, and copy machines) except for laptop computer as noted above;
5. Expenses normally covered by the indirect cost of the Trainee's institution;
6. Membership dues, subscriptions, books or journals;
7. Expenses for or related to moving from one institution to another.

## **IX. SUPPORT FROM OTHER SOURCES**

### **1. ALTERNATE FUNDING**

An applicant may not apply for, use or accept MDA funds for a Clinical Research Training Grant already supported for the SAME PURPOSE by funds from another public or private source.

## **X. CHANGE IN STATUS**

The continued use of grant funds following any major change in status of the Recipient 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**

The Recipient must notify MDA of unexpected absences as soon as possible. For planned absence, the recipient 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 continuing the research training. The letter must include the following:

- a. Inclusive dates of absence;
- b. Reason(s) for absence;
- c. Letter from mentor and chairman/dean stating that the Recipient can continue training upon his/her return.

When a request for continued use of grant funds during a prolonged absence 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. RELOCATION OR CHANGE OF MENTOR**

In the event that the Recipient's mentor relocates to a new institution during the term of the award, a letter must be sent to the MDA Research Department requesting authorization at least eight (8) weeks before the effective date of change in institution. The letter must include:

- a. Effective date - month/day/year - of change in institution;
- b. Complete address of the new institution. The new mailing address of the Recipient and mentor should also be included if it differs from that of the new institution;

- c. Revised educational plan for fulfilling the aims of the CR-TG.

If the mentor relocates, the Recipient may transfer to the new institution, structure a plan of remote communication and support, identify a new mentor subject to approval by MDA (see below), or return any unexpended funds and terminate the grant.

In order for a new mentor to be authorized, the new mentor must submit the same letters and statements required of the original mentor during the application process: a letter supporting the qualifications of the Recipient, and a statement describing how the mentor will participate in the training process of the Recipient. The candidate must submit a revised application cover sheet and a revised educational plan. All such submissions are subject to approval by MDA.

When continuation of the training grant and/or a transfer of funds to a new institution are authorized, a new application cover sheet signed by the Recipient's new institution is required. MDA's Research Department will provide instructions for transfer of funds between institutions.

When a transfer of institution or mentor 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 GRANT

When a Recipient withdraws from the Clinical Research Training Grant, 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.

### 4. CANCELLATION OF GRANT

If, for any reason, the Recipient of the Clinical Research Training Grant must relinquish the award, the Recipient should promptly 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 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 accomplish the aims of the grant. 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.

MDA also 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 MDA does not receive proof of applicable institutional Human Subject Protection or Animal Care Policies or if within one year of the scheduled funding start date MDA does not receive proof of required coursework completion;
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 discussed above.

## **XI. CURRICULUM VITAE**

A curriculum vita from the applicant and mentor of the Clinical Research Training Grant must be provided to MDA with the grant application.

## **XII. REPORT OF EXPENDITURES**

A Report of Expenditures form will be mailed to the financial officer of the Recipient's institution with a copy of the award letter. The financial officer of the institution must, within twelve weeks of the conclusion of each funding year of the grant, return the completed form to MDA with a check in the amount of all uncommitted and unexpended funds plus any unexpended accrued interest. When unexpended funds are not returned with the Report of Expenditures, the Report of Expenditures will be considered unacceptable and will be returned to the financial officer of the awarded institution. In such cases, MDA will expect the financial officer to remit payment in full within four (4) weeks.

## **XIII. REPORT OF PROGRESS**

Progress reports must be submitted at least eight (8) weeks prior to the expiration dates of year one. A final report must be submitted no later than four (4) weeks following the grant termination date. MDA may require additional progress reports at any time during an award period as a condition of continuing the award.

## **XIV. PUBLICATIONS AND NEWS RELEASES**

MDA expects timely publication of the results of all research projects it supports and requires that every such publication - whether in peer-reviewed journals, meeting abstract formats, or in review articles or similar publications - contain the following statement or its equivalent: "*Supported by MDA.*"

Funds to support MDA's research program come primarily from donations from private citizens. It is essential to the growth and maintenance of MDA and its research program that these donors be kept fully informed of the research progress their contributions make possible. Individuals and families affected by the neuromuscular diseases covered under its programs must also be kept fully informed of research progress. For these purposes MDA often issues press releases on newsworthy research developments and produces various publications for the public that report research activities. Such a press release or report may be issued on the occasion of the publication of an article in a professional journal or a presentation at a scientific or medical meeting.

To avoid misinterpretation of research results or the raising of false hopes about a possible treatment or cure for diseases covered under MDA programs, the Association requires the cooperation of the Principal Investigator in providing MDA with advance prepublication copies of all articles and abstracts reporting the results of MDA-supported research which MDA shall keep confidential. MDA also requires the cooperation of its Principal Investigators in participating in interviews as MDA may deem necessary. This cooperation will enable MDA to prepare press releases or other reports MDA issues on the research it supports.

## **XV. HUMAN AND/OR ANIMAL SUBJECTS/TISSUES**

### **I. RESEARCH PROTOCOL**

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

1. A complete copy of the research protocol approved by the Institution's Human Subjects Review Board and a copy of that Board's current approval notice;

2. A copy of the patient informed consent form(s) to be used;
3. Evidence that any relevant approved protocols for which the Recipient is not the PI have been amended to add the Recipient's name.

A copy of the Board's current approval notice and any such amendments described above, and a copy of the patient informed consent form must be submitted at the end of year one or prior to the start of any activities involving human subjects. This documentation is required for any clinical research project in which the Recipient is involved, whether or not the Recipient is the project's PI.

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 of this document are necessary. In addition, it is the responsibility of the Recipient and the institution to ensure that the institution has the following on 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 Recipient pertaining to the experimental drug(s) and/or device study.
3. This documentation is required for any clinical research project in which the Recipient is involved, whether or not the Recipient is the project's PI.

## III. PATIENT CHARGES

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

## IV. ANIMAL RESEARCH

MDA investigators should use animals and animal tissues for research purposes only when reasonable and practical alternatives do not exist. When attainment of the specific aims of a project require the use of animals and/or animal tissues, a detailed justification must be included in the research grant application submitted to MDA. The justification shall include statements confirming that institutional guidelines:

1. Are at least as protective as those of the National Institutes of Health;
2. Conform to all applicable laws and regulations;
3. Meet prevailing community standards for responsible scientific research;

4. Apply throughout the project to ensure the humane treatment of any animals involved in the project.

It is the responsibility of the institution to ensure that no MDA funds will be released for research involving humans and/or animals until the required documentation described above is on file with the appropriate official at the institution as well as MDA.

## **XVI. CONFLICT OF INTEREST**

Any potential conflict of interest the Recipient or the Recipient's Mentor 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 grantees will observe the highest ethical standards in the conduct of research.