

SYLVIA LAWRY PHYSICIAN FELLOWSHIP AWARD FOR TRAINING IN MS CLINICAL TRIALS

Sylvia Lawry, founder and long-time leader of the National MS Society and the International Federation of MS Societies, started her quest for a cure with one simple advertisement in The New York Times: “multiple sclerosis: will anyone recovered from it please contact patient.” From that humble start Sylvia Lawry founded the National MS Society, and until her death in 2001, garnered influence and resources and focused the attention of the public, medical and scientific communities worldwide to find the cause and cure of multiple sclerosis. To commemorate Sylvia Lawry’s life, passion and tenacious spirit, and as a living tribute to the difference one person can make, The National MS Society named the Physician Fellowship Program in her honor.

GENERAL

With the increasing number of new therapies being developed for use in MS, there is a need for physicians trained in conducting clinical trials. Clinical trials to test the safety and efficacy of therapies for multiple sclerosis are highly complex and require special expertise and knowledge to monitor this highly variable disease.

It is the intent of this program that the individual with an MD or equivalent medical degree will acquire formal training, under the tutelage of an established investigator, in a broad range of key elements associated with conducting clinical trials in MS. These may include design of study protocols, recruitment of patients, power calculations, randomization procedures, use of controls, identification of appropriate entrance and exclusion criteria, identification of primary and secondary outcome measures, maintenance and assessment of blinding, informed consent, safety monitoring and evaluation, and data access and statistical analysis. These elements must be integrated in the plan of training.

The proposal must provide documentation that:

- the clinical fellow will be actively trained in multiple ongoing MS clinical trials, preferably at various phases to provide exposure to the recruitment stage through data analysis.
- a formal curriculum appropriate for clinical trial training, including courses in biostatistics, epidemiology, or other related courses is available at the institution and will be part of the fellowship experience. Although it is not required, the review committee looks favorably on a training plan which includes the completion of a Master’s degree in clinical research or another related research topic.

Applicants are discouraged from including a detailed independent research project in the training proposal

In order to submit a proposal for research support, investigators must first register with our apply online site (www.mssocietyapplyonline.org) and complete a pre-application. Staff of the Research Programs Department will review the pre-application to determine whether the research plan is appropriate and relevant to our goals.

ELIGIBILITY

Previous Training: Individuals must have received a MD or equivalent medical degree from an accredited institution and; must be licensed to practice medicine in the United States. Residents who have or will have received training in one of the medical specialties relating to multiple sclerosis, and who are in the PGY3 or PGY4 stage or beyond, are eligible to apply;

Citizenship: There is no citizenship requirement; however, the individual applying for the award must be licensed to practice medicine in the United States at the time of application.

Activities and Time: Clinical fellowships are awarded to support training in clinical trials and are not intended to support the completion of internship and/or specialty board certification. Similarly, this clinical fellowship cannot be used to provide support for individuals whose primary responsibility is teaching and/or clinical service. It is expected that supervised training in the clinical evaluation and treatment of MS patients will be obtained as part of the fellow’s involvement in clinical trials. Fellows may spend up to 10% of their time in teaching or other clinical duties, if appropriate, unrelated to the specific aims of the fellowship.

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Mentor and Institution: Proposals may only be submitted by medical institutions in the United States where investigators are actively engaged in MS clinical research and where ongoing MS clinical trials are being conducted. The mentor's expertise must be established by previous participation in well-designed clinical trials in MS.

Before submitting an application, a candidate must arrange for appointment to an appropriate U.S. institution and acceptance by a mentor who will oversee the training. The application must be endorsed by the applicant's proposed mentor and the head of the department in which the training will be received. A plan of training must be formulated and agreed on by the mentor and the applicant, and described in detail in the application.

REVIEW OF APPLICATIONS

Timing: The Society utilizes a Web-based facility for the submission of Physician Fellowship applications. All applicants are required to use this facility for the completion of their proposals. In order to submit a proposal for research support, investigators must first register with our apply online site (www.mssocietyapplyonline.org) and complete a pre-application. Staff of the Research Programs Department will review the pre-application to determine whether the research plan is appropriate and relevant to our goals. Completed applications, including all required supporting documents, received by the Society by the August deadline will be considered for review.

Applications: The applicant and the mentor must provide an adequate description of the formal and informal training program, current or planned MS clinical trial(s), and how these essential elements are to be incorporated into the training plan. Applicants are discouraged from including a detailed independent research project in the training proposal. An itemized statement of all financial requirements, including salary, tuition, and relocation costs of travel must be included in the application. In addition, three letters of recommendation must be submitted online. It is the responsibility of the applicant to ensure that all letters are received by the deadline, and an application may be considered incomplete without them.

Interview: Each applicant must agree to a phone interview by a member of the Advisory Committee on Fellowships or its designee.

Evaluation Criteria: Applications will be evaluated on the following criteria:

- 1) the applicant's background, training, potential to develop into a productive physician scientist, and the phone interview
- 2) the environment in which the training program will be conducted, specifically, the qualification and the established expertise of the mentor in participation in well-designed clinical trials in MS, and the potential for intra- and inter-departmental/institutional interactions for the clinical fellow
- 3) description of the formal and informal training programs, including participation in ongoing clinical trials and the planned curriculum relevant to clinical trials, such as courses in biostatistics and/or epidemiology. Note that the inclusion of a detailed independent research plan may detract from the required elements of the training plan and result in a less favorable review
- 4) institutional commitment to the program, adequacy of existing resources and plans for use of institutional funds to augment training resources (for such costs as tuition, etc)

Review Group: All applications are reviewed by the Fellowship Advisory Committee of the Society.

CONDITIONS OF AWARD

Duration of Award: This award may be made for a period of up to three years. The Society is willing to consider requests for reinstatement of a fellowship interrupted by military service, maternity leave or other major events. Successful applicants who applied in PGY3 or PGY4 are expected to begin their fellowships following completion of their residencies.

Salary and Tuition Costs: Up to \$65,000 per year may be requested for salary, fringe benefits and/or tuition costs. These funds may be allocated in any proportion in each of the award years as agreed upon by the fellow, mentor and the institution. Specifics of the allocation must be requested in the original application and reported in the annual financial reports.

The total salary of the fellow may be supplemented by funds from other sources to a level commensurate with the current pay scale of the sponsoring institution, and with the applicant's professional status and previous training and experience. The extent of this supplementation must be stated in the application, and the Society must be notified of subsequent additional support. Under no circumstances may the conditions of salary supplementation interfere with, detract from, or prolong the trainee's approved Society's training program.

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Awards are paid to the training institution on a quarterly basis. The fellow, the mentor, and the grantee institution will each be advised by letter of the duration and amount of the award and will be provided with a budget that reflects the approved expenditures for each grant year. Payment of subsequent years is dependent upon a) availability of funds; and b) receipt, review, and approval by the Society of annual financial and research progress reports. Fellows are considered employees of the institution and their salaries are paid by the institution according to the payment policy and schedule of the institution.

No other funds are provided to defray the costs of training, and indirect costs are not allowed on this award.

Relocation Costs: Funds to cover the cost of travel to the institution where the training is provided are available but only for the fellow and not for family members or for transportation of household belongings. The relocation costs must be requested at the time of application and the amount requested must be comparable to economy class transportation by air or equivalent.

Tykeson Conference on MS for National MS Society Fellows and Faculty Awardees: Through a generous contribution from Mr. Donald Tykeson (active volunteer and member of the Society's National Board of Directors), the National MS Society will hold a meeting of all Society's fellows and faculty awardees on alternate years. All Society's fellows and faculty awardees whose awards are active at the time of the conference are required to attend at the Society's expense. The goal of this meeting is to improve the sharing of research information among the Society's awardees, develop a sense of community among our investigators, strengthen their commitment to MS, and establish new collaborations among their investigators.

Unexpended Funds: Any unexpended funds remaining at the end of each award year may be carried over to the next year. Unexpended funds remaining at the termination of the award must be returned to the Society.

Change in Terms of the Award: Any change to the conditions of an award, including a change in the direction of the fellowship training or in the level of activity by the fellow or mentor, requires prior approval by the Society. Failure to notify the Society will be considered grounds for revocation of a physician fellowship award.

Transfer of a Fellowship Award: The transfer of an award from one institution to another along with transfer of the fellow cannot be made without prior approval in writing by the Society. In the event that the fellow is unable to continue with the training, the fellowship award is not transferable to another candidate at the institution and will be terminated prematurely.

In order for a transfer to be approved by the Society, a new application face sheet and budget request is required from, and must be approved by, the new institution. Written approval from the new institution's Institutional Review Board must be received prior to initiation of payment. In addition, the original institution must submit an acceptable report of expenditures and return all unexpended funds to the Society before a final transfer can be made. No interruption of financial support should be involved if the request to transfer the award is received by the Society at least 90 days prior to the anticipated date of transfer and the financial report is submitted from the original institution prior to the transfer date.

Change of Mentor: If the fellow's mentor becomes unable to continue the supervision of the fellow's training, a replacement may be named by the sponsoring institution pending approval by the Society. Any fellow considering a change in mentor for other reasons must notify the Society in writing to obtain prior approval. However, in the event that the fellow is unable to continue with the training period, the fellowship award is non-transferable and the award will be terminated prematurely.

Personnel Policies: Fellows are not considered employees of the National Multiple Sclerosis Society but rather of the institution where the training is provided. The fellowship is to be administered in accordance with the prevailing policies of the sponsoring institution, including vacations, sick leaves, holidays, etc.

Termination of a Physician Fellowship: Whenever a fellow or a mentor elects to terminate a fellowship on a date prior to that indicated in the letter of award, the Society must be notified immediately in writing of the action taken and of the date involved. Grounds for revocation of a fellowship will be deemed to exist: (1) if a fellow is unable to carry out the research at the original institution; (2) the mentor requests in writing that the fellowship be terminated because of unsatisfactory performance by the fellow; or (3) if a fellow requests in writing that the fellowship be terminated for any reason; (4) if the fellow's mentor becomes unable to continue the supervision of the fellow's training and a replacement acceptable to the Society is not named within 30 days by the sponsoring institution; (5) if the fellow changes any aspect of the award from that which was originally approved by the Society, including the mentor, the department, the institution and/or the specific aims of the research studies, without prior notification and approval by the Society; (6) when annual reports of progress and recommendation for continuation are not received separately from both the mentor and the fellow within one month of the end of each award anniversary year; or (7) for a cause established by due process of law; or as a consequence of an institutional review committee's determination of fraud or malfeasance.

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ACCOUNTING PROCEDURES

- 1) **Annual Financial Reports:** A brief account of the expenses made for each fellowship award is due before each anniversary date during the term of an award. Any unexpended funds remaining at the end of each award year may be carried over to the next year. Forms and instructions for this report will be sent with the annual progress report by 30 days before the anniversary date of the award.
- 2) **Final Financial Reports:** A full account of all expenses made for a fellowship award is due within 90 days of the termination of the award. Any unexpended funds remaining at the end of the award must be returned to the Society. The form for this report will be sent with the final progress report and must be forwarded by the fellow to the financial officer of the awardee's institution. These forms are self-explanatory.
- 3) **Bonded Financial Officer:** The Society requires that the financial officer administering grant funds be bonded. Unless otherwise indicated in the application for an award, it is understood that such officials are bonded as a prerequisite to assumption of office.

PROGRESS REPORTS

Over the term of the award, the Society requires several different types of progress reports from recipients:

- 1) **Annual Progress Reports:** For Fellowships awarded for more than one year, the fellow must submit every twelve months an acceptable report of progress. As part of this report, the mentor must submit a letter of evaluation with a recommendation for continuation. This report is due before each anniversary date during the term of an award along with a copy of the current approval letter from the IRB. Approximately one month before the end of a funding cycle, the Society will email forms and detailed instructions for completing the progress report. Attached to the completed report should be reprints or pdf files of all published reports as well as preprints of all submitted manuscripts, which include research results obtained under the fellowship. Manuscripts will be respected as privileged communications.

Award payments to the institution will be discontinued after each twelve-month period pending receipt of such reports, unless the Society receives prior notification of an acceptable reason for the delay of such reports. When such reports become overdue by three months, the fellowship grant will be terminated automatically as of the date when the report was due. Grants so terminated will not be reactivated.

- 2) **Final Progress Report:** The fellow and the mentor are expected to submit separately a final report of progress to the Society within 15 days following the termination of the award. Approximately one month before the termination date, the Society will email forms and instructions for completing the progress report. The final report must include a summary of work conducted during the final year of support and the entire term, a statement describing the overall benefits of the training experience, future plans, and any new contact information.
- 3) **A Status Report:** The Society periodically (every 4-5 years) conducts surveys of its past postdoctoral fellows to assess their career output since their postdoctoral years. To assist the Society in keeping track of our former fellows, we request that the Society be notified of changes in their professional status, professional address, and email address.

PUBLICATIONS AND REPRINTS

All fellows are expected to send to the Society reprints or pdf files of each publication supported in whole or in part by the fellowship grant. As soon as a manuscript is accepted for publication, a copy of it, with the name of the journal and the expected date of publication, should be sent by email to the Associate Vice President of Research Information (cathy.carlson@nmss.org). Manuscripts will be respected as privileged communications. As soon as reprints of a published article are available, or if a press release from the institution is being prepared for distribution, please send to cathy.carlson@nmss.org.

The National Multiple Sclerosis Society must be acknowledged in all dissemination materials (e.g., publications, scientific exhibits, scientific presentations, press releases, etc.) related to research supported in full or in part by the Society. The following acknowledgment, or its equivalent, should be used:

"This investigation was supported (in part) by a Sylvia Lawry Physician Fellowship from the National Multiple Sclerosis Society."

