



**National
Multiple Sclerosis
Society**

FUNDING ANNOUNCEMENT

Health Care Delivery and Policy Research Program CONTRACT PRIORITIES for Fiscal Year 2014

Eligible applicants include private non-profit and for-profit entities, government organizations and multiorganizational consortia. Applicants who wish to apply for more than one of the following priorities must submit a separate application for each using the Society's Web-based proposal preparation and submission system:
www.mssocietyapplyonline.org.

- 1. What is the comparative effectiveness of comprehensive care vs. usual care for patients with multiple sclerosis?**
- 2. What is the overall cost-effectiveness of current MS treatments, including disease-modifying therapy, symptom management, and rehabilitation?**
- 3. What are MS patients' perspectives concerning priorities for their MS care, i.e., what they want and/or need?**
- 4. What are the optimal methodologies for including MS patients in the development of MS research, particularly health policy studies?**
- 5. Secondary analysis of existing datasets: \$100,000 for 1 year (plus 10% indirect costs).**
- 6. Investigator initiated health policy studies in multiple sclerosis. Topics include but are not limited to studies of the organization, quality, and financing of health care; development and testing of methodologies to evaluate the outcome of care; coding and reimbursement issues; and issues pertinent to subgroups of MS patients. Amount and term variable depending on the nature of the project.**

Deadlines:

A letter-of-intent is ***required***; authorization to submit a full application will be contingent upon an invitation from the Society following review of the letter-of-intent. All letters of intent must be submitted through the Society's Web-based proposal preparation and submission system: www.mssocietyapplyonline.org.

- Our receipt online of your two-page letter(s)-of-intent 9/30/2013
- Approval e-mailed to selected investigators to submit full applications (projected) 11/1/2013
- Our receipt online of your full application 1/8/2014
- Peer review committee meets 3/2014
- Notification of approval, conditional approval, or denial (projected) 6/2014
- Contract start date will be determined through negotiations with the Society

For more information contact:

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All letters-of-intent and full applications are reviewed by a peer-review panel consisting of scientists and clinician-scientists drawn from a variety of relevant specialties, including health policy, neurology, epidemiology, and others. This peer-review panel operates in a way very similar to NIH peer-review study sections. Proposals are evaluated on the basis of scientific merit and relevance to multiple sclerosis. Detailed reviewer's comments are provided to all investigators submitting full applications, whether or not they are recommended for funding. Funding recommendations are made without geographic bias and neither the National Board of Directors of the National MS Society nor donors play a role in the process. All funding recommendations are reviewed by the Society's Research Programs Advisory Committee (RPAC), a panel similar to a NIH council. Review by the RPAC helps to ensure the fairness and integrity of the Society's peer review process, which has been in place for more than 60 years.

Priority 1: What is the comparative effectiveness of comprehensive care vs. usual care for patients with multiple sclerosis?

The goal of the proposed study is to acquire, analyze, and interpret data in order to evaluate the comparative effectiveness of comprehensive MS care relative to usual care.

The National Multiple Sclerosis Society invites qualified investigators to submit two-page letters-of-intent through our Web-based system describing a proposed study to evaluate the comparative effectiveness of comprehensive MS care vs. traditional, non-comprehensive models of care. We have defined comparative effectiveness research according to the US Department of Health and Human Services. Herein the conduct and synthesis of research should compare the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The proposed study should focus on a comparison of at least two models of MS care, and should include outcomes encompassing quality of care and costs. While not a formal part of comparative effectiveness research, we will ask for an evaluation of current cost of care.

Background:

There has long been a debate concerning the relative value of comprehensive, coordinated MS care delivered by MS specialist teams in tertiary centers. Is such care really superior to the traditional model of office-based neurological care delivered by generalists or solo MS specialists? Although MS specialists have argued in favor of the comprehensive, coordinated model, rhetoric has tended to substitute for research in much of the debate. Moreover, insurers have never acknowledged any unique value in the comprehensive model through preferential reimbursement. In addition it is not clear if the comprehensive model is the best fit for all patients, especially those with mild and minimally active disease. Other issues complicating the evaluation of the comprehensive model include the extent to which such a model is even feasible for patients living in rural areas where specialized MS centers or even solo MS specialists do not generally exist.

In any evaluation of MS care models a number of issues need to be addressed. These include: 1) short and long-term clinical outcomes and quality of care measures; 2) direct care costs; 3) patient satisfaction; and 4) the accessibility of care. Insurers are in many cases ahead of the health policy research field in their utilization of some of these parameters to formulate policy. It will therefore be increasingly important to collect and interpret scientifically rigorous data concerning the outcomes of different MS care models as well as the resources needed to achieve those outcomes.

Priority 2: What is the overall cost-effectiveness of current MS treatment, including disease-modifying therapy, symptom management, and rehabilitation?

The goal of the proposed study is to acquire, analyze, and interpret data in order to evaluate the cost-effectiveness of MS treatment, including disease-modifying therapy, symptomatic therapy, and rehabilitation therapies. Because costs can vary by provider and location, variability in costs should be addressed by this analysis.

The National Multiple Sclerosis Society invites qualified investigators to submit two-page letters-of-intent through our Web-based system describing a proposed study to evaluate the overall cost-effectiveness of MS care as a whole, including use of disease-modifying therapies, management of symptoms, and rehabilitation.

Background:

The complexities of MS require that treatment should be multi-faceted. While disease-modifying therapies can alter disease activity and slow progression, they do not necessarily relieve symptoms or restore function. As a result, most people with MS are also in need of treatments to alleviate symptoms such as fatigue and spasticity. Moreover, the loss of independence that can accompany MS requires that people with MS have access to the restorative potential of rehabilitation. Rehabilitation is particularly important for those patients with the more progressive forms of MS. While multi-faceted care would seem to be the logical approach to MS care, by nature it comes with significant resource requirements. The time required to provide multi-faceted care and the resources needed for such care result in such care being costly. While many studies have examined the cost-effectiveness of MS disease-modifying therapies, scant attention has been paid to the cost-effectiveness of MS treatment as a whole.

What are the actual benefits of multi-faceted MS treatment? How substantial are these benefits? At what cost are these benefits achieved? Would it be possible to achieve comparable benefits at lower cost?

Depending on the outcome, results of a study addressing the above questions could help to support more substantial reimbursement models based on a favorable trade-off of costs vs. benefits. The Society and its stakeholders could use the findings to open and enhance a dialogue with policymakers and third-party payers to the benefit of both providers and people living with MS. Moreover, the results could help to bolster the validity of guidelines concerning the use of multi-faceted care for people with MS. In addition, findings from such a study could have implications well beyond MS as the population ages and as a larger segment of the population finds itself living with chronic, disabling conditions.

Priority 3: What are MS patients' perspectives concerning priorities for their MS care, i.e., what they want and/or need?

The goal of the proposed study is to acquire, analyze, and interpret data in order to explore what patients are looking for in terms of their MS care, i.e., their priorities for the components of such care.

The National Multiple Sclerosis Society invites qualified investigators to submit two-page letters-of-intent through our Web-based system describing a proposed study to explore the perspectives of people with MS concerning their priorities for the components to be included in their MS care. The proposed study should gather information directly from people with MS using survey and/or qualitative methods in order to obtain valid and comprehensive information that addresses the above question.

Background:

In recent years there has been much discussion concerning the components and design of MS care. Numerous guidelines and recommendations have been published, but these have almost exclusively been either "evidence-based" or derived through "expert consensus." The patients toward whom such care is directed have generally been excluded from the conversation, leading to a largely paternalistic strategy in the design of MS care.

The situation in MS care is in contrast to the long-standing trend toward greater consumer participation in the assessment of health care quality and satisfaction with care. For example, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) consists of surveys that allow consumers to assess their health care experiences along a number of different parameters toward the goal of advancing patient-centered care.

MS and its care constitute a complex and life-long nexus of personal and societal experiences. The individual's active participation in this care is essential in order for MS care to be most beneficial. Such active participation may include adherence to therapy plans, decision-making concerning therapy options, vigilance for incipient complications, learning about MS and its treatment, inclusion of a broad range of strategies, e.g., exercise, among many others. If successful, the proposed study could help the Society and providers to design individualized care models that would capitalize on patient preferences and thereby enhance the active participation of patients. The result would be the optimization of MS care and enhanced outcomes of such care.

Priority 4: What are the optimal methodologies for including MS patients in the development of MS research, particularly health policy studies?

Purpose:

The goal of the proposed study is to acquire, analyze, and interpret data concerning the best ways to incorporate patient perspectives concerning the development of MS research.

The National Multiple Sclerosis Society invites qualified investigators to submit two-page letters-of-intent through our Web-based system describing a proposed study to evaluate and/or develop optimal strategies for the inclusion of patient perspectives in the development of MS research in general and health policy studies in particular.

Background:

During the last three decades MS research has grown significantly in terms of its quantity, breadth, and success. The direction of this research has come from many sources including investigator-initiated ideas, government directives, private funding organization initiatives, and consensus-building scientific gatherings. However, the input of people with MS and their families concerning the direction that such research should take has been minimal at best. While consumers are rarely in a position to fully comprehend the intricacies of scientific questions and methods, their voice should be heard, since they are the ones who have to live and cope with the full ramifications of MS. This need for the patient perspective is particularly compelling in regard to health policy research which addresses questions concerning the organization and quality of health care.

The trend toward greater consumer participation in the design of research has accelerated recently. Perhaps the best example of this is the the Patient-Centered Outcomes Research Institute (PCORI) which *“helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.”* PCORI was authorized by Congress as part of the Patient Protection and Affordable Care Act and to date has funded a wide variety of studies, all of which incorporate the above principles. More recently the FDA’s PDUFA V has mandated *“patient-focused drug development”* as an integral part of the drug regulatory process.

While it is important to incorporate these trends into MS research, there is at present scant guidance concerning the best ways to integrate the patient perspective into the breadth of MS research. If successful the proposed study would provide a roadmap for researchers, administrators, and policymakers to establish appropriate and effective methods for people with MS and their families to provide valuable input concerning the development of MS research.

Methodological Considerations for Priorities 1 – 4

The proposed study could combine a variety of research methodologies including qualitative research methods (e.g., focus groups), survey methods (e.g., mail, phone, and/or face to face interviews), and analyses of existing datasets, or other methods, although it is anticipated that some primary data collection will be needed. Qualitative research should include adequate methods for structured scoring and analysis of data. Novel means of data collection are encouraged, where appropriate. Collection of data in whatever form should be undertaken in such a way as to maximize, to the extent feasible, that the results can be generalized to the target MS population or subpopulation (for example pediatric patients, patients living in rural areas, etc.).

If surveys are implemented, particular attention should be paid to the proposed samples, including how they will be drawn, how subject selection will be conducted, and what steps will be taken to ensure that they are as broadly representative as possible of the target population. Applicants should present a plan that justifies the proposed sample selections and minimizes selection biases to the extent that it is feasible and economically possible to do so.

If existing datasets are utilized, the investigators should ensure that such datasets are reasonably representative of the target populations that are the subjects of this announcement and include key variables needed to accomplish the study's aims that are aligned with this announcement.

Study design and data collection should be planned so as to ensure the validity and interpretability of the resulting data. The protocol should include procedures to ensure data collection is implemented in a consistent way and that all data are complete.

The protocol should emphasize the use of standardized techniques with recognized reliability and validity. Measures should be both comprehensive and parsimonious, i.e., variables of interest should be thoroughly and soundly assessed and unnecessary and redundant measures should be avoided. The selection of measures should be adequately justified and the measures themselves described in reasonable detail.

The data analytic plan should include a strong justification for the proposed sample size(s) along with a detailed plan for the analysis of the data. It is strongly suggested that a statistician with experience in the type of study proposed be included as an integral member of the investigative team. Where appropriate, a health economist with experience relevant to the proposed study should also serve as a member of the team.

Where appropriate, applicants are encouraged to consider scientifically rigorous designs such as randomized controlled trials. Control groups could take various forms such as treatment comparisons, wait-list groups, placebo conditions, etc.

Dissemination Plan:

In collaboration with the Society, the proposed project must develop **and implement** a comprehensive dissemination plan. The purpose of this plan is to ensure that the

findings derived from the study will be utilized effectively to publicize the implications of the study to a wide audience. The dissemination plan may include a variety of components including: 1) publication of results in appropriate refereed journals; 2) integration of findings into the various programs of the Society; 3) materials and programs for both client and professional education; and 4) other approaches such as Web-based material, etc. Implementation of the dissemination plan will in all likelihood involve appropriate departments of the Society in collaborative efforts. The proposal should include the broad outlines of a dissemination plan. The exact details will be worked out in collaboration with the Society once the project is underway. To facilitate collaboration with the Society, the PI will meet with the Society project officer and other members of the Society staff during the first year of the project to discuss implementation of the dissemination plan. Funds for this purpose should be included in the proposed budget.

In order to facilitate dissemination of findings to the scientific community, the final payment on the contract will be retained until 1) the final research report is received and approved by the Society and 2) the investigators have submitted an article reporting the findings to a peer-reviewed journal of their choice.

Full implementation of the dissemination plan, particularly those components that involve the Society, may extend beyond the term of the project. However, the contractor will only be expected to assume operational responsibility for components of the plan implemented during the term of the project.

Organizational Considerations:

Applicants should provide evidence for their ability to organize and manage all phases of the proposed project. Applications should include letters verifying willingness to participate on the part of any proposed collaborators.

Applicants should provide evidence for their ability to organize and manage studies of the type proposed, recruit the required number of subjects (if applicable), and analyze and disseminate the results of the study. The application should describe how study procedures will be standardized and coordinated across participating locations. If appropriate, applicants should provide evidence of expertise and experience in conducting and interpreting the results of qualitative research. Such expertise may reside with the applicant or it can be provided in the form of a subcontract to an appropriate co-investigator.

Applications should include a detailed timeline with specific milestones and indication of the deliverables that will be provided at each milestone to verify accomplishment of objectives. The deliverables will be described in detail in the contract and will be the result of negotiations between the Society and the contractor. These deliverables will include periodic reports of progress in the study along with a final comprehensive report.

The final report should include a detailed data analysis along with a discussion of the findings of the study and their implications. It should also include specific recommendations based on the findings of the study. These recommendations should point to future measures that go beyond the dissemination plan developed and

implemented as part of the study, e.g., specific strategies that the Society could implement in order to address the issues identified by the project. These recommendations could encompass further research, advocacy, programs, educational efforts, etc. While the length of the final report will depend on the nature of the study and its findings, based on previous contracts funded by the Society, applicants should anticipate preparation of a report encompassing 200-300 pages or more.

Study Dataset:

Subsequent to the completion of the study and if feasible, the investigators will deliver to the Society a complete set of all data collected as part of the study in machine readable form with appropriate format statements based on a widely used statistical analysis package such as SAS or SPSS. The dataset will be accompanied by sufficient documentation (e.g., detailed data dictionaries, etc.) to allow the staff of the Society and their consultants to utilize the data with minimal consultation with the investigators. Alternatively the investigator and the investigator's institution may, with the approval of the Society, develop and implement an alternative plan to make the study data available for public use. In most cases, data collected as part of the study are the property of the Society. However, the Society realizes that under certain circumstances institutional rules or conflicting contractual arrangements will necessitate a modification in the aforementioned policy. In addition, the Society strongly encourages investigators to utilize these data for the preparation of scientific articles, conference presentations, and other materials as appropriate to a prescribed dissemination plan.

After appropriate privacy safeguards have been implemented, the study dataset will be made available to outside investigators. Outside investigators will be required to submit a detailed proposal to the Society describing how they intend to utilize the data. The proposal will be evaluated by a peer-review group and data will be released only to those investigators whose proposals pass the peer-review and have been reviewed and approved by the institutional review board from the institution of the investigator submitting the proposal.

Priority 5: Secondary analysis of existing datasets

Purpose:

The goal of the proposed study is to acquire, analyze, and interpret data from one or more existing datasets in order to address significant health policy questions concerning MS.

Background:

MS is a complex disease which can lead to a wide variety of symptoms and a broad range of disabilities. Treatment of individuals with MS is complicated, particularly when the disease is advanced. The costs resulting from MS are high and involve substantial amounts attributable to health care, lost productivity, personal care, and myriad out of pocket costs. Examination of existing datasets can provide a cost-effective means to investigate the quality and accessibility of MS health care, the organization of MS health care, and the costs associated with such care. Although some investigators have exploited existing datasets to address questions as described above, much remains to be done in order to refine our understanding of these complex issues.

Examples of Datasets:

There are a number of existing datasets that could be exploited in order to address the types of studies mentioned in this announcement. Several examples are listed below. This listing should not be considered exhaustive but rather is meant to provide examples of the types of datasets that could be utilized. Others that could also prove useful exist.

Sonya Slifka Longitudinal Multiple Sclerosis Study – Contact:
nicholas.larocca@nmss.org

North American Research Committee on MS Registry – Contact:
<http://www.narcoms.org/research>

Nurses' Health Studies – Contact: <http://www.channing.harvard.edu/nhs>

Medical Expenditure Panel Survey – Contact:
http://www.meps.ahrq.gov/mepsweb/about_meps/index_researcher.jsp

Medicaid datasets – Contact: http://www.resdac.umn.edu/Medicaid/data_available.asp

Home Health Outcome and Assessment Information Set – Contact:
http://www.resdac.umn.edu/OASIS/data_available.asp

MarketScan® Research Databases – Contact:
<http://marketscan.truvenhealth.com/marketscanportal/>

Contract Support:

Funds will be provided to support a contract of up to one year duration to conduct a study as described above, the results of which could be used by the National Multiple Sclerosis Society and others to improve the quality, accessibility, and cost-effectiveness of MS care.

Methodological Considerations:

The investigators should ensure that the dataset(s) selected are reasonably representative of the target populations that are the subjects of this announcement and that the questions to be addressed are not only significant but also: 1) capable of being addressed with the proposed existing dataset(s) and 2) not previously studied or published using the same dataset(s) to address the same questions.

The data analytic plan should include a strong justification for the anticipated or proposed sample size(s) along with a detailed plan for the analysis of the data. It is strongly suggested that a statistician with experience in the type of study proposed be included as an integral member of the investigative team. It is also recommended that a health economist be included if costs or other financial data are to be an important part of the analytic plan.

Dissemination Plan:

In collaboration with the Society, the proposed project must develop **and implement** a comprehensive dissemination plan. The purpose of this plan is to ensure that the findings derived from the study will be utilized effectively to publicize the implications of the study to a wide audience. The dissemination plan may include a variety of components including: 1) publication of results in appropriate refereed journals; 2) integration of findings into the various programs of the Society; 3) materials and programs for both client and professional education; and 4) other approaches such as Web-based material, etc. Implementation of the dissemination plan will in all likelihood involve appropriate departments of the Society in collaborative efforts. The proposal should include the broad outlines of a dissemination plan. The exact details will be worked out in collaboration with the Society once the project is underway. To facilitate collaboration with the Society, the PI will meet with the Society project officer and other members of the Society staff during the first year of the project to discuss implementation of the dissemination plan. Funds for this purpose should be included in the proposed budget.

In order to facilitate dissemination of findings to the scientific community, the final payment on the contract will be retained until 1) the final research report is received and approved by the Society and 2) the investigators have submitted an article reporting the findings to a peer-reviewed journal of their choice.

Full implementation of the dissemination plan, particularly those components that involve the Society, may extend beyond the term of the project. However, the contractor will only be expected to assume operational responsibility for components of the plan implemented during the term of the project.

Organizational Considerations:

Applicants should provide evidence for their ability to organize and manage all phases of the proposed project. Applications should include letters verifying willingness to participate on the part of any proposed collaborators.

Applicants should provide evidence for their ability to organize and manage studies of the type proposed and analyze and disseminate the results of the study. If applicable, the application should describe and confirm access to the dataset(s) through letters of support or other means.

Applications should include a detailed timeline with specific milestones and indication of the deliverables that will be provided at each milestone to verify accomplishment of objectives. The deliverables will be described in detail in the contract and will be the result of negotiations between the Society and the contractor. These deliverables will include periodic reports of progress in the study along with a final comprehensive report.

The final report should include a detailed data analysis along with a discussion of the findings of the study and their implications. It should also include specific recommendations based on the findings of the study. These recommendations should point to future measures that go beyond the dissemination plan developed and implemented as part of the study, e.g., specific strategies that the Society could implement in order to address the issues identified by the project. These recommendations could encompass further research, advocacy, programs, educational efforts, etc. While the length of the final report will depend on the nature of the study and its findings, based on previous contracts funded by the Society, applicants should anticipate preparation of a report encompassing 200-300 pages or more.

Priority 6: Investigator initiated health policy studies in MS.

Purpose:

The goal of this priority is to encourage the submission of proposals for the study of important health policy questions relevant to multiple sclerosis.

Background:

Unlike the other priorities in this announcement, these proposals will not be in response to a Society initiated health policy question but will be investigator initiated. For several years the Health Care Delivery and Policy Research program of the Society only funded studies in response to Society generated research priorities. Two or three such priorities have been announced each year. While this program resulted in a number of excellent studies, it lacked any provision for capitalizing on the creativity inherent in investigator initiated studies. Oftentimes investigators had contacted the Society with interesting and potentially significant questions to be addressed in the realm of health policy research but until recently we have had no mechanism through which to address the funding of such studies. The Investigator Initiated Health Policy Studies in MS program is designed to fill that gap.

Examples of Topics Relevant to the Program:

HCDPR is a field of inquiry that examines the organization, financing, and management of health care and their impact on access, delivery, cost, outcomes and quality of such care. HCDPR complements the Society's basic and clinical research programs by addressing significant issues related to the implementation of health care. The following are provided as *examples only* and should not be considered as a list of funding priorities. Many other topics could be relevant to the program.

Examples of Health Services Research Studies

- Innovative clinical outcomes data collection methods and/or distance health applications that utilize new communication and health information technologies
- Quantitative and qualitative data concerning the impact on people with MS of the 24-month waiting period for SSDI-linked Medicare benefits
- Barriers to physical access of health care procedures among people with MS
- Maintenance rehabilitation of people with MS: impact on clinical outcomes and cost of policies limiting rehabilitation services unless improvement can be documented
- Availability, accessibility, and utilization of health care, and patient care-seeking patterns
- Patient preferences for alternative treatments, providers, care settings, etc.
- Patient adherence to and retention in treatment
- Organization, delivery, and staffing for health care
- Financing of health care, i.e., third-party payment, reimbursement, etc.
- Costs, cost-effectiveness, cost-benefit and other economic aspects of health care
- Practice patterns and diffusion of technologies/interventions

- Quality assurance programs/techniques
- Guidelines, standards, and criteria for health care and health care outcomes
- Health care administration and management
- Development and testing of methodologies to evaluate the outcome of care

Examples of Intervention Studies

- Impact of adult day care vs. standard care on prevention of nursing home placement
- Comparison of the effectiveness of different strategies for patient adherence to treatment with disease modifying drugs
- Evaluation of two different approaches to facilitating doctor-patient communication
- Comparison of traditional vs. Web-based approaches to patient education
- An investigation of strategies to improve access to disease modifying drugs
- Demonstration project for improving MS care through use of case managers

Funding levels:

There are no set funding levels or terms of award for these proposals. As a general guide, our regular grants are usually three years in duration with an average of \$150,000-\$200,000 in direct costs per year. However, proposals vary from one to five years and from under \$100,000 total to over \$1 million. The budget for your proposal should be contingent on the actual needs as determined by the research plan.

How to apply:

A letter-of-intent is required; no full application will be considered unless the application is in response to an invitation from the Society following review of the letter-of-intent.

1. Read the funding cycle timetable on page 2 of this announcement for a list of important milestones.
2. Register at our apply online site, if you have not already done so: www.mssocietyapplyonline.org
3. Once you are registered, log in to our apply online site and complete and submit your two-page letter-of-intent using the pre-application facility and following the instructions on the next page.
4. Optionally, contact Dr. LaRocca to discuss your research idea before submitting the letter-of-intent.
5. Your letter will be reviewed by the Health Care Delivery and Policy Research Advisory Committee
6. You will be informed of the decision of the Committee concerning whether or not you are invited to submit a full proposal.
7. If invited to submit a full application, log in to our apply online site and begin preparation of your full application.
8. You must submit your invited, full-length proposal **in electronic form only** by 11:59 PM, Eastern Time, January 8, 2014.

GUIDELINES FOR THE LETTER-OF-INTENT

Investigators wishing to apply for funds should submit a **letter-of-intent**, up to a maximum of two single-spaced pages, for each priority for which they seek support. The letter(s)-of-intent **must be in Adobe Portable Document Format (PDF)** and must be prepared using our apply online facility: www.mssocietyapplyonline.org. Instructions for use of the Web site appear on the next page. Letters-of-intent that are e-mailed to the Society or mailed in paper form will not be considered and will be discarded. Investigators should **not** submit full proposals at this time. **The deadline for our receipt of letters-of-intent is 11:59 PM, Eastern Time, 9/30/2013.** An applicant who submits a letter-of-intent will receive an e-mail indicating that the Society has received the letter.

Letters-of-intent should include the following information in summary form:

- Priority to be studied. For investigator initiated proposals, list "Investigator Initiated" as the priority. (A separate letter should be submitted for each priority addressed.)
- Project objectives.
- Brief statement of the methodology to be used, including sample, measures, and design.
- Estimates of the timetable and budget for completion of the project.
- Identification and resources of the applicant organization(s) and a brief statement of the qualifications of the main project staff.
- Name, title, address, telephone and FAX numbers, and e-mail address of the proposed principal investigator for the study.
- **Do not include** any of the following: cover letters, biographical sketches, CV's, or attachments of any kind. Your submission should include only those elements indicated on the apply online site.

Based on a screening of the letters-of-intent by the HCDPR Advisory Committee, invitations to submit full applications, together with instructions for submitting the application, will be e-mailed to selected investigators on or about 11/1/2013. **The deadline for our receipt of full applications is 11:59 PM, Eastern Time, 1/8/2014.**

All proposals will be reviewed by an independent, multi-disciplinary, volunteer peer review committee. Award notification will be sent on or about June 2014. In some cases, based upon the review committee's recommendations, an application may receive a "conditional approval," pending negotiations involving staff of the National Multiple Sclerosis Society, our advisors, and the applicant, concerning aspects of the proposal. Approved applications -- including applications that were initially conditionally approved and have subsequently been successfully negotiated -- will be funded to begin on a date to be determined by the Society.

Letters-of-intent must be submitted through our apply online site www.mssocietyapplyonline.org by 11:59 PM, Eastern Time, **9/30/2013**. Letters submitted after that date, letters submitted by e-mail, and letters submitted in paper form **will not be reviewed.**

INSTRUCTIONS FOR USE OF THE APPLY ONLINE WEB SITE

The Society has Changed Its Application Procedures:

The following changes to the Society's application procedures have been implemented:

- A Web site has been established for preparation and submission of proposals. The Web site is www.mssocietyapplyonline.org
- Passwords for accessing the site never expire and a new password will not be needed for each cycle.
- Submission of proposals is now exclusively electronic for **all** parts of the proposal, including signature page and appendix materials, and no paper copies of any part of the proposal will be sent to the Society.
- The application process itself now consists of two parts, a short pre-application (which includes the letter-of-intent described above) and the full application.
- The basic elements of the application remain largely unchanged but have been re-ordered and reformatted.

How to Register with the New System

If you have applied to the Society before using our **old system**, you will need to register and be approved for access to the Web site. If you have used the **new system**, you do not need to register again. If you have never used the new system, go to the following Web site: www.mssocietyapplyonline.org and once you are at the login page, click on "Register Here." Complete the online registration form and submit your registration by clicking on the word "Register." This will submit your request for access to the site to the Research Programs staff of the Society. The staff will review your registration information to verify that you are qualified to apply for funding from the Society. You will receive notice of approval or disapproval **WITHIN 2 BUSINESS DAYS**. If approved, you will receive an e-mail message containing your login credentials. If you do not receive a message approving or disapproving your registration within two business days of your registration, contact Dr. LaRocca.

Once you have obtained a user ID and password, go to www.mssocietyapplyonline.org and log in at the login page. Once you log in, you will be able to see which funding opportunities are active along with the deadlines for each. You will also be able to begin the preparation of your application. In the new system your password never expires and you will not need to obtain a new password in order to apply for other funding programs or subsequent cycles.

The Pre-Application (Letter-of-Intent)

In the past prospective applicants were required to contact a member of the Society's Research Programs staff to obtain clearance before submitting a proposal. While the Society still encourages personal contact and discussion of possible ideas for proposals, in the current system this process has been formalized somewhat through the use of a "Pre-Application" step. For each funding opportunity, there is a pre-application that must be completed and submitted to the Society before the applicant can prepare a full application. For the HCDPR program, the pre-application includes the letter-of-intent described above and is reviewed by a peer review panel. If your

letter-of-intent is approved, you will receive an e-mail message stating so and you will be able to begin preparation of the full application.

How to Complete the Pre-Application

Once you are logged in, click on “Funding Opportunities” and then on the Health Care Delivery and Policy Research Contracts - January 2014 funding opportunity. Once you are on the “Opportunity Details” page, the steps are as follows:

- Click on “Start a New Application”
- Complete the “General Information” page which consists of the name of the PI, the title of the study, and the name of the organization.
- Save the “General Information” page and mark it as “complete.”
- Click on “Go to Application Forms.”
- Click on “Letter of Intent” and then on “Add” at the top of the page.
- Once you click on “Add” you will upload your letter-of-intent in PDF format.
- Save the Letter of Intent section.
- Then click on “Mark as Complete” and “Submit.”

When you submit the pre-application, it will automatically be sent to Dr. LaRocca to begin the review process.

How to Complete the Full Application

If and when your letter-of-intent has been approved, you will be notified and you can log in and begin to prepare the full application. When you log in, click on “Funding Opportunities.” Then click on the Health Care Delivery and Policy Research Contracts - January 2014 funding opportunity. This will take you to a page listing any applications that you have open for editing. Find the application that you wish to work on (this would be the pre-application that you submitted and which was approved by the Society) and click on the words “Apply Final” on the right side of the list. This will open the “General Information” section. Make any necessary changes and then click on “Save.” When the next page appears, click on “Go to Application Forms.” You are now ready to complete the remaining sections of the application.

Detailed instructions for completion of the full application will be available for download in the “Opportunity Details” section of the funding opportunity on or before November 1. Please read these instructions carefully before preparing your full application.