Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Investigator-Initiated Partnership Award

Funding Opportunity Number: W81XWH-14-MSRP-IIPA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 4, 2014
- **Invitation to Submit an Application:** July 2014
- **Application Submission Deadline:** 11:59 p.m. ET, September 3, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, September 8, 2014
- **Peer Review:** November 2014
- **Programmatic Review:** January 2015

Change for Fiscal Year 2014: *The CDMRP eReceipt System has been replaced with the Electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2014 (FY14) Multiple Sclerosis Research Program (MSRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The MSRP, established in FY09, is dedicated to identifying and funding promising research projects that are relevant to the prevention, etiology, pathogenesis, assessment, and treatment of MS and to ultimately lessen its personal and societal impact. Appropriations for the MSRP from FY09 through FY13 totaled $23.1 million (M). The FY14 appropriation is $5M.

B. Award Information

The MSRP Investigator-Initiated Partnership Award (IIPA) mechanism is being offered for the first time in FY14 with the goal of attracting promising investigators and new perspectives on a research project to improve MS patient care and/or quality of life.

The Investigator-Initiated Partnership Award supports the development of translational research collaborations among ***no more than three independent investigators*** (known as partners), who synergistically combine efforts to address a central problem or question in MS. ***The application should demonstrate each partner's contribution and criticality to the project, which together bring a new perspective to MS research and create the synergy of the team.*** A proposed project in which one of the partners merely supplies tissue samples or access to patients does not meet the intent of this mechanism. The success of the project must depend on the contribution of unique skills and expertise of each partner. The application must include plans clearly outlining the process for interactions between all partners. The plans must include communication structure and meeting schedules, coordination of research milestones, progress updates, plans for data transfer and analysis, and sharing of results. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving the high levels of cooperation needed to ensure the successful completion of the project.

Observations that drive a research project may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and anecdotal data. The ultimate goal is to move an observation forward into clinical application. Important aspects of the Investigator-Initiated Partnership Award are as follows:

1. **Partnership:**
    - ***The partnership must consist of no more than three partners; the three partners include the Initiating PI and one or two Partnering PIs.*** The application should clearly describe each partner's role, expertise, and why they are essential to the project.
    - ***At least one partner must be a clinician, and at least one partner must be a research scientist.***

- ***At least one partner must have experience in either MS research and/or MS patient care, and at least one partner must be from outside of the MS field.*** Experience in MS research is defined by a history of previous or current MS research funding and peer-reviewed MS publications.
- ***The proposed collaboration must be new in that the proposed team as a <u>whole</u> cannot have collaborated previously.*** Some, but not all, partners of the proposed collaboration may have collaborated with each other in the past. Previous collaboration is defined by a history of past or current shared research funding and/or joint peer-reviewed publication of research. Co-authorship on review papers and/or symposium summaries is not considered previous research collaboration.

2. **Impact**: Applications should describe both the potential short- and long-term outcomes of the proposed research and their potential impact on improving MS patient care and/or quality of life.
3. **Preliminary Data**: Preliminary data to support the feasibility of the research project and research approaches are required; however, these data do not need to come from the MS research field.

***NEW* – Guidelines for Animal Research:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis SC et al. 2012. A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.nc3rs.org.uk/page.asp?id=1357.

The FY14 MSRP *Investigator-Initiated Partnership Award does not allow clinical trials;* however, research involving human anatomical substances or human subjects is permitted under this funding opportunity. It does support correlative studies that are associated with an existing or completed clinical trial and projects that develop clinical endpoints for clinical trials. Refer to the General Application Instructions, Appendix 6, for additional information about studies involving human subjects, human subjects' data, or human anatomical substances. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided in the electronic Biomedical Research Application Portal (eBRAP) at https://ebrap.org/eBRAP/public/Program

Use of Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and

requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information. The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section L.

C. Eligibility Information

- ***The partnership must consist of no more than three partners; the three partners include the Initiating PI and one or two Partnering PIs.*** The application should clearly describe each partner's role, expertise, and why they are essential to the project. Each PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).
- ***At least one partner must be a clinician, and at least one partner must be a research scientist.***
- ***At least one partner must have experience in either MS research and/or MS patient care, and at least one partner must be from outside of the MS field.*** Experience in MS research is defined by a history of previous or current MS research funding and peer-reviewed MS publications.
- ***The proposed collaboration must be new in that the proposed team as a <u>whole</u> cannot have collaborated previously.*** Some, but not all, partners of the proposed collaboration may have collaborated with each other in the past. Previous collaboration is defined by a history of past or current shared research funding and/or joint peer-reviewed publication of research. Co-authorship on review papers and/or symposium summaries is not considered previous research collaboration.
- The clinician(s) must be an M.D., M.D./Ph.D., D.V.M./M.D., or equivalent with clinical duties and/or responsibilities.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable combined total direct costs for the entire period of performance are **$1.2M** plus indirect costs.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- A separate award will be made to each PI's organization.
- The PIs are expected to be equal partners in the research, and direct cost funding should be divided by tasks and costs associated with tasks not necessarily equal among partners.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions***.

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Clinical trial costs

Intramural (DoD), other federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

The CDMRP expects to allot approximately $3.84M of the $5M FY14 appropriation to fund approximately 2 Investigator-Initiated Partnership Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

New for FY14: ***The CDMRP has replaced its eReceipt System with eBRAP.*** Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at *https://ebrap.org/eBRAP/public/UserGuide.pdf)*. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted

through Grants.gov, provided there is no cause for administrative rejection of the application (see Section IV.A., Rejection).

The Investigator-Initiated Partnership Award mechanism is structured such that the partnership must consist of no more than three partners; the three partners include the Initiating PI and one or two Partnering PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PIs will be identified as Partnering PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. Each Partnering PI must follow the link in this email and register with the eBRAP in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive notification of invitation via email from eBRAP.

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-14-MSRP-IIPA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The Initiating PI is responsible for submission of all pre-application components.

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the USAMRAA Contracting/Grants Officer.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

  FY14 MSRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  The partnership must consist of no more than three partners; the three partners include the Initiating PI and one or two Partnering PIs. The Initiating PI must enter the contact information for the Partnering PIs in the Partnering PI section.

- **Required Files – Tab 4**

  Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Research Approach:** State the project's hypothesis/objective, rationale, specific aims, and study design. ***The inclusion of preliminary data relevant to the proposed project, but not necessarily in MS, is required.*** All preliminary data provided should be from the clinic or laboratory of the Initiating PI, Partnering PI(s) or other member(s) of the collaborating team named on the pre-application.

    This award may not be used to conduct clinical trials.

  - **Partnership:** Describe the role for each of the PIs in the partnership, including the unique perspective and expertise each brings to the project, and how this collaboration is new and appropriate for achieving the research goals. Explain how the composition of disciplines and expertise in the proposed collaboration are synergistic and bring new perspectives to MS research.

  - **Impact:** Explain how the proposed collaboration will produce results that are likely to translate, whether in the short- or long-term, into improved MS patient care and/or quality of life.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- Biographical Sketches (four-page limit per Initiating PI and four-page limit per each Partnering PI).

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the MSRP, pre-applications will be screened based on the following criteria:

  - **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the hypothesis/objective. Whether the research approach is reasonable based on the preliminary data.
  - **Partnership:** Whether each partner, and the partnership as a whole, meets the eligibility criteria. To what degree the expertise and unique perspectives of the collaborating partners contribute to an experimental approach likely to produce results greater than those of the partners working independently. How well the research narrative conveys each partner's role, expertise, and criticality to the project. To what extent the composition of the disciplines and expertise of the partnership represent a new collaboration with new perspectives in MS research.
  - **Impact:** To what degree the proposed collaboration will produce results, whether in the short- or long-term, likely to successfully translate into improved MS patient care and/or quality of life.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Forms

Applications will not be accepted unless the Initiating PI has received notification of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a "Changed/Corrected Application" with the Previous Grants.gov Tracking ID ***prior to the application submission deadline (which occurs earlier than the end of the application verification period).***

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned unique log numbers by eBRAP. Each Grants.gov application package must be submitted using the unique log number. Note: All associated applications (Initiating and Partnering PI[s]) must be submitted by the Grants.gov deadline.

Grants.gov application package components: For the Investigator-Initiated Partnership Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

    - **Attachment 1: Project Narrative (15-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

        - **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations.

        - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** State the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the proposed project in detail using the outline below. *The inclusion of preliminary data relevant to the proposed project, but not necessarily in the MS field, is required.* All preliminary data should be from the clinic or laboratory of the Initiating PI, Partnering PI(s), or other member(s) of the collaborating team named on the application.
- **Experimental Design:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Include specific examples of roles of the partners and the synergistic elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.nc3rs.org.uk/page.asp?id=1357). If human subjects or human anatomical substances will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

  This award cannot be used to conduct clinical trials.
- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. As appropriate, provide a statistical plan and sample size estimate for each study aim and the method by which it was derived, including power analysis calculations.
- **Project Coordination and Communication:** Describe plans for project coordination and communication, including communication structure and meeting schedules, allocation of resources, coordination of research milestones, progress updates, plans for data transfer, analysis, and sharing of results among all partners and institutions participating in the project.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
  - References Cited: List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate

whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information. ***Provide this information for each PI.***

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide letters, signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from the collaborating individuals or organization other than the Initiating Partner and each Partnering PI that will demonstrate that the PIs have the support or resources necessary for the proposed work.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  Technical abstracts should be written using the following outline:

  - Background: Present the ideas and reasoning behind the proposed project.

- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Summarize the potential short- and long-term outcomes of the proposed research and their potential impact on improving MS patient care and/or quality of life.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."

  Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.***

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.
  - Describe the ultimate applicability of the research.
    - What types of MS patients will it help, and how will it help them?
    - What are the potential MS clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a clinically relevant outcome?
    - What are the likely contributions of this study to advancing the field of MS research and improving MS patient care and/or quality of life?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

  The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Program Announcement and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Investigator-Initiated Partnership Award mechanism, use the SOW format example titled "Collaborative PI Projects." The SOW must be in PDF format prior to attaching.

  Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf."

  Explain in detail why the proposed research project, in deriving unique benefit from the particular collaboration through the expertise and unique perspectives of each partner, whether in the short- or long-term, is likely to produce results to improve MS patient care and/or quality of life.

- **Attachment 7: Partnership Statement (two-page limit):** Upload as "Partnership.pdf."

  Personnel: Identify each partner's role(s) in the partnership for fulfilling the eligibility requirements of this award by name. A partner may fit more than one category.

  - Research scientist(s)
  - Clinician(s)
  - Partner(s) with experience in MS research and/or MS patient care
  - Partner(s) from outside of MS research field

  Partnership:

  - Unique Perspectives: Describe how the combination of disciplines of the partners brings new perspectives into the MS research field. Describe how the individual efforts and unique perspective, when combined, result in capabilities as a team to accomplish the proposed project. The proposed team as a whole cannot have collaborated previously; describe how the team will come together to approach and complete the research proposal.
  - Synergy: Describe how the proposed partnership involves a substantial contribution by each partner and exchange of ideas and information. Describe how the collaboration results in a level of productivity to effect an outcome that will be greater than that achievable by each partner working independently.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
     - Include biographical sketches for both the Initiating and Partnering PI(s).
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
     - Include previous/current/pending support for both the Initiating and Partnering PI(s).

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The combined total direct costs for the Initiating and Partnering PI(s)' budgets cannot exceed $1.2M.

5. **Project/Performance Site Location(s) Form**: Refer to the General Application Instructions, Section II.C.5., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

Application Components for the Partnering PI(s):

Each Partnering PI MUST follow the link in the email from eBRAP and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. **SF 424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - **Attachment 5: Statement of Work (SOW) (three-page limit): For the Investigator-Initiated Partnership Award mechanism, use the SOW format example titled "Collaborative PI Projects."** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.2., for detailed information on completing the SOW. ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.***

3. **Research & Related Budget: Refer to the General Application Instructions, Section II.C, for detailed information.**

   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

   Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PIs should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed $1.2M.

4. **Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C.5., for detailed information.**

5. **R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section II.C.6., for detailed information.**

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for

determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on (a) technical merit and (b) the relevance to the mission of the DHP and MSRP and to the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
    - **Research Strategy and Feasibility**
        - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data, and logical reasoning.
        - How well the hypotheses or objectives, aims, experimental design, sample size, methods, and statistical analysis plans are developed and integrated in the project.
        - If animal studies are included, how well they are designed to achieve reproducible and rigorous results.
        - How well the research plan supports a collaborative relationship with clearly defined processes for interactions between all partners and institutions involved.
        - How well the PIs acknowledge potential problems and address alternative approaches.
    - **Personnel and Partnership**
        - Whether all partners, and the proposed partnership as a whole, meet the eligibility requirements.
        - To what extent the composition of the expertise and unique perspectives of the collaborating partners is appropriate to accomplish the proposed research goals.

- To what extent the proposed partnership brings new perspectives to the MS research field.
- To what degree the proposed partnership is likely to result in a level of productivity that is greater than that achievable by each partner working independently.
- To what extent the levels of effort by the partners and other key personnel will ensure success of the proposed work.
- How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all partners and institutions.

- **Impact**
  - To what degree the proposed study will produce results, whether in the short- or long term, likely to successfully translate into improved MS patient care and/or quality of life.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - To what degree the quality and extent of organizational support are appropriate.
  - If multi-institutional, the appropriateness of the Intellectual and Material Property Plan.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether the resources are divided appropriately among all PIs
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP and FY14 MSRP, as evidenced by the following:

- Adherence to the intent of the award mechanism
- Program portfolio composition]
- Programmatic relevance
- Relative impact

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- All associated (Initiating and Partnering PI[s]) applications are not submitted by the deadline.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY14 MSRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14 MSRP IP members can be found at http://cdmrp.army.mil/msrp/panels/panels14.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The Initiating and/or Partnering PI(s) do not meet the eligibility criteria.
- The partnership as a whole does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section J, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

Questions related to application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI(s) Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.		
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	Partnership Statement: Upload as Attachment 7 with file name "Partnership.pdf."		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.		