Program Announcement

Defense Health Program Defense Medical Research and Development Program

Department of Defense Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Idea Award

Funding Opportunity Number: W81XWH-12-MSRP-IA Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), April 24, 2012
- Invitation to Submit an Application: May 2012
- Application Submission Deadline: 11:59 p.m. ET, July 17, 2012
- **Peer Review:** September 2012
- **Programmatic Review:** October 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Multiple Sclerosis Research Program (MSRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The MSRP was established in 2009 to provide support for research of exceptional scientific merit. Appropriations for the MSRP from FY09 through FY11 totaled \$14.3 million (M). The FY12 appropriation is \$3.8M.

The objective of the FY12 MSRP is to support pioneering ideas and high-impact research relevant to the prevention, etiology, pathogenesis, assessment, and treatment of multiple sclerosis (MS) that will move the research field toward achieving the program's vision to prevent the occurrence; cure, reverse, or slow the progression; and lessen the personal and societal impact of MS.

B. MSRP Focus Areas (revised for FY12)

The FY12 MSRP encourages applications that address critical needs of the MS community in the following focus areas:

- Pathophysiological basis of disease progression
 - Biological mechanisms of cortical damage in MS
 - Pathological basis of cognitive impairment in MS
 - New and/or improved measures for evaluating cognition in clinical research
 - Treatment strategies for cognitive deficits including, but not limited to new or repurposed agents, and rehabilitation
- Gene-environment interactions in MS
 - Environmental influences that modify specific genetic pathways associated with MS disease risk and/or progression
 - Maternal environment influences on MS risk in genetically susceptible offspring
 - Genetic influences on biological processes that are relevant to MS and responsive to environmental factors
 - Epigenetic changes due to environmental exposures and their impact on biological processes that are relevant to MS
- Technological development of hardware and/or software instruments for clinical research data capture and modeling
 - Development and validation of measuring tools for real-time assessment of patient outcomes relevant to MS progression or activity
 - Development of in vivo biosensors relevant to MS
 - Novel integrated analysis and modeling of multidisciplinary MS patient data sets (clinical, neuroscience, endocrine, genomic, exomic, transcriptomic, proteomic,

microbiomic data, etc.) to better understand MS disease activity, progression, and clinical outcomes.

C. Award Information

The MSRP Idea Award promotes new ideas that are in the early stages of development and have the potential to yield high-impact findings and new avenues of investigation. This award mechanism supports conceptually innovative, high-risk/potentially high-reward research that could ultimately lead to critical discoveries in understanding the causes and progression of MS and/or improvements in patient care and/or quality of life. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale.

The following are significant features of this award mechanism:

- 1. Innovation: Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. This may include high-risk/potentially high-gain approaches to MS research, provided that there is the potential for significant impact on understanding the causes and progression of MS and/or improvements in patient care and/or quality of life. Research that is merely an incremental advance (the next logical step) is not considered innovative and will not be considered for funding under this award mechanism.
- 2. Impact: Proposed research projects should address a central critical issue or question in MS research. High-impact research will, if successful, significantly advance current methods and concepts toward the MSRP vision.
- **3. Preliminary Data:** Preliminary data, unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application, and/or data from the published literature that are relevant to MS and the proposed research project should be included. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, applications should be based on a sound scientific rationale that is established through logical reasoning or a critical review and analysis of the literature.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research projects (new and ongoing) involving human subjects and/or human anatomical substances 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), and the local Institutional Review Board of record. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DoD. Refer to the General Application Instructions, Appendix 5, for general regulatory requirements. *Clinical trials are not allowed.* A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The FY12 MSRP is not offering an award mechanism that will support clinical trials; PIs seeking funding for a clinical trial are encouraged to investigate other

funding agencies for support. Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects' data, or human anatomical substances. Definitions of human subject use may be accessed at https://cdmrp.org/Program_Announcements_and_Forms/.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities 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 K.

D. Eligibility Information

- Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$400,000** 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 **2** 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.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

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

The CDMRP expects to allot approximately \$3.2M of the \$3.8M FY12 appropriation to fund approximately five Idea 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 multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<u>https://cdmrp.org/</u>) and (2) application submission through Grants.gov (<u>http://www.grants.gov/</u>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<u>http://www.grants.gov/</u>) basic search using the Funding Opportunity Number: W81XWH-12-MSRP-IA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<u>https://cdmrp.org/</u>). 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 application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at <u>help@cdmrp.org</u> or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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
- Collaborators and Conflicts of Interest (COI) Tab 3

FY12 MSRP Integration Panel (IP) members should not be involved in any pre-application or application. A list of the FY12 MSRP IP members can be found at <u>http://cdmrp.army.mil/msrp/panels/panels12.shtml</u>. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at <u>help@cdmrp.org</u> or 1-301-682-5507.

• Required Files – Tab 4

Preproposal Narrative (two-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

Use a separate paragraph to address each point below.

- Identify which FY12 MSRP Idea Award Focus Area or central issue in MS the proposed research will address.
- Describe the **problem**, **question**, **or knowledge gap** addressed by the proposed research, and why the problem is **significant**.
- State the **hypothesis or objective** that will guide the proposed research.
- Summarize the **specific aims and experimental approaches** that will be pursued to test the hypothesis.
- Anticipate how successful research results would **impact** the MS community and/or further MS research.
- Explain why the proposed research is **innovative**.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application 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.
- **Key Personnel Biographical Sketches (four-page limit per individual):** Include biographical sketches for the PI and other key collaborators.
- Submit Pre-Application Tab 5

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

• Other Documents Tab

No additional documents are required.

Pre-Application Screening

• Pre-Application Screening Criteria

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

- Adherence to the intent of the award mechanism
- Research Idea:
 - How well the proposed research project addresses one of the FY12 Focus Areas or a central issue in MS.
 - How well the proposed research addresses a significant problem, question, or knowledge gap in MS research.

• Personnel

- Whether the PI meets the eligibility requirements.
- To what degree the PI and research team's backgrounds and MS-related expertise are appropriate to successfully address the proposed research idea.
- **Innovation:** How well the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other uniquely creative qualities.
- **Impact:** To what degree the proposed research project, if successful, will make a short- or long-term impact that significantly advances studies in MS.

Notification of Pre-Application Screening Results

Following the pre-application screening, 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.

Pre-application notification dates are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the 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 (<u>http://www.grants.gov/</u>). For the Idea Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Idea 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 (eight-page limit): Upload as "ProjectNarrative.pdf."

Describe the proposed project in detail using the outline below.

• **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe how the previous experience of the PI and research team relates to the proposed research project. Preliminary data, unpublished results from the laboratory of the PI or collaborators named on this application, and/or data from the published literature that are relevant to the proposed research project should be included.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this application.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls and statistical plan, in sufficient detail for evaluation. Include specific examples of innovative elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical substances will be used, include a plan for the recruitment of subjects or the acquisition of samples, and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects.
- 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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
 - 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 a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
 - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

Describe the proposed research project including the following elements: background, hypothesis or objective, study design, and innovative aspects of the proposed research project.

The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

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

Include an overview of the proposed research project that can be readily understood by lay persons. Clearly describe the central critical problem or question to be addressed by the proposed research project, the innovative aspect of the research, and the impact that the project results might have on the field of MS research and/or patient community. Do not duplicate the technical abstract.

- Attachment 5: Statement of Work (SOW) (two-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.
- Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf."

Summarize how the proposed work is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

Although not all-inclusive, the following examples are ways in which proposed work may be innovative; these examples are intended to help PIs frame the innovative features of the research proposed:

- Study concept Investigation of a novel idea and/or research question
- Research method or technology Use of novel research methods or new technologies, including technology development, to address a research question
- Novel method or technology Development of a novel method or technology for prevention, detection, diagnosis, or treatment
- Existing methods or technologies Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended
- Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf."

Describe why the proposed research project is important to understanding the causes and progression of MS and/or improvements in patient care and/or quality of life.

Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research.

Describe the long-term impact: Explain the potential long-term impact of this study on understanding the causes and progression of MS and/or improvements in patient care and/or quality of life. Describe the anticipated long-term gains from

this research course and compare these to MS information/products currently available, if applicable.

- 3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as "Biosketch LastName.pdf."
 - PI Current/Pending Support (no page limit): Upload as "Support LastName.pdf." •
 - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch LastName.pdf."
 - Key Personnel Current/Pending Support (no page limit): Upload as "Support LastName.pdf."
- 4. Research & Related Budget: Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
- 5. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section II.C., for detailed information.

D. **Submission Dates and Times**

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

E. **Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) 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

Application Review and Selection Process A.

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD and MSRP and the specific intent of the award DoD FY12 Multiple Sclerosis Idea Award

mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <u>http://cdmrp.army.mil/about/fundingprocess.shtml</u>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the meritbased selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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 Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

• Innovation

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research project is a new idea and not the next logical step or continuation of a previous research project.
- How the proposed research represents more than an incremental advance upon published data.

• Impact

- To what degree the research project, if successful, will make an important contribution that significantly advances our understanding of the causes and the progression of MS and/or improves the patient care and/or quality of life.
- How well the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) are described.
- How well the anticipated long-term gains from this research course are described and compared to information/products currently available, if applicable.

• Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, MS-relevant preliminary data, or logical reasoning.
- How well the hypothesis or objective, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PI identifies potential problems and addresses alternative approaches.
- Whether the application includes an appropriate statistical plan with power analysis, if applicable.

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

- Personnel
 - How the research team's background and MS-related expertise are appropriate to accomplish the proposed work.
 - To what degree the levels of effort are appropriate for successful completion of the proposed research project.
- Environment
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research project.
- Budget
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- Application Presentation
 - To what extent the writing, clarity, and presentation of the application components influenced the review.
- 2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and MSRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Ratings and evaluations of the peer reviewers
 - Relative impact and innovation

- Relevance to program objectives
- Responsiveness to one of the FY12 MSRP Focus Areas or a central issue in MS.

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt 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 exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY12 MSRP 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 document. A list of the FY12 MSRP IP members can be found at http://cdmrp.army.mil/msrp/panels/panel12.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- 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.
- The proposed research is, or requests funding for, a clinical trial.
- The PI 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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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: 1-301-682-5507

Email: <u>help@cdmrp.org</u>

B. Grants.gov Contact Center

Questions related to application submission through the 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: 1-800-518-4726

Email: <u>support@grants.gov</u>

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. 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	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
Attachments Form	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 6.	
	Upload Impact Statement (Impact.pdf) as Attachment 7.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
Senior/Key Person Profile (Expanded)	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete 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.	