

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-13-SCI-IIRA

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), June 24, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 16, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** January - February 2014

This Program Announcement 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.

TABLE OF CONTENTS

I. Funding Opportunity Description	3
A. Program Description	3
B. FY13 SCIRP Areas of Encouragement.....	3
C. Award Information.....	5
D. Eligibility Information	7
E. Funding	7
II. Submission Information	8
A. Where to Obtain the Application Package.....	8
B. Pre-Application Submission Content and Form	8
C. Application Submission Content and Form	11
D. Submission Dates and Times	16
E. Other Submission Requirements.....	16
III. Application Review Information.....	16
A. Application Review and Selection Process.....	16
B. Application Review Criteria	16
C. Recipient Qualification	18
D. Application Review Dates	18
E. Notification of Application Review Results	18
IV. Administrative Actions	19
A. Rejection	19
B. Modification.....	19
C. Withdrawal.....	19
D. Withhold	20
V. Award Administration Information	20
A. Award Notice	20
B. Administrative and National Policy Requirements.....	20
C. Reporting.....	20
D. Award Transfers.....	20
VI. Agency Contacts	21
A. CDMRP Help Desk.....	21
B. Grants.gov Contact Center.....	21
VII. Application Submission Checklist	22

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Spinal Cord Injury Research Program (SCIRP) 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 SCIRP was initiated in 2009 to fund innovative projects that have the potential to make a significant impact on improving the health and well-being of military Service members, Veterans, and other individuals living with SCI. Appropriations for the SCIRP from FY09 through FY12 totaled \$67.85 million (M). The FY13 appropriation is \$30M.

The FY13 SCIRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of SCI-focused research. Applications from investigators within the military Services, and applications involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other federal Government agencies are highly encouraged. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid scientific rationale.

The SCIRP has identified seven Areas of Encouragement for the FY13 program. Not all Areas of Encouragement are applicable to each award mechanism offered by the FY13 SCIRP.

B. FY13 SCIRP Areas of Encouragement

The FY13 SCIRP encourages applications that specifically address one or more of the following areas related to **acute SCI**:

1. Pre-hospital, en route care, and early hospital management of SCI, including but not limited to:
 - The mechanisms of the effects of hemorrhagic shock and hypovolemic resuscitation on SCI
 - Effects of vibration, G-forces and hypobarica as experienced in military medical evacuations
 - Identification and validation of prognostic assessments
2. Development, validation and timing of promising interventions to address issues **during the first year after SCI**, for example, deep vein thrombosis, infection, and pressure ulcers. **Note: Studies of neuroprotective drug interventions are not encouraged.**
3. Identification and validation of best practices **during the first year after SCI** including but not limited to:
 - Surgical interventions
 - Critical care interventions
 - Rehabilitation interventions
 - Musculoskeletal health

The FY13 SCIRP also encourages applications that rigorously and definitively address one or more of the following issues which may occur at **any time after SCI**:

4. Bladder, bowel, and sexual dysfunction
5. Neuropathic pain and sensory dysfunction
6. Functional deficits
7. The ambulatory and non-ambulatory clinical benefits of exoskeletal systems

Alignment with current Department of Defense (DoD) research and collaboration with military researchers and clinicians is encouraged. The following websites may be useful in identifying ongoing areas of DoD research interest within the FY13 SCIRP Areas of Encouragement.

Air Force Research Laboratory

<http://www.wpafb.af.mil/afrl>

Center for Neuroscience and Regenerative Medicine

<http://www.usuhs.mil/cnrm/>

Clinical and Rehabilitative Medicine Research Program

<https://crmrp.amedd.army.mil>

Combat Casualty Care Research Program

<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research Programs <http://cdmrp.army.mil>

Defense Advanced Research Projects Agency <http://www.darpa.mil>

Defense Medical Research and Development Program

<http://dmrdp.fhpr.osd.mil/home.aspx>

Defense Technical Information Center <http://www.dtic.mil>

Military Infectious Disease Research Program <https://midrp.amedd.army.mil>

Military Operational Medicine Research Program <https://momrp.amedd.army.mil>

National Center for Telehealth and Technology <http://t2health.org/>

National Museum of Health and Medicine <http://www.medicalmuseum.mil>

Naval Health Research Center

<http://www.med.navy.mil/sites/nhrc>

Navy and Marine Corps Public Health Center

<http://www.med.navy.mil/sites/nmcphc>

Office of Naval Research

<http://www.med.navy.mil>

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

<http://www.acq.osd.mil/>

U.S. Army Medical Research Acquisition Activity <https://www.usamraa.army.mil/>

U.S. Army Medical Research and Materiel Command <https://mrmc.amedd.army.mil>

U.S. Army Research Laboratory

<http://www.arl.army.mil>

U.S. Department of Defense Blast Injury Research Program

<https://blastinjuryresearch.amedd.army.mil/>

U.S. Naval Research Laboratory

<http://www.nrl.navy.mil>

U.S. Department of Veterans Affairs, Office of Research and Development

<http://www.research.va.gov>

Walter Reed Army Institute of Research

<http://wrair-www.army.mil>

C. Award Information

The SCIRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY09. Since then, 162 Investigator-Initiated Research Award applications have been received, and 32 have been recommended for funding.

The IIRA is intended to support studies that have the potential to make an important contribution to SCI research and/or patient care. Projects are expected to be innovative, address an Area of Encouragement, and impact the health care needs of military Service members, Veterans, and/or their family members and caregivers. All applications must specifically and clearly address the military relevance of the proposed research project. Collaboration with military researchers and clinicians is encouraged.

Research projects may focus on any phase of research from basic through translational, including preclinical studies in animal models or human subjects, as well as correlative studies associated with an existing clinical trial. Observations that drive a research idea may be derived from laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data.

Applications must include preliminary or published data that is relevant to SCI and the proposed research project.

Optional Qualified Collaborator: The FY13 SCIRP strongly encourages multidisciplinary collaborations among academic scientists and clinicians, industry scientists, the military Services, the VA, and other federal Government agencies. Collaborations with early-career investigators in the SCI field are encouraged. ***Although more than one collaborator may participate in the application, only one may be named for this option.***

The Principal Investigator (PI) must submit a Statement of Collaboration that clearly identifies the collaborating investigator and addresses how each of the criteria listed below are met. Additionally, the collaborator must provide a biographical sketch (see Section II.C.3) and a letter of collaboration (see Section II.C.2) describing his/her involvement in the proposed research project. It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and collaborator.

- The collaborator must significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
 - A proposed research project in which the collaborator merely supplies tissue samples or access to patients will not meet the intent and will not be qualified for the higher level of funding.
 - At least a 10% level of effort is required of the collaborator. Contribution of the collaborator should be reflected in the application's budget.
- The collaborator must be in a position with freedom to pursue independent research goals without formal mentorship.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. A clinical trial is defined as a prospective accrual of human subjects in which an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested with 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 human subject of that intervention or interaction. For more information on clinical trials and clinical research, a Human Subject Resource Document is provided on the Congressionally Directed Medical Research Programs (CDMRP) eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/. Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the FY13 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-13-SCIRP-CTA).

Use of Human Subjects and Human Anatomical Substances: All DoD-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US 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 directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Use of Military and VA Populations: If applicable, access to target military or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

Use of Common Data Elements (CDE): The use of the spinal cord injury CDE standards developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at <http://www.commondataelements.ninds.nih.gov/SCI.aspx>, is encouraged. Additionally, the government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission of data to such repositories will be addressed during award negotiations.

The 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 K.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is desirable, but not an eligibility requirement.
- 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.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$450,000** plus indirect costs. If requesting an Optional Qualified Collaborator, the maximum allowable direct costs for the entire period of performance are **\$525,000** plus indirect costs. More cost-effective studies that do not request the full available funding amount are encouraged.
- 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.
- Applications requesting the higher level of funding that do not include an Optional Qualified Collaborator who meets the requirements will have the budget reduced as appropriate.

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.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI(s) to disseminate project results at one DoD sponsored meeting. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials not allowed)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meeting described above

The CDMRP expects to allot approximately \$7.44M of the \$30M FY13 appropriation to fund approximately 10 Investigator-Initiated Research 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 CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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-13-SCIRP-IIRA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.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@cdmrp.org or 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**

FY13 SCIRP Integration Panel (IP) members

(<http://cdmrp.army.mil/scirp/panels/panels13.shtml>) 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@cdmrp.org or 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. 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 application.

Note: *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

The Preproposal Narrative must adhere to the following outline:

- **Background/ Readiness:** State the ideas and reasoning on which the proposed research project is based. Clearly state the type of study proposed (e.g., discovery, development, animal validation, human validation, etc.), and demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research.
- **Hypothesis and Approach:** Concisely state the project's hypothesis and describe the scientific approach. Include appropriate controls, and demonstrate that the work is appropriately powered. State explicitly how the proposed research project is innovative.
- **Impact:** State explicitly how the proposed research project addresses one or more of the FY13 Areas of Encouragement or, if the project does not address an Area of Encouragement, provide justification that the proposed research project addresses an important problem related to SCI.
- **Military Relevance:** Describe how the proposed research project is applicable to the health care needs of military Service members, Veterans, and/or their family members and caregivers.

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 used in the Preproposal Narrative.
- PI Biographical Sketch (two-page limit): Include a biographical sketch for the PI only.

- **Submit Pre-Application – Tab 5**

This tab must be completed for the pre-application to be accepted and processed by 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 DHP and the SCIRP, pre-applications will be screened based on the following criteria:

- **Background/ Readiness:** How well the described research demonstrates solid scientific rationale for SCI research and provides sufficient evidence that the research is ready to move into the proposed stage of research (e.g., discovery, development, animal validation, human validation, etc.).
- **Hypothesis and Approach:** How well a clear hypothesis is stated and supported through scientific rationale and referenced literature, and how well the project's approach will address the hypothesis. To what degree the project is innovative.
- **Impact:** How well the proposed research project addresses one or more of the FY13 Areas of Encouragement or provides justification that the proposed research project addresses an important problem related to SCI. If successful, how the proposed research project will impact clinical practice and improve the treatment of SCI and its consequences.
- **Military Relevance:** How well the proposed research project directly or indirectly benefits military Service members, Veterans, and/or their family members and caregivers.

- **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. 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 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 (<http://www.grants.gov/>).

Grants.gov application package components: For the Investigator-Initiated Research 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 (10-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.

Describe the proposed research project in detail using the outline below. *The Project Narrative must include preliminary or published data that is relevant to SCI and the proposed research project.*

- **Background/Readiness:** Present the ideas and reasoning behind the proposed research project, and clearly demonstrate that there is sufficient scientific evidence to support moving into the proposed stage of research. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective(s) to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If the proposed research project is part of a larger study, present only tasks that the SCIRP award would fund.
- **Research Strategy and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*

- **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 research 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.
 - 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, confirming the laboratory space, equipment, and other resources available for the project.
 - Letters of Collaboration (required for Optional Qualified Collaborator): 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 research project.
 - 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 K, for more information about the CDMRP expectations for making data and research resources publicly available. Include plans for utilizing the spinal cord injury CDE standards developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at <http://www.commondataelements.ninds.nih.gov/SCI.aspx>. Additionally, the government reserves the right to identify repositories for submission of data for

archive. Any costs associated with submission will be addressed during award negotiations.

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

Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not typically have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects. Clarity and completeness within the space limits of the technical abstract are highly important.

- Background/Readiness: Present the ideas and reasoning behind the proposed research project, including sufficient scientific evidence to support moving into the proposed stage of research.
- Objective/Hypothesis: State the objective(s)/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the proposed research project.
- Study Design: Briefly describe the study design, including appropriate controls.
- Impact: Briefly describe how the proposed research project will have an impact on advancing the treatment of SCI and its consequences and, if applicable, how it addresses one or more FY13 SCIRP Areas of Encouragement.
- Innovation: Briefly describe how the proposed research project uses innovation to advance the treatment of SCI and its consequences.
- Military Relevance: Briefly describe the relevance of the proposed research project to the health care needs of military Service members, Veterans, and/or their family members and caregivers.

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

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed research project. Do not duplicate the technical abstract.
 - Describe the ultimate applicability of the research.
 - What types of patients will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of the proposed research project to advancing the field of SCI research?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Beyond the potential benefit of the research for military populations and Veterans, describe the impact of this study on the broad field of SCI research and/or patient care. Address the impact on one or more of the FY13 SCIRP Areas of Encouragement or provide justification that the proposed research project addresses an important problem related to SCI. Include an assessment of the likelihood that a successful outcome of the proposed research project will lead to a practical application in individuals living with SCI. The following are examples of ways in which proposed studies, if successful, may have an impact. *Although not all-inclusive*, these examples are intended to help PIs frame the impact of the proposed research project:
 - Has the potential to advance the field of research in SCI.
 - Has the potential to change the standard of care.
 - Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.” Summarize how the proposed research project is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. *Although not all-inclusive*, the following examples are ways in which the proposed research project may be innovative and are intended to help PIs frame the innovative features:
 - 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 preventing, detecting, diagnosing, or treating SCI.
 - 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 8: Military Relevance Statement (one-page limit):** Upload as “Military.pdf.” Demonstrate how the proposed research project is applicable to the health care needs and quality of life of military Service members, Veterans, and/or their family members and caregivers. If the active duty military, Veteran, or military family member population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population.

- **Attachment 9: Statement of Collaboration (required if requesting an Optional Qualified Collaborator, two-page limit).** Upload as “Collaboration.pdf.” The following components should be addressed:
 - The PI must identify the Optional Qualified Collaborator and address all criteria described above in Section I.C., Award Information.
 - In addition, the Optional Qualified Collaborator must describe how he/she will significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
 - It should be clear that the success of the proposed research project depends on the complementary skills and contributions of both the PI and collaborator.
 - **Attachment 10: Approval for Access to Military and VA Populations (if applicable, one-page limit per site):** Upload as “ApprovalAccess.pdf.” A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies involving active duty military, Veterans, or military family members; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., 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.”
 - Key Personnel Previous/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 [title page](#) 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. 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 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 makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and the SCIRP and the specific intent of the 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 <http://cdmrp.army.mil/about/fundingprocess.shtml>.

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 Criteria

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance:

- **Research Strategy and Feasibility**
 - How well the preliminary data and scientific rationale support the proposed research project and demonstrate sufficient evidence to support moving into the proposed stage of research.
 - How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Impact**
 - How well the proposed research project addresses a critical problem in SCI research or patient care.
 - How well the proposed research project will make original and important contributions toward the goal of advancing SCI research or patient care.
 - How well the proposed research project addresses one or more of the FY13 Areas of Encouragement or provides justification that the proposed research project addresses an important problem related to SCI.
- **Innovation**
 - To what degree 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.
 - How well the proposed research project represents more than an incremental advance upon published data.
- **Personnel**
 - To what extent the background and expertise of the PI and other key personnel are appropriate to accomplish the proposed research project.
 - To what extent the levels of effort by the PI and other key personnel are appropriate to ensure the success of this project.
 - How well the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed research project.
 - Optional Qualified Collaborator (if applicable)
 - Whether the collaborator's experience, expertise, and involvement represent a significant contribution to the proposed research project such that it could not be accomplished without his/her involvement.
 - Whether the collaborator meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration.

The following unscored criteria will also contribute to the overall evaluation of the application:

- **Environment**

- To what extent the scientific environment is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- To what extent the quality and level of institutional support are appropriate for the proposed research project.

- **Budget**

- Whether the budget is appropriate for the proposed research project 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 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 FY13 SCIRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Military relevance
- Program portfolio composition, including the FY13 Areas of Encouragement
- Programmatic relevance
- Relative impact and innovation

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 notification of the funding recommendation. 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 the CDMRP eReceipt System 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:

- 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.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Preproposal Narrative and the Project 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 FY13 SCIRP 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 FY13 SCIRP IP members can be found at <http://cdmrp.army.mil/scirp/panels/panels13.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.
- 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 project 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 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, 2014. 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: 301-682-5507

Email: help@cdmrp.org

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: 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	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Military Relevance Statement (Military.pdf) as Attachment 8.	
	Upload Statement of Collaboration (Collaboration.pdf), if applicable, as Attachment 9 (if applicable).	
	Upload Approval for Access to Military and VA Populations (ApprovalAccess.pdf), if applicable, as Attachment 10.	
	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 (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.	