

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-14-SCIRP-IIRA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 10, 2014
- **Invitation to Submit an Application:** August 2014
- **Application Submission Deadline:** 11:59 p.m. ET, October 30, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, November 4, 2014
- **Peer Review:** December 2014
- **Programmatic Review:** February 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) 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 provide support for research of exceptional scientific merit that has 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 FY13 totaled \$97.85 million (M). The FY14 appropriation is \$30M.

The FY14 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 three Areas of Encouragement for the FY14 program. In addition, applications that address other relevant research areas may be considered.

B. FY14 SCIRP Areas of Encouragement

The FY14 SCIRP encourages applications that specifically address one or more of the following areas:

1. Pre-hospital, en route care, and early hospital management of SCI
2. Development, validation, and timing of promising interventions to address consequences of SCI and to improve recovery, including, but not limited to:
 - Ambulatory and non-ambulatory clinical benefits of exoskeletal systems
 - Bladder, bowel, and autonomic dysfunction
 - Cardiometabolic dysfunction
 - Deep vein thrombosis
 - Functional deficits
 - Neuropathic pain and sensory dysfunction
 - Pressure ulcers
 - Respiratory dysfunction
 - Sexual dysfunction

3. Identification and validation of best practices in SCI care including but not limited to:
- Critical care interventions
 - Musculoskeletal health
 - Rehabilitation interventions
 - Surgical interventions

Projects focused on other research areas relevant to SCI may be submitted for consideration, provided that sufficient justification is included in the application.

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 FY14 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 Diseases 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/index.cfm>

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** mechanism was first offered in FY09. Since then, 211 Investigator-Initiated Research Award applications have been received, and 47 have been recommended for funding.

The SCIRP **Investigator-Initiated Research Award** is intended to support studies that have the potential to make an important contribution to SCI research and/or patient care.

Important aspects of this award mechanism include:

- **Impact:** Applications should articulate both the short- and long-term impact of the proposed research. Projects should address an FY14 Area of Encouragement or other research areas relevant to SCI.
- **Military Relevance:** Projects should impact spinal cord injured military Service Members, Veterans, and/or their family members, as well as their caregivers. All applications must specifically and clearly address the military relevance of the proposed research project. Collaboration with military researchers and clinicians is encouraged.
- **Preliminary Data:** 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 and/or published data that is relevant to SCI and the proposed research project.

Investigator-Initiated Research Award applications 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. ***Clinical trials are not allowed under this funding opportunity.***

Optional Qualified Collaborator: The FY14 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, Research & Related Senior/Key Person Profile](#)) and a letter of collaboration (see [Section II.C.2, Attachment 8, Statement of Collaboration](#)) 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.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to submit [Attachment 10, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. 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>.

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 at <https://ebrap.org/eBRAP/public/Program>

PIs wishing to apply for funding for a clinical trial should utilize the FY14 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-14-SCIRP-CTA).

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.

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 (CDEs): Use of the spinal cord injury CDEs 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 for all human subjects research. 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 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.

D. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- 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.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$500,000** plus indirect costs. If requesting an Optional Qualified Collaborator, the maximum allowable direct costs for the entire period of performance are **\$750,000** 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.
- The Government reserves the right to fund an application at the lower funding level if the Optional Qualified Collaborator does not meet the eligibility criteria or intent of the mechanism.

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:

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

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 \$5.2M of the \$30M FY14 SCIRP appropriation to fund approximately 6 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 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](#)).

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-SCIRP-IIRA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the 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.

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 SCIRP 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.

- **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 (two-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:

- **Background/Research Problem:** State the ideas and reasoning on which the proposed research project is based. Clearly demonstrate that there is sufficient rationale for the proposed research.
- **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the scientific approach. Include a description of controls, as appropriate, and demonstrate that the work is appropriately powered.
- **Impact:** Describe the impact of this study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY14 Areas of Encouragement or other relevant research area(s).
- **Military Relevance:** Describe how the proposed research project is applicable to spinal cord injured military Service Members, Veterans, and/or their family members, as well as their caregivers.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* 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.
 - 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.

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/Research Problem:** How well the background and scientific rationale demonstrate sufficient evidence to support the proposed research project.

- **Specific Aims and Study Design:** How well the specific aims are stated and supported through scientific rationale and referenced literature and how well the proposed research project’s approach will address these aims.
- **Impact:** How well the proposed research project addresses one or more FY14 Areas of Encouragement or other relevant research area(s) and will make important contributions towards the goal of advancing SCI research, patient care, and/or improving quality of life.
- **Military Relevance:** How well the proposed research project directly or indirectly benefits spinal cord injured military Service Members, Veterans, and/or their family members, as well as their 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 Forms

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/>).

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).***

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 project in detail using the outline below. ***The Project Narrative must include preliminary and/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 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.
 - **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility. Describe the statistical plan as appropriate for the proposed research. 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. ***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 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 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.
 - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- 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. Include plans for use of the spinal cord injury CDEs 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 the proposed stage of research.
- **Hypothesis or Objective:** State the hypothesis/objective to be tested. Provide evidence or rationale that supports the hypothesis/objective.
- **Specific Aims:** State the specific aims of the proposed research project.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Briefly describe the impact of this study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY14 Areas of Encouragement or other relevant research area(s).
- **Military Relevance:** Briefly describe the relevance of the proposed research project to spinal cord injured military Service Members, Veterans, and/or their family members, as well as their 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.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 Research Award mechanism, use the SOW format example titled “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Describe the short- and long-term impact of this study on the field of SCI research, patient care, and/or quality of life, including 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. Address the impact on one or more of the FY14 SCIRP Areas of Encouragement or other relevant research area(s) identified by the PI. If the proposed research project does not address one of the FY14 Areas of Encouragement, provide justification that it addresses an important problem related to 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: 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 spinal cord injured military Service Members, Veterans, and/or their family members, as well as their 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 8: 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 9: 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).
- **Attachment 10: Animal Research Plan (if applicable, 3-page limit):** Upload as “AnimalResPlan.pdf”

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

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.”
- 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.4., 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.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.

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 DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the 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 Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and SCIRP and to 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 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 listed in decreasing order of importance:

- **Study Design 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, specific aims, research strategy, methods, and analyses are developed and integrated into the project.
 - To what extent the proposed research project is feasible as described.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.

- How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- **Impact**
 - How well the proposed research project will make important contributions toward the goal of advancing SCI research and/or patient care.
 - How well the proposed research project addresses a critical problem in SCI research, patient care, and/or quality of life.
 - If the proposed research project does not address one of the FY14 Areas of Encouragement, how well the PI provides justification that it addresses an important problem related to SCI.
- **Personnel**
 - To what extent the background and expertise of the key personnel are appropriate to accomplish the proposed research project.
 - To what extent the levels of effort by the 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.

In addition, 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.
 - If applicable, to what degree the intellectual and material property plan is appropriate.

- **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 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 SCIRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Military relevance
 - 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 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 specific limits will be removed prior to review for all documents other than the Preproposal Narrative and 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 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 documentation. A list of the FY14 SCIRP IP members can be found at <http://cdmrp.army.mil/scirp/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 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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this announcement will be governed by the award terms and conditions, which conform to DoD's implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

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. Quarterly technical progress reports will be required.

E. Award Transfers

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	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."	
	Military Relevance Statement: Upload as Attachment 7 with file name "Military.pdf."	
	Statement of Collaboration: Upload as Attachment 8 with file name "Collaboration.pdf," if applicable.	
	Approval for Access to Military and VA Populations: Upload as Attachment 9 with file name "ApprovalAccess.pdf," if applicable.	
	Animal Research Plan: Upload as Attachment 10 with file name "AnimalResPlan.pdf," if applicable.	
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 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.	