

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Qualitative Research Award

Funding Opportunity Number: W81XWH-15-SCIRP-QRA

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 13, 2015
- **Invitation to Submit an Application:** August 2015
- **Application Submission Deadline:** 11:59 p.m. ET, October 14, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, October 19, 2015
- **Peer Review:** December 2015
- **Programmatic Review:** February 2016

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 2015 (FY15) Spinal Cord Injury Research Program (SCIRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). 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 FY14 totaled \$127.85 million (M). The FY15 appropriation is \$30M.

The FY15 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.

B. FY15 SCIRP Areas of Encouragement

The FY15 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:
 - Bladder, bowel, and autonomic dysfunction
 - Cardiometabolic dysfunction
 - 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
 - Interventions for musculoskeletal health
 - Rehabilitation interventions
 - Surgical interventions
 - Psychosocial and behavioral interventions in military/Veteran populations

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 FY15 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 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

<https://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 **Qualitative Research Award** mechanism was first offered in FY10. Since then, 32 Qualitative Research Award applications have been received, and 10 have been recommended for funding.

The intent of the **Qualitative Research Award** is to support *qualitative research studies* that will help researchers and clinicians better understand the experiences of individuals with SCI and thereby identify the most effective paths for adjusting to disability and/or improving overall quality of life, health, and functional status after SCI. This mechanism is specifically focused on military and Veteran populations in the years after SCI, examining the issues, barriers, and promoters of success for Service members during the transition from initial injury and acute care through rehabilitation and community reintegration; therefore, collaboration with military and VA researchers and clinicians is encouraged. Factors that may affect the rehabilitation and reintegration of spinal cord-injured Service members include, but are not limited to, age, gender, ethnicity, family members/caregivers, psychological health, severity of injury, type of medical care (e.g., civilian, VA or military facility), and co-morbid conditions.

Qualitative research is a form of social inquiry that focuses on understanding how people interpret and make sense of their experiences and the world in which they live (i.e., seeks to understand the human experience). Observations that drive a research idea may be derived from basic discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. *Appropriate qualitative research topics include, but are not limited to, the explorative, descriptive, predictive, or explanatory study of the:*

- Barriers preventing Service members with SCI from returning to active duty, returning home, or reintegrating into the community.
- Impact of personal factors and co-morbid medical conditions that influence or mediate a patient's health or quality of life during hospitalization following SCI.
- Impact of cultural values and beliefs on the success of rehabilitation and community reintegration.
- Impact of medical care decisions (e.g., choice of civilian, VA, or military facility, treatment type, etc.) on the success of rehabilitation and community reintegration.
- Impact of care provision on the spouse and/or families of the spinal cord injured to include career issues, emotional stress, physical strain and injury, intimacy, etc.
- Factors and strategies for improving psychosocial adjustment and adjustment to disability for people with SCI and their family and friends; the influence of family and friends' involvement in the individual's life experiences on quality of life and health outcomes.
- Impact of perceived access to care and care coordination on effectiveness of care delivery and success of rehabilitation.
- Impact of aging and age-related changes in social support that may limit one's ability to become more fully integrated into society.

Preliminary and/or published data relevant to SCI and the proposed research project are encouraged, but not required.

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 whereby 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>

Principal Investigators (PIs) wishing to apply for funding for a clinical trial should utilize the FY15 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-15-SCIRP-CTA).

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All 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 5, and the Human Subject Resource Document available on the eBRAP “[Funding Opportunities & Forms](#)” web page 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 CDMRP intends that information, 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 3, 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, nonprofit, 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 anticipated direct costs budgeted for the entire period of performance will not exceed **\$500,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$500,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- 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.

Refer to the General Application Instructions, Section II.C.5., 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.5. of the General Application Instructions.*

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to disseminate project results at one DoD-sponsored meeting. Costs associated with travel to this meeting 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)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs 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 Section II.A. 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 may be executed through a direct fund transfer (e.g., 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.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately \$3.2M of the \$30M FY15 SCIRP appropriation to fund approximately 4 Qualitative 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 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.

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/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

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.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-SCIRP-QRA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

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 may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA 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**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - FY15 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.
- **Conflicts of Interest (COIs) – Tab 4**
 - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).
- **Pre-Application Files – Tab 5**

Note: 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, and how the project meets the definition of qualitative research as described in this PA.
- **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 FY15 SCIRP 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 PDF 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 (five-page limit): Include a biographical sketch for the PI only.
- **Submit Pre-Application – Tab 6**
 - 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 FY15 Areas of Encouragement or other relevant research area(s) and will make important contributions toward 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. Full Application Submission Content

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

Grants.gov application package components: For the Qualitative 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**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition,

Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **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 may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

Preliminary and/or published data relevant to SCI and the proposed research project are encouraged, but not required.

- **Background:** Identify the major research problem to be addressed. Describe the ideas and reasoning on which the proposed research project is based. Clearly demonstrate that there is sufficient scientific evidence to support the proposed stage of research. Cite relevant literature, and describe previous experience most pertinent to this project, including data from pilot studies, if applicable.
- **Research Problem:** Discuss the research problem and why it is important. Explain why a qualitative, rather than a quantitative, approach is more appropriate to address the research problem.
- **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:** Describe the specific theoretical perspective of qualitative research on which the study is based, as well as the overall study design. Address potential problem areas and present alternative methods and approaches. The following important components of qualitative study design and methods should be addressed:
 - **Data collection:** Describe the proposed methods for sampling, collection, interviewing, and recording/documentation, in sufficient detail for analysis. Discuss how these methods are systematic and rigorous, and appropriate to address the qualitative research questions. If methods will evolve from and be informed by the research itself, describe how the rigor of these processes will be maintained. Describe and articulate specific benchmarks to ensure the research is progressing in an efficient, timely, and thorough manner.
 - **Subject recruitment:** Include a detailed plan for the recruitment of subjects or the acquisition of samples, and demonstrate access to the targeted population.
 - **Data analysis:** Describe the analysis plan for the research proposed, as well as the plan for developing the rules for coding, if applicable, and discuss

how these methods are appropriate to the qualitative approach. Describe how the analyses are systematic, rigorous, and appropriate to address the qualitative research questions.

- **Credibility:** Describe how the plan for documenting procedures, interviewing, developing the rules for coding, making decisions, and rationale for decisions made supports consistency, dependability, and duplicability of results. Describe the steps taken to control biases and preconceptions. Explain how the project's proposed design and analyses will yield trustworthy, credible, and confirmable results.
- **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 will result in the removal of those items or may result in 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: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
 - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- Intellectual Property
 - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. 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 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available. Include plans for utilizing 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.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers. The technical abstract should provide an appropriate description of the project’s key aspects; clarity and completeness within the space limits of the technical abstract are highly important.

- Background: Present the ideas and reasoning behind the proposed research project, including sufficient scientific evidence to support the proposed stage of research.
- Research Problem: Discuss the research problem and why it is important. Explain why a qualitative approach, rather than a quantitative approach, is more appropriate to address the research problem.

- Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design and type of analyses.
 - 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 FY15 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.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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 proposal. Do not duplicate the technical abstract.
 - Describe the ultimate applicability of the research. What types of individuals will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected timeline for achieving the desired outcome?
 - If the research is too basic for clinical applicability, describe the interim outcomes.
 - Describe the likely contributions of the proposed research project to improving our understanding of individuals with SCI and/or identifying the most effective paths for adjusting to disability and/or improving overall quality of life, health, and functional status after SCI.
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP [“Funding Opportunities & Forms”](#) web page. For the Qualitative Research Award mechanism, use the SOW format example titled “SOW for Clinical Research.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.
 - **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 FY15 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 FY15 Areas of Encouragement, provide justification that it addresses an important problem related to SCI.

- **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 active duty military, Veteran, or military family member populations will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research project, 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: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit): Upload as “Surveys.pdf.”** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe the PI’s prior experience using the proposed data collection tools and the psychometrics previously generated from their use.
 - **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- or VA-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).
 - **Attachment 10: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “[Funding Opportunities & Forms](#)” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
- **PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf.”** The suggested biographical sketch format is available on the “[Funding Opportunities & Forms](#)” web page in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (five-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.5., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
 5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.
 6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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, Section II.A., for information on Grants.gov registration 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 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 DHA RDA Directorate and 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 highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

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

B. Application Review Process

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

- **Research Problem**
 - How well the major research problem is identified and the relevance of the proposed research project to SCI is justified.

- How well the selection of a qualitative approach, rather than a quantitative approach, is justified.
 - How well the research questions or topics are described and appropriate to address the research problem.
 - How clearly the specific theoretical basis for the study is stated, and is shown to drive the framing of the research question(s).
- **Study Design**
 - How appropriate the proposed design of the study, the sampling technique, and the data collection and recording method(s) are to address the research question and to yield trustworthy, credible, robust, and confirmable results.
 - If methods will evolve from and be informed by the research itself, such as the use of snowball sampling techniques, how well the PI describes the method(s) used to maintain the rigor of these processes.
 - How well the PI demonstrates access to, and ability to recruit, the appropriate population(s) (military, Veteran, and/or family/caregiver).
 - How well the documentation of procedures, decisions, and rationale for decisions and conclusions supports consistency, dependability, and duplicability of results, and prevents biases and preconceptions.
 - How consistent the data analysis plan remains with the research problem and theoretical basis of the study.
 - How well the project obtains ongoing feedback from the participants, especially regarding interpretation of data and study conclusions.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How well the PI has described and articulated specific benchmarks to ensure the research is progressing in an efficient, timely, and thorough manner.
 - **Impact**
 - If successful, how the study will improve our understanding of individuals with SCI and/or identify the most effective paths for adjusting to disability and/or improving overall quality of life, health, and functional status after SCI.
 - How well the proposed research project addresses a critical problem in SCI research, patient care, and/or quality of life.
 - How well the proposed research addresses one of the FY15 Areas of Encouragement. If the proposed research project does not address one of the FY15 Areas of Encouragement, how well the PI provides justification that it addresses an important problem related to SCI.

- **Personnel**

- How appropriate the relevant education, training, and experience of the key personnel are to accomplish the proposed research project.
- How appropriate the levels of effort are by the key personnel to ensure success of this project.
- How well the PI's record of accomplishment, particularly with the use of qualitative methods, demonstrates his/her ability to accomplish the proposed research project.

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 extent 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 and select the application(s) that, individually or collectively, will best achieve the program objectives, 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 FY15 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.

C. Withdrawal

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

- A FY15 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 FY15 SCIRP IP members can be found at <http://cdmrp.army.mil/scirp/panels/panels15>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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.
- If a clinical trial is proposed, the application will be withdrawn.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

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, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the 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 the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, 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 Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Military Relevance Statement: Upload as Attachment 7 with file name "Military.pdf."	
	8	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 8 with file name "Surveys.pdf," if applicable.	
	9	Approval for Access to Military and VA Populations: Upload as Attachment 9 with file name "ApprovalAccess.pdf," if applicable.	
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.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.	