

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Translational Research Award

Funding Opportunity Number: W81XWH-16-SCIRP-TRA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 21, 2016
- **Invitation to Submit an Application:** July 2016
- **Application Submission Deadline:** 11:59 p.m. ET, September 21, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, September 26, 2016
- **Peer Review:** November 2016
- **Programmatic Review:** January 2017

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 2016 (FY16) 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 (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing 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 spinal cord injury (SCI). Appropriations for the SCIRP from FY09 through FY15 totaled \$157.85 million (M). The FY16 appropriation is \$30M.

The FY16 SCIRP challenges the scientific community to design 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. FY16 SCIRP Areas of Encouragement

The FY16 SCIRP encourages applications that specifically address one or more of the following areas:

- Pre-hospital, en route care, and early hospital management of SCI
- 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
- 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 the mission of the SCIRP 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 are encouraged. The following websites may be useful in identifying ongoing areas of DoD research interest within the FY16 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
<http://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 Translational Research Award (TRA) mechanism was first offered in FY12. Since then, 49 TRA applications have been received, and 11 have been recommended for funding.

The SCIRP TRA is intended to support translational research that will accelerate the movement of promising ideas in SCI research into clinical applications. Although not all-inclusive, some examples include demonstration studies of pharmaceuticals and medical devices in preclinical systems, and/or clinical research on therapeutics, devices, or practice using human tissues or resources.

The ultimate goal of translational research is to move an observation forward into clinical application and accelerate the clinical introduction of healthcare products, technologies or practice guidelines. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data. However, Principal Investigators (PIs) should not view translational research as a one-way continuum from bench to bedside. The research plan should involve a reciprocal flow of ideas and information between basic and clinical science. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at <http://clincancerres.aacrjournals.org/content/14/18/5664.full> (a report of the National Cancer Institute Translational Research Working Group).

New for FY16: *The SCIRP TRA may include a pilot clinical trial where limited clinical testing of a novel intervention or device is necessary to inform the next step in the continuum of translational research. Such pilot clinical trial studies should be small, represent only a portion of the proposed Statement of Work, and be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement. The F16 TRA may also support correlative studies that are associated with an ongoing or completed clinical trial and projects that optimize the design of future clinical trials. Research projects may also include preclinical studies in animal models, human subjects, and human anatomical substances. Applications that do include a pilot clinical trial as part of the proposed research will have additional submission requirements and review criteria.*

Investigators seeking support for a study consisting only of a clinical trial should utilize the FY16 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-16-SCIRP-CTA).

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

Optional Qualified Collaborator (OQC): The FY16 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 and between investigators at different institutions are highly encouraged. To meet this goal, the FY16 SCIRP TRA offers the Optional Qualified Collaborator Option and allows for higher maximum direct costs for qualifying applications. ***Although more than one collaborator may participate in the application, only one OQC may be named for this option.***

The PI must submit a Statement of Collaboration that clearly identifies the OQC and addresses how each of the criteria listed below are met. Additionally, the OQC 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 9: 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 OQC.
- The application should explain how the inclusion of the OQC addresses some or all of the program's goals of promoting multidisciplinary and multi-institutional collaborations among academic scientists and clinicians, industry scientists, early-career investigators, the military Services, the VA, and other federal government agencies.
- At least a 10% level of effort is required of the OQC, and this should be reflected in the budget.
- A proposed research project in which the OQC merely supplies tissue samples or access to patients will not meet the intent of the award mechanism and will not qualify for the higher level of funding.
- The OQC must be in a position that offers freedom to pursue independent research goals without formal mentorship; for example, a PI/OQC pair consisting of a mentor and a postdoctoral fellow does not meet the intent of the mechanism.

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.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." *Allow at least 2 to 3 months for*

ACURO regulatory review and approval processes for animal studies. Refer to General Application Instructions, Appendix 6, for additional information.

In addition to research involving human subjects and human anatomical substances, the FY16 SCIRP TRA also supports projects that include a limited pilot clinical trial. 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 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>

Funded clinical trials are required to file the study in the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov. Refer to the General Application Instructions, Appendix 6, Section C, for further details.

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 USAMRMC ORP, Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing and demonstrating such access. If possible, access to target military and/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 military Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see [Section II.C., Full Application Submission Content, Attachment 2, Supporting Documentation](#)). If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources. Note that access to a Veteran population for clinical studies may only be obtained by (1) collaboration with a VA investigator where the VA investigator has a substantial role in the research or (2) advertising to the general public.

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 strongly 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 4, Section K.

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 Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.*
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years
- Application submissions with a single Principal Investigator:
 - The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1,250,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1,250,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

- Application submissions with an Optional Qualified Collaborator:
 - If requesting an **Optional Qualified Collaborator**, the anticipated direct costs budgeted for the entire period of performance will not exceed **\$1,500,000**. Collaborating organizations should budget associated indirect costs in accordance with each 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.
- Any application that requests the higher level of funding and that does not include an **Optional Qualified Collaborator** will have its budget reduced as appropriate.
- 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.

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
- Research-related subject costs
- Clinical research costs
- Clinical trials costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year in addition to the required DoD-sponsored meeting described above.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal***

agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.

The CDMRP expects to allot approximately \$6M of the \$30M FY16 SCIRP appropriation to fund approximately 3 Translational 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(s).

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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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.

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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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. Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

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-16-SCIRP-TRA 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.

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):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - 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 SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down 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.
- **Tab 3 – Collaborators and Key Personnel**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.

- FY16 SCIRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel 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.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- **Tab 4 – Conflicts of Interest (COIs)**
 - 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). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.
- **Tab 5 – Pre-Application Files**

Note: Upload documents 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) 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. If applicable, clearly identify which aims describe the pilot clinical trial and how the outcome of the pilot clinical trial will optimize the design of future clinical trials or inform the next step in the continuum of translational research.
- **Translational Potential:** Describe how the proposed research will allow for a reciprocal flow of ideas between basic and clinical science. Explain how the

project will accelerate promising laboratory research findings into clinical applications.

- **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 FY16 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 and 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.
- Key Personnel Biographical Sketches (five-page limit per individual): Include a biographical sketch for the PI and Optional Qualified Collaborator (if applicable) only.

- **Tab 6 – Submit Pre-Application**

- 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. If applicable, how well the outcome of the pilot clinical trial will optimize the design of future clinical trials or inform the next step in the continuum of translational research.
- **Translational Potential:** How well the project will accelerate promising, well-founded research findings into clinical applications.
- **Impact:** How well the proposed research project addresses one or more FY16 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 and caregivers.

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

Following the pre-application screening, PI 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. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 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*.

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

Grants.gov application package components: For the Translational 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. **SF424 (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 (12-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 *one* of the two outlines below, depending on whether or not a pilot clinical trial is included in the proposed research. ***The Project Narrative must include preliminary or published data that is relevant to SCI and the proposed research project.***

Outline for projects without a pilot clinical trial:

- **Background/Readiness:** Present the ideas and scientific rationale behind the proposed research project, and clearly demonstrate that there is sufficient evidence, including preliminary data, 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 this SCIRP award would fund.
- **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of their 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 or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data.

Outline for projects that do include a pilot clinical trial: (Note: the Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.)

- **Background/Readiness:** Present the ideas and scientific rationale behind the proposed research project, and clearly demonstrate that there is sufficient evidence, including preliminary data, 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. Clearly identify which aims comprise the pilot clinical trial portion of the research.
- **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Describe the statistical plan as appropriate for the proposed research. Address potential problem areas and present alternative methods and approaches. For human subjects or human anatomical samples or data, include a detailed plan for the recruitment of subjects or the acquisition of samples or data.
- **Pilot Clinical Trial:** Provide plans for initiating and conducting the pilot clinical trial during the course of this award. Further details of the pilot clinical trial will be required in Attachment 11.
 - Describe the type of clinical trial to be performed and outline the proposed methodology in sufficient detail to show a clear course of action. Briefly, identify the intervention to be tested, projected outcomes, study variables, controls, and endpoints. Describe potential challenges and alternative strategies where appropriate.
 - Describe how the pilot clinical trial is ***clearly linked*** to the laboratory research studies that will also be performed through this award.
 - Include a description of how the proposed work is responsive to the intent of the FY16 SCIRP TRA in including only exploratory clinical testing of a novel intervention or device necessary to inform the next step in the continuum of translational research. Describe how the pilot clinical study is small, represents only a portion of the proposed Statement of Work, and will be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement.

- If applicable, describe how the proposed work supports a correlative study that is associated with an ongoing or completed clinical trial, or supports a project that is intended to optimize the design of future clinical trials.
 - As appropriate, outline a regulatory strategy for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other FDA approvals).
- **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 Patents: 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 (required for applications including an OQC): Provide a signed letter from the OQC (if applicable) and each collaborating individual or organization that demonstrate that the PI has the support or resources necessary for the proposed work.
 - Letter(s) of Support for Use of Military and VA Populations or Resources (if applicable): If the proposed research plan involves access to active duty military

and/or VA patient populations or resources, include a letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

- Intellectual Property
 - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
 - 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 K, 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.
- Quad Chart: Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP “Funding Opportunities & Forms” web page at <https://ebrap.org/eBRAP/public/Program>

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** 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 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/Readiness: Present the ideas and scientific rationale behind the proposed research project, including sufficient evidence to support the proposed stage of research.
- Hypothesis or Objective: State the hypothesis(es)/objective(s) to be tested. Provide evidence or rationale that supports the hypothesis(es)/objective(s).
- Specific Aims: State the specific aims of the proposed research project. Identify which aims relate to a pilot clinical trial (if applicable).
- 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 FY16 Areas of Encouragement or other relevant research area(s).
- Translation: Briefly describe how the proposed research project will translate promising, well-founded research findings into clinical applications for SCI. If a pilot clinical trial is included, explain how this is necessary to inform the next step on the translational spectrum.
- Military Relevance: Briefly describe the relevance of the proposed research project to spinal cord injured military Service members, Veterans, and/or their family members and caregivers.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** 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 community. Do not duplicate the Technical Abstract.

- Describe the objectives and rationale for the proposed research in a manner that will be readily understood by readers without a background in science or medicine.
 - Describe the ultimate applicability of the research.

- What persons with SCI will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - If the proposed research includes a pilot clinical trial, how this will advance work along the translational spectrum?
 - What is the projected time it may take to achieve a person-related outcome?
 - If the research is too basic for immediate clinical applicability, describe the interim outcomes.
 - What are the likely contributions of the proposed research project to advancing the field of SCI research, patient care and/or quality of life?
- **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 (<https://ebrap.org/eBRAP/public/Program.htm>). For the Translational Research Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., 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 clinical application in individuals living with SCI. Address the impact on one or more of the [FY16 SCIRP Areas of Encouragement](#) or other research area(s) identified by the PI. If the proposed research project does not address one of the FY16 Areas of Encouragement, provide justification that it addresses an important problem related to SCI.
 - **Attachment 7: Translation Statement (one-page limit): Upload as “Translation.pdf.”** Describe the translational aspect of the proposed research. The ultimate goal of translational research is to move an observation forward into clinical application and accelerate the introduction of healthcare products, technologies or practice guidelines for clinical use. State explicitly how the proposed research project is translational in nature and describe how it will help to move an observation forward into clinical practice and allow for the reciprocal transfer of ideas between basic and clinical science. If the proposed research includes a pilot clinical trial, explain how the preclinical and pilot clinical trial aims are connected and necessary to advance the research towards clinical implementation. Include a clear description of the next step in the translation of the results of this research after the end of the project.
 - **Attachment 8: Military Relevance Statement (one-page limit): Upload as “Military.pdf.”** Demonstrate how the proposed research project is applicable to the healthcare needs and quality of life of spinal cord injured military Service

members, Veterans, and/or their family members and caregivers. If 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 relevant military population.

- **Attachment 9: Statement of Collaboration (required if requesting an Optional Qualified Collaborator, two-page limit). Upload as “Collaboration.pdf.”** The following components should be addressed:
 - Provide the name of the OQC and address all eligibility criteria described above in [Section I.C., Award Information](#).
 - Describe how the OQC will significantly contribute to the proposed research project such that it could not be accomplished without his/her involvement.
 - Clearly explain how success of the proposed research project depends on the complementary skills and contributions of both the PI and OQC.

- **Attachment 10: Animal Research Plan (if applicable, 3-page limit): Upload as “AnimalResPlan.pdf.”** If 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 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).

- **Attachment 11: Pilot Clinical Trial Plan (if applicable, 3-page limit): Upload as “ClinTrialPlan.pdf.”**
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Identify the intervention to be tested and describe the projected outcomes. Demonstrate the availability of the intervention, including IDE/IND status (or other FDA approvals), as applicable.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of and access to the appropriate patient population(s), as well as the ability to accrue sufficient subjects for the clinical trial.
 - As appropriate for the proposed pilot clinical trial, describe the statistical model and data analysis plan with respect to the study objectives. If applicable, include power analysis calculations.
 - **Attachment 12: 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 (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **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 (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
- Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **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.4., 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.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.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 12, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. 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 or 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.*** 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 submission rejection.

F. Other Submission Requirements

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

All extramural 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 consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and SCIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).* 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 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:

- **Translational Potential**

- How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for individuals living with SCI.
- How well the project allows for the reciprocal transfer of ideas between basic and clinical science, as applicable.

- **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(es) or objective(s), 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.
- If applicable, 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 proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- How well the application demonstrates utilization of the spinal cord injury CDEs, as applicable.

- **Clinical Strategy (for applications including a pilot clinical trial):**

- How well the proposed pilot clinical trial meets the requirements of the FY16 SCIRP TRA with regard to being small, representing only a portion of the proposed Statement of Work, and being utilized to establish feasibility of a potential approach or aiding in device, intervention or future clinical trial design refinement.
- How clearly linked the pilot clinical trial is to the laboratory research studies that will also be performed through this award.
- How the clinical trial portion of the application is designed with appropriate study variables, controls, and endpoints.
- How the application demonstrates the ability to accrue a sufficient number of subjects.

- How the application demonstrates that availability of and access to the intervention to be tested.
- How well the regulatory strategy is outlined, including, if applicable, how appropriate is the plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other Food and Drug Administration [FDA] approvals).
- **Impact**
 - How effective the proposed research project will be in making 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.
 - How well the proposed research addresses one or more of the FY16 SCIRP Areas of Encouragement. If the proposed research project does not address one of the FY16 SCIRP Areas of Encouragement, how well the PI provides justification that it addresses an important problem related to SCI.
- **Personnel**
 - To what extent the backgrounds and expertise of the PI and key personnel are appropriate to accomplish the proposed research project.
 - To what extent the levels of effort by the PI and key personnel are appropriate to ensure the success of this project.
 - How well the PI's record of accomplishments demonstrates his/her ability to accomplish the proposed research project.
 - Optional Qualified Collaborator (if applicable):
 - Whether the OQC meets the criteria for an Optional Qualified Collaborator as verified by the Statement of Collaboration.
 - To what extent the OQC's experience, expertise, and involvement represent a significant intellectual contribution to the proposed research project such that it could not be accomplished without his/her involvement.

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 direct maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.
 - Whether the budget is appropriate for the proposed research.
 - **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 criteria are used by programmatic reviewers:
- a. **Ratings and evaluations of the peer reviewers**
 - b. **Relevance to the mission of the DHP and FY16 SCIRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Military relevance
 - Program portfolio composition
 - 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:

- An FY16 SCIRP Programmatic Panel 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 FY16 SCIRP Programmatic Panel members can be found at <http://cdmrp.army.mil/scirp/panels/panels16>.*
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the

identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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, 2017. Refer to the General Application Instructions, Appendix 4, 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 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 H, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations may be requested.

E. Award Transfers

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer. An Organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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

C. 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; International 1-606-545-5035

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
SF424 (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	Translation Statement: Upload as Attachment 7 with file name "Translation.pdf."	
	8	Military Relevance Statement: Upload as Attachment 8 with file name "Military.pdf."	
	9	Statement of Collaboration: Upload as Attachment 9 with file name "Collaboration.pdf," if applicable.	
	10	Animal Research Plan: Upload as Attachment 10 with file name "AnimalResPlan.pdf," if applicable.	
	11	Pilot Clinical Trial Plan: Upload as Attachment 11 with file name "ClinTrialPlan.pdf," if applicable.	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 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.	