

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Spinal Cord Injury Research Program**

**Clinical Research Development Award**

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-17-SCIRP-CRDA**

**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), August 8, 2017
- **Invitation to Submit an Application:** September 2017
- **Application Submission Deadline:** 11:59 p.m. ET, November 29, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, December 4, 2017
- **Peer Review:** January 2018
- **Programmatic Review:** March 2018

*This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## **II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY**

### **II.A. Program Description**

Applications to the Fiscal Year 2017 (FY17) Spinal Cord Injury Research Program (SCIRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 FY16 totaled \$187.85 million (M). The FY17 appropriation is \$30M.

The FY17 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.

#### **II.A.1. FY17 SCIRP Areas of Encouragement**

The FY17 SCIRP encourages applications that specifically address one or more of the following areas:

- Pre-hospital, prolonged field care, 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
  - Depression in the early period after injury

- Identification and validation of best practices in SCI care throughout the lifetime of the individual, including, but not limited to:
  - Critical care interventions
  - Interventions for musculoskeletal health
  - Rehabilitation interventions, including activity-based, physical, or occupational therapies
  - 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 FY17 SCIRP Areas of Encouragement.

Air Force Research Laboratory  
<http://www.wpafb.af.mil/afrl>

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

Center for Neuroscience and  
 Regenerative Medicine  
<http://www.usuhs.mil/cnrm/>

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

Clinical and Rehabilitative Medicine  
 Research Program  
<https://crmrp.amedd.army.mil>

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

Combat Casualty Care Research Program  
<https://ccc.amedd.army.mil>

Naval Health Research Center  
<http://www.med.navy.mil/sites/nhrc>

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

Navy and Marine Corps Public Health  
 Center <http://www.med.navy.mil/sites/nmcphc>

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

Office of Naval Research  
<http://www.med.navy.mil>

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

Office of the Under Secretary of Defense for  
 Acquisition, Technology and  
 Logistics <http://www.acq.osd.mil/>

Military Infectious Diseases  
 Research Program  
<https://midrp.amedd.army.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://www.wrair.army.mil>

## II.B. Award Information

The SCIRP Clinical Research Development Award (CRDA) mechanism was first offered in FY16. Since then, 14 CRDA applications have been received, and two have been recommended for funding.

The anticipated direct costs budgeted for the entire period of performance for an FY17 SCIRP CRDA will not exceed \$100,000. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The FY17 SCIRP CRDA is intended to support planning and development activities necessary to initiate a future clinical study with the potential to have a significant impact on SCIs. The future study to be developed through the CRDA may be clinical research or a clinical trial (as defined, [below](#)). The FY17 SCIRP CRDA also encourages the inclusion of junior investigators on the research team.

*Relevance of the research to military and/or Veteran populations affected by SCI is a key element of this award mechanism. Collaboration with military or VA researchers and clinicians is highly encouraged. Inclusion of active duty military or Veteran populations is very highly encouraged. If the research will involve other populations, the relevance to the military or Veteran populations and the rationale for the inclusion of the other populations must be clearly articulated by the applicant.*

SCIRP CRDA recipients are expected to be ready to apply for advanced funding in the program year following completion of their CRDA and are encouraged to apply for future SCIRP funding through an appropriate FY19 or FY20 SCIRP Program Announcement, if offered. Release of FY19 or FY20 SCIRP Program Announcements and any subsequent awards will be contingent upon the availability of Federal funds for the program and competitive selection. Award of an FY17 SCIRP CRDA is in no way an assurance of funding for a future SCIRP award(s).

**Preliminary data are required.** The FY17 SCIRP CRDA is a planning award and is not intended to support preclinical or clinical studies to generate preliminary data or proof-of-principle. However, proposal of final [supporting] studies as required by the U.S. Food and Drug Administration (FDA) for initiation of the future clinical study is allowed in the FY17 SCIRP CRDA. Applicants proposing such experiments should include evidence of communication with the FDA in [Attachment 2, Supporting Documentation](#). **Other preclinical**

**studies are not supported by this funding opportunity.** Applicants looking to submit proposals for clinical trials should apply to the FY17 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-17-SCIRP-CTA); applicants seeking funding for other research studies may consider applying to the FY17 SCIRP Investigator-Initiated Research Award (Funding Opportunity Number: W81XWH-17-SCIRP-IIRA) or the FY17 SCIRP Translational Research Award (Funding Opportunity Number: W81XWH-17-SCIRP-TRA).

Important tasks to consider in an FY17 SCIRP CRDA application include, but are not limited to:

- Planning for appropriate regulatory approvals (for example, Institutional Review Board (IRB) submissions and FDA submissions such as FDA Investigational New Drug (IND)/Investigational Device Exemption (IDE) applications)
- Composing the research team and initiating collaborations necessary for the future clinical research project
- Recruiting junior investigators to the research team
- Developing the research plan and statistical design
- Developing the clinical protocol
- Establishing access to appropriate patient populations or resources
- Developing training procedures
- Planning for potential intellectual or material property issues
- Developing a transition plan with associated resources and collaborations to continue to the next phase of research, including involvement of industry partners, if applicable
- Developing a data analysis/statistical plan and/or modeling for adaptive trial design
- Note: Past and current SCIRP Clinical Trial Award Program Announcements have required extensive descriptions of clinical trial components. FY17 SCIRP CRDA applicants are encouraged to reference the FY17 SCIRP Clinical Trial Award Program Announcement to become familiar with its requirements to help direct proposed activities during the CRDA period of performance.

***As stated in [Section II.H.2.c, Withdrawal](#), CDRA applications that propose a clinical trial in the CRDA period of performance may be administratively withdrawn.***

A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information, a Human Subject Resource Document is provided at <https://ebrap.org/eBRAP/public/Program.htm>.

**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) prior to research implementation. This administrative review requirement is in addition to the local 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.*** When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC 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. Principal Investigators (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 the General Application Instructions, Appendix 1, for additional information.

**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](http://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. 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 [https://www.elsevier.com/data/promis\\_misc/622936arrive\\_guidelines.pdf](https://www.elsevier.com/data/promis_misc/622936arrive_guidelines.pdf).

**Use of Military and VA Populations or Resources:** Obtaining access to target military or VA patient population(s) or resources is an important element in the planning for the future clinical study. Where applicable, the application should include confirmation of this access or a plan for how it will be obtained. Confirmation of access should consist of a letter of support, signed by the lowest ranking person with approval authority for future clinical studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases (use [Attachment 8, Access Plan for Military and VA Populations and Resources](#), to provide this letter). 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 SCI 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 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 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to [Section II.F.1, Federal Award Notices](#).

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.**

**Government Agencies within the United States:** Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*



**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission:* Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.

**Note:** Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

**II.C.1.b. Principal Investigator:** Independent investigators at all academic levels (or equivalent) are eligible to submit applications.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <http://orcid.org/>.

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

## **II.D. Application and 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).*

**Extramural Submission** is defined as an application submitted by a non-DoD organization to Grants.gov.

***Intramural Submission*** is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

### **II.D.1. Address to Request Application Package**

***Submitting Extramural and Intramural Organizations:*** Pre-application content and forms can be accessed at eBRAP (<https://eBRAP.org>).

***Submitting Extramural Organizations:*** Full application packages can be accessed at Grants.gov.

***Submitting Intramural DoD Organizations:*** Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

### **II.D.2. Content and Form of the Application Submission**

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

***Pre-application Submission:*** All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (<https://eBRAP.org/>).

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.

***Full Application Submission:*** Full applications must be submitted through the online portals as described below.

***Submitting Extramural Organizations:*** Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

***Submitting Intramural DoD Organizations:*** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

eBRAP allows intramural organizations to submit full applications following pre-application submission.

***For both Extramural and Intramural applicants:*** A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.

#### **II.D.2.a. Step 1: Pre-Application Submission Content**

**During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.**

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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](mailto: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 be either 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 be either 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.

[FY17 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 II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto: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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, 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>). Pre-applications or 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

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 the General Application Instructions, Appendix 3, Section C, 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 underlying the proposed future clinical study. Briefly describe the level of scientific evidence that supports the progression of this research to a clinical study. Specify the future study population, the intervention to be investigated, if applicable, and indicate the phase of the study and/or class of device, as appropriate.
- **Development Plan:** Concisely state the specific aims and tasks to be accomplished in the 1-year period of performance of the FY17 SCIRP CRDA. Include a description of planned interactions with the FDA and local IRB, as appropriate, and how the planned tasks will support obtaining any IND/IDE approvals as needed for initiation of the proposed future clinical study. Include a description of how the planning period will be used to build the research team, develop the research plan and clinical protocol, statistical plans, plans for subject recruitment, and other tasks necessary to support the future clinical study.
- **Impact:** Describe the impact of the future clinical study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY17 SCIRP Areas of Encouragement or other relevant research area(s).
- **Military Relevance:** Describe how the proposed future clinical study 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 files* and are limited to the following:
  - **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, reference title, and reference source, including 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 (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.*

- **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 future clinical study.
- **Development Plan:** How well the specific aims and tasks to be accomplished in the one-year period of performance of the FY17 SCIRP CRDA are stated and justified.
- **Impact:** How well the proposed future clinical study addresses one or more FY17 SCIRP 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 future clinical study 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, 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 time frame for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

#### **II.D.2.b. Step 2: Full Application Submission Content**

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. Refer to the General Application Instructions, Section III, 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

### II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-17-SCIRP-CRDA from Grants.gov ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ).	Download application package components for W81XWH-17-SCIRP-CRDA from eBRAP ( <a href="https://ebrap.org/">https://ebrap.org/</a> ).
<b>Full Application Package Components</b>	
<b>SF424 (R&amp;R) Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">R&amp;R Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
<b>Application Package Submission</b>	
<b>Submit package components to Grants.gov</b> ( <a href="https://www.grants.gov/">https://www.grants.gov/</a> ). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need to be modified, an updated	<b>Submit package components to eBRAP</b> ( <a href="https://ebrap.org/">https://ebrap.org/</a> ). <b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application

Extramural Submissions	Intramural DoD Submissions
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.	submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.
<b><u>Application Verification Period</u></b>	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <b><i>with the exception of the Project Narrative and Budget Form</i></b> , may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <b><i>with the exception of the Project Narrative and Budget Form</i></b> , may be modified.
<b>Further Information</b>	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

***The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.***

Application viewing, modification, and verification in eBRAP are 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.

***Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.***

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



## II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only –**

**SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications –**

**Attachments:**

*Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are 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, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full 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) 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.

- **Future Clinical Study:** Describe briefly the rationale for the future clinical study and include a literature review, preliminary studies, and preclinical data that led to its development.
  - Describe the hypothesis and/or objectives of the future clinical study.
  - Specify the anticipated target population for the future clinical study, and how access is available, or will be obtained, to such a population.
  - Explain the research question to be addressed and/or intervention to be tested. If an intervention will be tested, include relevant information about its source, FDA approval/review status (as applicable), availability, efficacy, dosing (if applicable), and mechanism of action (if known).
- **Development Plan:** Describe the work to be conducted during the FY17 SCIRP CRDA period of performance clearly stating how each task is necessary for the

initiation of the future clinical study. Where relevant, identify potential problems and potential alternative approaches.

- Describe the overarching goals of the work to be done in the FY17 SCIRP CRDA period of performance.
- If final [supporting] studies as required by the FDA for initiation of the future clinical study are proposed, describe the aims, research design, methods, and analysis in sufficient detail for evaluation, including how the preclinical studies will be completed within the timeframe of the FY17 SCIRP CRDA. Evidence of communication with the FDA should be provided in [Attachment 2, Supporting Documentation](#). Details of the proposed experiments should include the rationale for the choice of model, randomization and blinding protocols, and statistical plan with sample size and power analysis.
- Provide a timeline and plans for coordination of IRB submission and approval at each study site, as applicable.
- If applicable, describe detailed plans for carrying out the IND/IDE application process, including timelines, milestones and planned interactions with the FDA. The path to FDA application and approval (IND/IDE or other) for the future clinical study should be outlined as clearly as possible.
- If applicable, describe planning for safety and clinical monitoring, including compliance with Good Clinical Practice (GCP) guidelines, if applicable.
- Describe the timeline and plans to finalize the experimental design and develop applicable clinical protocol and related documents (e.g., consent form, questionnaires) for the future clinical study, as applicable.
- Describe plans to identify and resolve potential intellectual or material property issues, as applicable.
- Describe how sample size estimates will be calculated, how a plan for statistical analyses will be developed, and how a human subjects recruitment plan, if applicable, will be formulated. Include plans to engage a statistician and other experts as appropriate.
- Describe plans establishing access to the relevant study population.
- Describe plans to develop applicable data collection/monitoring procedures, a data analysis plan, and other data collection tools.
- Describe how a plan to share and disseminate data and other resources created by the future clinical study with the greater research community will be developed.
- Describe how any other preparatory activities will be accomplished.

- **Study Team:** Describe the PI’s background and expertise in SCI research and in conducting clinical studies. Describe the experience and contributions of other key study team members.
  - Describe plans for developing the research team and obtaining any research resource or professional collaborations for the future clinical study, if applicable. Include plans for training team members, as appropriate. Address any involvement of DoD or VA clinicians and scientists.
  - Describe how the proposed future clinical study will offer opportunities for involvement of junior investigators in clinical research, if applicable.
- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

***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, 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. 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.
- Regulatory Communications: Include any communications with the FDA or local IRB relevant to tasks to be completed in the 1-year FY17 SCIRP CRDA period of performance, including any documents relevant to obtaining required IND/IDE approvals.
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
  - 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 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- 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.htm>
- **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 reasoning behind the future proposed clinical study.
  - Clinical Question: Hypothesis and/or objective to be addressed in the future clinical study.
  - Development Plan: Briefly describe how the work proposed for the FY17 SCIRP CRDA period of performance will lead to the future proposed clinical study.
  - Impact: Briefly describe the short- or long-term impact of the future clinical study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY17 SCIRP Areas of Encouragement or other relevant research area(s).
  - Military Relevance: Briefly describe the relevance of the proposed future clinical study 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.” 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 development project in a manner that will be readily understood by readers without a background in science or medicine.
  - What are the tasks that will be accomplished during the FY17 SCIRP CRDA period of performance to enable the future clinical study?
  - Describe the ultimate applicability of the future clinical study.
  - What persons with SCI will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a person-related outcome?
  - What are the likely contributions of the future clinical study 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 Clinical Research Development Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”** Describe the short- and long-term impact of the proposed **future clinical 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 future clinical study will lead to a practical application in individuals living with SCI. Address the impact of the future clinical study on one or more of the FY17 SCIRP Areas of Encouragement. If the future research project does not address one of the FY17 SCIRP Areas of Encouragement, provide justification that it addresses an important problem related to SCI. **Explain how the work in the present FY17 SCIRP CRDA project is necessary for the success of the future clinical study.**
- **Attachment 7: Military Relevance Statement (one-page limit): Upload as “Military.pdf.”** Demonstrate how the proposed future clinical study is applicable to the healthcare needs and quality of life of spinal cord-injured Service members, Veterans, and/or their family members, as well as their caregivers. If Service members, Veterans,

or military family member population(s) will be used in the proposed future research project, describe the population(s), the appropriateness of the population(s) for the proposed future research, and the feasibility of using the population. If a non-military population will be used for the proposed future research project, explain how the results will be applicable to Service members, Veterans, and/or their family members and/or caregivers.

- **Attachment 8: Access Plan for Military and VA Populations and Resources (if applicable): Upload as “Access.pdf.”** Describe the military/VA target populations or resources (e.g., active duty or reserve military, Veterans, or military family members; military- or VA-controlled study materials; databases; and/or restricted facilities) necessary for the future clinical study. Describe planning activities during the FY17 SCIRP CRDA period of performance to obtain access to the populations or resources. If access has already been obtained, include a letter of support, signed by the lowest-ranking person with approval authority as part of Attachment 8.
- **Attachment 9: DoD Military 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 DoD Military 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 III.A.7, for detailed information.
- **Extramural and Intramural Applications –**
  - Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.
  - **PI Biographical Sketch (six-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 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.
  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf.”
  - **Key Personnel Biographical Sketches (six-page limit each):** Upload as “Biosketch\_LastName.pdf.”
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf.”

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.

**Project/Performance Site Location(s) Form):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

**R&R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.6, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

### **II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

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. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

### **II.D.4. Submission Dates and Times**

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application



submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

### **Applicant Verification of Full Application 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 a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

### **II.D.5. Funding Restrictions**

The maximum period of performance is **1** year.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$100,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$100,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

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. 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
- Administrative costs
- Support for establishing collaborations
- Database generation

- Software development
- Costs associated with Institutional Review Board (IRB) and/or FDA applications and reviews
- Travel between collaborating organizations
- Clinical research costs (clinical trials not allowed)
- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.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 the General Application Instructions, Section III.A.4.*

*The CDMRP expects to allot approximately \$0.48M of the \$30M FY17 SCIRP appropriation to fund approximately 3 Clinical Research Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.*

#### **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

### **II.E. Application Review Information**

#### **II.E.1. Criteria**

##### **II.E.1.a. Peer Review**

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

- **Clinical Impact**
  - How well the proposed future clinical study addresses a critical issue in understanding and/or treatment of SCI.

- How the anticipated outcomes of the proposed future clinical study will provide/improve short-term benefits for individuals with SCI.
- How significantly the long-term benefits of the proposed future clinical study may impact patient care and/or quality of life.
- If the anticipated study population does not include Service member or Veteran participants and/or their family members or caregivers as all or a portion of the future study population, how well the PI has made the case that the results will be applicable to these populations.
- How well the future clinical study addresses an FY17 SCIRP Area of Encouragement or provides justification that is addressing an important problem related to SCI.
- **Research Question**
  - How well the preliminary data and scientific rationale support the proposed future clinical study and demonstrate sufficient evidence for moving into the proposed stage of research at the end of the FY17 SCIRP CRDA.
  - How well the hypothesis or objectives of the future clinical study are described.
- **Development Plan Strategy and Feasibility**
  - To what degree the work proposed for the FY17 SCIRP CRDA period of performance is justified as necessary to enable the future clinical study.
  - To what extent the proposed tasks are feasible as described and achievable within the FY17 SCIRP CRDA period of performance.
  - How well the proposed tasks for the FY17 SCIRP CRDA period of performance support the successful initiation of the future clinical study, including:
    - How well constructed the plans are to finalize the experimental design and develop any required clinical protocols and associated documents for the future clinical study.
    - How the plans to develop data collection and monitoring tools and data analyses are appropriate for the scope of the future clinical study.
    - How well the application addresses considerations such as statistical support, planning, and intellectual and material property agreements.
    - To what extent the plans for obtaining all necessary regulatory approvals (e.g., IRB and FDA IND/IDE application and review processes) and plans for safety and clinical monitoring, including compliance with GCP, if applicable, are feasible and likely to lead to success.

- If applicable, how well the proposed experiments to generate final [supporting] studies as required by the FDA for initiation of the future clinical study are supported by communication with the FDA and are designed to achieve the described objectives, including appropriateness of the choice of model and endpoints/outcome measures to be used.
- How well the plans for other preparatory activities are described and whether they are appropriate to enable the future clinical study.

- **Personnel**

- To what extent the background and expertise of the PI and key personnel are appropriate to accomplish the proposed project.
- How the levels of effort are appropriate for successful conduct of the proposed work.
- How well the application describes plans to recruit appropriate expertise to the future clinical study research team.
- If applicable, to what extent the proposed project includes plans to integrate DoD or VA researchers and clinicians to the future clinical research team.
- If applicable, how well junior investigators will be integrated into the future clinical research team.

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

- **Budget**

- Whether the maximum **direct** costs are equal to or less than the allowable maximum direct costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed work.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

### **II.E.1.b. 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:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 SCIRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Military relevance
  - Program portfolio composition
  - Relative impact

### **II.E.2. 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 Commanding General, USAMRMC, on behalf of the DHA 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. 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 II.E.1.b, 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 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

### **II.E.4. Anticipated Announcement and Federal Award Dates**

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

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.

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

***Extramural Organizations:*** An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the

research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

***Intramural Organizations:*** Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

#### **II.F.1.a. Award Transfers**

As this is a one-year period of performance award, organizational transfers will not be allowed, and approval of a change of PI will be on a case-by-case-basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

#### **II.F.2. Administrative and National Policy Requirements**

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. Annual progress reports as well as a final progress report will be required.

Quarterly technical progress reports and quad charts will be required.

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

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the [July 2016 R&D General Terms and Conditions](#). The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the [February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations](#).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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](mailto:help@eBRAP.org)

### **II.G.2. Grants.gov Contact Center**

Questions related to extramural 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](mailto: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 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.

## **II.H. Other Information**

### **II.H.1. Program Announcement and General Application Instructions Versions**

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516b. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

### **II.H.2. Administrative Actions**

After receipt of pre-applications or applications, the following administrative actions may occur:

#### **II.H.2.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.

#### **II.H.2.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.

#### **II.H.2.c. Withdrawal**

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

- An FY17 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 FY17 SCIRP Programmatic Panel members can be found at <http://cdmrp.army.mil/scirp/panels/panels17>.*
- The application fails to conform to this Program Announcement 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 FY17, 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The application proposes a clinical trial within the FY17 SCIRP CRDA period of performance.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

#### **II.H.2.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.

### II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance <b>(Extramural submissions only)</b>	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) <b>(Intramural submissions only)</b>	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Military Relevance Statement: Upload as Attachment 7 with file name "Military.pdf."	
	Access to Military and VA Populations and Resources: Upload as Attachment 8 with file name "Access.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 9 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.	

<b>Application Components</b>	<b>Action</b>	<b>Completed</b>
Research & Related Budget <b>(Extramural submissions only)</b>	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget <b>(Intramural submissions only)</b>	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

## **APPENDIX 1: ACRONYM LIST**

ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SCIRP	Spinal Cord Injury Research Program
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs