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
Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-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), May 29, 2019
- Invitation to Submit an Application: June 2019
- Application Submission Deadline: 11:59 p.m. ET, August 27, 2019
- End of Application Verification Period: 5:00 p.m. ET, August 30, 2019
- Peer Review: October 2019
- Programmatic Review: January 2020
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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2019 (FY19) 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 FY18 totaled $247.85 million (M). The FY19 appropriation is $30M.

The FY19 SCIRP challenges the scientific community to design research that will foster new directions 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 U.S. Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged. The SCIRP supports research across the continuum of care from initial injury throughout life and encourages the scientific community to address the impact of proposed research on mortality for individuals with SCI. The SCIRP supports groundbreaking research, and all projects must demonstrate solid scientific rationale.

II.A.1. FY19 SCIRP Translational Research Award (TRA) Focus Areas

To meet the intent of the award mechanism, applications must address at least one of the FY19 SCIRP TRA Focus Areas. Applications may address more than one Focus Area. In particular, applications combining biomarker studies with studies of one or more of the following Focus Areas are encouraged: preserving and protecting tissues after injury; bladder dysfunction, bowel dysfunction, and neuropathic pain; and rehabilitation and regeneration. Applications using clinically relevant combinations of interventions within or across Focus Areas are also encouraged. The FY19 SCIRP TRA Focus Areas are:

- Preserving and protecting spinal cord tissue at time of injury for improved neurologic outcomes:
  - Responsive projects may include surgical and acute care management of SCI.
  - Early therapeutics (devices and pharmacologic interventions) to stabilize SCI in the prehospital environment and during transport are encouraged.
Applications proposing neuroprotective interventions need to demonstrate a clinically feasible window for treatment and more than an incremental improvement over existing therapies.

- Identifying and validating biomarkers for diagnosis, prognosis, and for evaluation of treatment efficacies:
  - Biomarkers must focus on diagnosis, prognosis, progression, and/or recovery of SCI.
  - Projects with a clear link between a biomarker and underlying physiology are encouraged. Projects can include imaging and other modalities.
  - Applications should demonstrate a clear path to clinical use.
  - Biomarker studies directed at identifying the best single or combination of treatments for individuals (personalized medicine) are encouraged.
  - Clinical trials are not supported in the FY19 SCIRP TRA biomarkers Focus Area; however, ancillary biomarker studies with existing clinical trials are allowed and encouraged.

- Bladder dysfunction, bowel dysfunction, and neuropathic pain:
  - Includes studies of the mechanisms of bladder and bowel dysfunction and pain in individuals with SCI where the application demonstrates a clear path from increased understanding to advancing treatments.
  - Includes developing and testing interventions such as drugs, devices, and rehabilitation strategies.
  - Studies addressing the needs of and treatments for individuals with SCI across the full lifespan from acute to chronic injury are encouraged.
  - Studies relevant to this Focus Area using qualitative research approaches are allowed.

- Psychosocial issues relevant to SCI in individuals with SCI and their caregivers:
  - Applications directly addressing the needs of Service members and Veterans are strongly encouraged. Applications including other populations must show clear relevance to Service members and/or Veterans.
  - Applications addressing the needs of caregivers are encouraged.
  - Studies of depression, resilience, and self-management are especially encouraged.
  - Studies may address the causes of psychosocial issues and/or interventions designed to promote adjustment, independent living, and social participation, and to improve quality of life.
○ Preclinical animal studies are not responsive to this Focus Area.

○ Studies relevant to this Focus Area using qualitative research approaches are allowed.

- Rehabilitation and regeneration—maximizing the function of the residual neural circuitry, including harnessing neuroplasticity and recovery to improve function after SCI.

○ Studies that address critical questions of dosing, targeting, or safety required to move the research toward clinical use are supported.

○ Applications studying mechanisms of regeneration or identifying novel therapeutic targets must include a feasible projected pathway for translation and clinical implementation.

○ Basic research projects designed to understand general mechanisms underlying axonal sprouting, regeneration, or neuroplasticity are discouraged unless they directly address translatable approaches.

○ Studies relevant to this Focus Area using qualitative research approaches are allowed.

II.A.2. Award History

The SCIRP TRA mechanism was first offered in FY12. Since then, 135 TRA applications have been received, and 25 have been recommended for funding.

II.B. Award Information

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, PIs should not view translational research as a one-way continuum from bench to bedside. The research plan is encouraged to 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); applicants are strongly encouraged to refer to these pathways in their applications.
Applicants need to clearly articulate three points along the translational research spectrum:

- Where the field is now;
- Where the field will be after the successful completion of the proposed research project; and
- What the next step will be after completion of the proposed project.

Any specific regulatory milestones, e.g., submission of an application for an Investigational New Drug/Investigational Device Exemption (IND/IDE), should be included.

As applicable to the FY19 SCIRP TRA Focus Area(s) of the research, applications to the FY19 SCIRP TRA may include preclinical studies in animal models and clinical research involving human subjects and human anatomical substances. The FY19 SCIRP TRA may also support ancillary studies that are associated with an ongoing or completed clinical trial and projects that optimize the design of future clinical trials. The FY19 SCIRP TRA also allows funding for 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 (SOW), and be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement. Applications that consist entirely of a clinical trial do not meet the intent of the FY19 SCIRP TRA. Applications that do include a pilot clinical trial as part of the proposed research will have additional submission requirements and review criteria. (See the definition of a clinical trial on page 8.) Applications including animal studies must include a clear justification for the animal model chosen including relevance to human SCI.

Investigators seeking support for a study consisting only of a clinical trial should utilize the FY19 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-19-SCIRP-CTA).

Applications seeking support for a basic, early study relevant to SCI may consider the FY19 SCIRP Investigator-Initiated Research Award mechanism (Funding Opportunity Number: W81XWH-19-SCIRP-IIRA).

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

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

Consumer Advocate Involvement: The research team must include one or more SCI consumer advocates, who will be integral throughout the planning and implementation of the research project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. As a lay representative, each consumer advocate must be an individual with a SCI or his/her caregiver, and he/she should be active in a SCI advocacy organization. The consumer advocate’s role in the project should be independent of his/her employment, and he/she cannot be an employee of any of the organizations.
participating in the application. The consumer advocate’s role should be focused on providing objective input on the research and its potential impact for individuals with or caring for an individual with a SCI.

The anticipated direct costs budgeted for the entire period of performance for an FY19 SCIRP TRA will not exceed $1,250,000. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The CDMRP expects to allot approximately $6M to fund approximately three FY19 SCIRP TRA applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

Awards will be made no later than September 30, 2020. For additional information refer to Section II.F.1, Federal Award Notices.

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 the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement.

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) and the award will identify the specific substantial involvement. 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.

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 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*. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. 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 as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in Attachment 5: Statement of Work (SOW). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. 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](https://ebrap.org/eBRAP/public/Program.htm)) for additional information.

**New FY19 definition:** A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in 32 CFR 219.

Funded clinical trials are required to file the study in the National Institutes of Health (NIH) clinical trials registry, [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Refer to the General Application Instructions, Appendix 1, Section C, for further details.

Principal Investigators (PIs) are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix II.

**Use of DoD or VA Resources:** If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief.
If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed 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). 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 9, 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 https://journals.plos.org/plosone/article/file?type=supplementary&id=info:doi/10.1371/journal.pone.0146533.s001.

**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. 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.

**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 (NINDS) 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.

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 academic institutions, biotechnology companies, foundations, other Federal Government organization other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov 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) may be named by the organization as the PI on the application.

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 https://orcid.org/.
II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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.

Extramural Submissions:

• Pre-application content and forms must be accessed and submitted at eBRAP.org.

• Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions:

• Pre-application content and forms must be accessed and submitted at eBRAP.org.

• Full application packages must be accessed and submitted at eBRAP.org.
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/).

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

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. 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. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Intramural DoD Organization Submissions: 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.

For Both Extramural and Intramural Applicants: eBRAP allows 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 full 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 or 301-682-5507 prior to the application submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required 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 will delay 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 or 301-682-5507 to request a change in designation.

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.

The applicant organization and associated PIs 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.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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**
  
  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 Research & Related 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 Research & Related 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, key personnel, including the consumer advocate(s) associated with the application.

**FY19 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 or 301-682-5507.

• 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).

• 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. If applicable, clearly identify which aims describe the proposed preclinical or clinical studies and which describe the pilot clinical trial. Describe 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:** Explain how the project will accelerate promising laboratory research findings into clinical applications. Where applicable, describe how the proposed research will allow for a reciprocal flow of ideas between basic and clinical science.
Clearly articulate three points along the translational research spectrum. Any specific regulatory milestones, e.g., submission of an application for an IND/IDE, should be included.

- Where the field is now;
- Where the field will be after the successful completion of the proposed research project; and
- What the next step will be after completion of the proposed project.

**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 FY19 SCIRP TRA Focus Areas.

**Relevance to Military Health:** 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 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. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. A biographical sketch should be included for the consumer advocate(s).

**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 addressed in the outlined research project. 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 from where the field is now to where the field will be at the completion of the research project and what the next steps will be after completion of the work.

- **Impact:** How well the proposed research project addresses one or more FY19 SCIRP TRA Focus Areas and will make important contributions toward the goals of advancing SCI research, patient care, and/or improving quality of life.

- **Relevance to Military Health:** 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, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated 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 notification of invitation has been received.

*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 must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission.
Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader must be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the same version of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application Package Location</strong></td>
<td>Download application package components for W81XWH-19-SCIRP-TRA from Grants.gov (<a href="https://www.grants.gov">https://www.grants.gov</a>) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.</td>
</tr>
<tr>
<td><strong>Full Application Package Components</strong></td>
<td>Download application package components for W81XWH-19-SCIRP-TRA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</td>
</tr>
<tr>
<td><strong>SF424 Research &amp; Related Application for Federal Assistance Form:</strong> Refer to the General Application Instructions, Section III.A.1, for detailed information.</td>
<td>Tab 1 – Summary: Provide a summary of the application information.</td>
</tr>
<tr>
<td>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
<td>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</td>
</tr>
<tr>
<td>Descriptions of each required file can be found under Full Application Submission Components:</td>
<td>- Attachments</td>
</tr>
<tr>
<td>- Research &amp; Related Personal Data</td>
<td></td>
</tr>
<tr>
<td>- Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td></td>
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<tr>
<td>- Research &amp; Related Budget</td>
<td></td>
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<tr>
<td>- Project/Performance Site Location(s) Form</td>
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<tr>
<td>- Research &amp; Related Subaward Budget Attachment(s) Form (if applicable)</td>
<td>- Key Personnel</td>
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<tr>
<td>- Budget</td>
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<tr>
<td>- Performance Sites</td>
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<tr>
<td>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</td>
<td></td>
</tr>
<tr>
<td>Extramural Submissions</td>
<td>Intramural DoD Submissions</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td><strong>Application Package Submission</strong></td>
<td><strong>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</strong></td>
</tr>
<tr>
<td>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</td>
<td>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</td>
</tr>
<tr>
<td><strong>Submit a Grants.gov Workspace Package.</strong> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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.</td>
<td></td>
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</tbody>
</table>

<p>| <strong>Application Verification Period</strong> | |
| 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 may be modified with the exception of the Project Narrative and Research &amp; Related Budget Form. | After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive 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 may be modified with the exception of the Project Narrative and Research &amp; Related Budget Form. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline. |</p>
<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tracking a Grants.gov Workspace Package.</strong></td>
<td><strong>Further Information</strong></td>
</tr>
<tr>
<td>After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</td>
<td>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</td>
</tr>
</tbody>
</table>

**Both Extramural and Intramural Organizations:** Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Research & Related Budget Form 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. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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 Research & Related 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 have 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 (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) 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 are 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 applicable, briefly describe the relevance of the animal model chosen to human SCI—full details will be required in the Animal Research Plan (Attachment 9). 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. If applicable, describe the SCI CDEs to be used.

**Outline for projects with 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 during award negotiation.)

- **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 preclinical or clinical studies and which aims comprise the pilot clinical trial portions 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 studies using animals, briefly describe the relevance of the animal model chosen to human SCI—full details will be required in the [Animal Research Plan (Attachment 9)](attachment). 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 10](attachment).

  - 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 (including SCI CDEs if applicable), study variables, controls, and endpoints. Describe potential challenges and alternative strategies where appropriate.

  - Describe how the pilot clinical trial is **clearly linked** to the preclinical or clinical 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 FY19 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 (SOW) ([Attachment 5](attachment)), 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 an ancillary 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, briefly outline a regulatory strategy for applying for and obtaining Investigative New Drug/Investigative Device Exemption (IND/IDE) status (or other U.S. Food and Drug Administration [FDA] approvals).
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.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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.
- Consumer Advocate Letter(s) of Commitment: Provide a letter signed by each consumer advocate confirming her/his role and commitment to participate on the research team.


- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 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.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.

- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- 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.
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 FY19 SCIRP TRA Focus Areas.

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 as part of the proposed research, explain how this is necessary to inform the next step on the translational spectrum.

Relevance to Military Health: 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 and/or their caregivers 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 the research findings 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 (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 FY19 SCIRP TRA 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.
- 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 applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other Government agency.

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 FY19 SCIRP TRA Focus Areas.

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 as part of the study, explain how the preclinical and pilot clinical trial aims are connected and necessary to
advance the anticipated research outcomes toward clinical implementation. Clearly articulate three points along the translational research spectrum:

- Where the field is now;
- Where the field will be after the successful completion of the proposed research project; and
- What the next step will be after completion of the proposed project.

○ **Attachment 8: Relevance to Military Health 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 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: Animal Research Plan (if applicable; three-page limit): Upload as “AnimalResPlan.pdf.”** If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. 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. Be specific as to why the animal SCI model (contusion, hemostatic clip compression, etc.) was chosen over other models and how it is optimal for addressing the study aims and is relevant to human SCI.

- 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).
- Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

○ Attachment 10: Pilot Clinical Trial Plan (if applicable; three-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 11: Regulatory Strategy (required only if proposing a pilot clinical trial; no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “Regulatory.pdf”. Provide the information requested below and provide supporting documentation as applicable.
  - State the product/intervention name.

For products/interventions that do not require regulation by the FDA or an international regulatory agency:
  - Explain why the product/intervention is exempt from FDA oversight. Provide confirmation that the pilot clinical trial does not require regulation by the FDA in writing from the IRB of record or the FDA. If the pilot clinical trial will be conducted at international sites, provide equivalent information relevant to the host country(ies) regulatory requirements. No further information for this attachment is required.

For products/interventions that require regulation by the FDA and/or an international regulatory agency:
  - State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.
If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor’s understanding of all sponsor responsibilities and commitment to oversee execution of the study.

For the FY19 SCIRP TRA, if an IND or IDE is required, it must be submitted to the FDA prior to the FY19 SCIRP TRA application submission deadline. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed pilot clinical trial. Provide the date of submission, application number, and sponsor for any existing FDA applications in place. If there are any existing cross-references in place, provide the application number and associated sponsor. Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold). Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.

If an IND or IDE has already been obtained for the investigational product, provide a copy of the acceptance from the FDA.

If the pilot clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

Provide the current status for manufacturing development (e.g., manufacturer’s name, Good Manufacturing Practices (GMP)-compliant lots available, status of stability testing, etc.), non-clinical development (e.g., test facility name, status of pivotal Good Laboratory Practices (GLP) toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy. Include
considerations for compliance with current GMP, GLP, and Good Clinical Practices (GCP) guidelines.

- **Attachment 12: Consumer Advocate Statement (one-page limit): Upload as “ConsumerAdvocate.pdf”**. The Consumer Advocate Statement should be written by the PI. Provide the name(s) of the consumer advocate(s) and their affiliation with a SCI advocacy organization(s). Describe the integral roles that the consumer advocate(s) will play in the planning, design, implementation, and evaluation of the research. Describe how the consumer advocates’ knowledge of current spinal cord issues and research will contribute to the project.

- **Attachment 13: Transition Plan (two-page limit): Upload as “Transition.pdf”**. Describe/discuss the methods and strategies proposed to move the intervention to the next phase of development (further development of the intervention, clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. The post-award transition plan should include the components listed below.

  - Details of the funding strategy to transition to the next level of development, clinical testing and/or commercialization (e.g., specific industry partners, specific funding opportunities to be applied for). Include a description of collaborations and other resources that will be used to provide continuity of development.

  - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.

  - A brief schedule and milestones for transitioning the intervention to the next phase of development (i.e., next-phase clinical trials, commercialization, delivery to the military or civilian market, incorporation into clinical practice, and/or approval by the FDA).

  - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
A risk analysis for cost, schedule, manufacturability, and sustainability

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.

Attachment 14: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”. All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

Attachment 15: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”. If a military facility (Military Health System facility, research laboratory, medical 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

Extramural and Intramural Applications

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: 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.

Research & Related Senior/Key Person Profile (Expanded): 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.

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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
○ 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.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.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.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

○ **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 15. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

Applicant organizations and all sub-recipient 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 organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete
the entire SAM registration process. If an applicant has not fully complied with the requirements at 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

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.

Extramural Submission: 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, with the exception of the Project Narrative and Budget Form, may be modified.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, with the exception of the Project Narrative and Budget Form, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is 3 years.
The anticipated direct costs budgeted for the entire period of performance will not exceed **$1,250,000.** 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 **$1,250,000** 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.

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.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Clinical trial costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY19 SCIRP TRA.
- Travel costs for the PI to travel to one DoD-sponsored meeting in the lifetime of the award. For budget purposes, it is suggested that these costs be included in year 2 of the award. This is in addition to the scientific/technical meeting described above.

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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 funds 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.5, 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.5.*
Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award’s period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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 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 application describes where the field is now, including the current state of knowledge or practice, and how well it describes and justifies how the proposed work will move the field closer to a clinical application by the end of the study.
    - How well the application describes feasible next steps to be taken after the end of the proposed study toward a clinical application for individuals with SCI.
  - How well the project allows for the reciprocal transfer of ideas between basic and clinical science, as applicable.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **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/hypotheses 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 application acknowledges potential problems and addresses alternative approaches.

○ If applicable, how well the animal study (or studies) is (are) designed to achieve the objectives, including the endpoints/outcome measures to be used and how well the animal model chosen reproduces the human injury.

○ How well the proposed research is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, statistical analysis, and data handling.

○ How well the application demonstrates utilization of the SCI CDEs, as applicable.

○ How well the regulatory strategy is outlined, including, if applicable, how appropriate the plan is for applying for and obtaining IND/IDE status (or other FDA approvals).

• Clinical Strategy (for applications including a pilot clinical trial)

○ How well the proposed pilot clinical trial meets the requirements of the FY19 SCIRP TRA with regard to being small, representing only a portion of the proposed SOW, 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 proposed pilot clinical trial is to the preclinical research studies that will also be performed through this award.

○ How well the pilot clinical trial portion of the application is designed with appropriate study variables, controls, and endpoints.

○ How well the application demonstrates the ability to accrue a sufficient number of subjects.

○ How well the application demonstrates that availability of and access to the intervention to be tested.

• Impact

○ How effective the proposed research project will be in making important contributions toward the goals of advancing SCI research, patient care, and/or quality of life.

○ How well the proposed research addresses one or more of the FY19 SCIRP TRA Focus Areas.

• 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.

○ To what extent the background and expertise of the consumer advocate(s) is/are appropriate for involvement in the proposed research and how well the application describes how the consumer advocate(s) will be integrated into the research team.

○ How well the PI’s record of accomplishments demonstrates his/her ability to accomplish the proposed research project.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

• **Environment**
  ○ To what extent the scientific environment is appropriate for the proposed research project.
  ○ How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  ○ 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 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 research.

• **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 FY19 SCIRP, as evidenced by the following:
  ○ Adherence to the intent of the award mechanism
- Relevance to military health
- 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, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is programmatic review, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA). 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 https://cdmrp.army.mil/about/2tierRevProcess. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the FY19 SCIRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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, as defined in 2 CFR 200.88, 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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 (DoDGARs), 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 supported with FY19 funds are anticipated to be made no later than September 30, 2020. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from 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 document.

Federal Government Organizations: Funding made 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through 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. PI Changes and 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.
Unless otherwise restricted, changes in PI will be allowed at the discretion of the Grants Officer, provided the intent of the award mechanism is met.

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 DoDGARs found in 32 CFR, Chapter I, 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 latest DoD R&D General Terms and Conditions, the USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions 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. If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

Annual progress reports and quad charts as well as a final progress report will be required.

Quarterly technical progress reports may be required.

In-person presentations may be requested.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan” available on the on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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 Representations (see General Application Instructions, Appendix 5, Section B).

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

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

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 20190218d. The Program Announcement numeric version code will match the General Application Instructions version code 20190218.
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 FY19 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 FY19 SCIRP Programmatic Panel members can be found at https://cdmrp.army.mil/scirp/panels/panels19.
- The application fails to conform to this Program Announcement description.
- 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 FY19, the identities of
the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval 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.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application proposes a different research project than that described in the pre-application.

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

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<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
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<tr>
<td>SF424 Research &amp; Related Application for Federal Assistance (Extramural submissions only)</td>
<td>Complete form as instructed</td>
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<td>Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)</td>
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<td>SF424 Research &amp; Related Application for Federal Assistance (Extramural submissions only)</td>
<td>Complete form as instructed</td>
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<td>SF424 Research &amp; Related Application for Federal Assistance (Extramural submissions only)</td>
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<td><strong>Attachments</strong></td>
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<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf”</td>
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<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf”</td>
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<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf”</td>
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<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf”</td>
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<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf”</td>
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<td>Impact Statement: Upload as Attachment 6 with file name “Impact.pdf”</td>
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<td>Translation Statement: Upload as Attachment 7 with file name “Translation.pdf”</td>
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<td>Relevance to Military Health Statement: Upload as Attachment 8 with file name “Military.pdf”</td>
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<td>Pilot Clinical Trial Plan: Upload as Attachment 10 with file name “ClinTrialPlan.pdf”</td>
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<td>Regulatory Strategy: Upload as Attachment 11 with file name “Regulatory.pdf”</td>
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<td>Application Components</td>
<td>Action</td>
<td>Completed</td>
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<tr>
<td>DoD Military Budget Form(s): Upload as Attachment 15 with file name “MFBudget.pdf” if applicable.</td>
<td>DoD Military Budget Form(s): Upload as Attachment 15 with file name “MFBudget.pdf” if applicable.</td>
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<tr>
<td>Research &amp; Related Personal Data</td>
<td>Complete form as instructed</td>
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<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field</td>
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<td></td>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field</td>
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<tr>
<td></td>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field</td>
<td></td>
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<tr>
<td>Research &amp; Related Budget (Extramural submissions only)</td>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field</td>
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<tr>
<td>Budget (Intramural submissions only)</td>
<td>Complete the DoD Military Budget Form and justification</td>
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</tr>
<tr>
<td>Project/Performance Site Location(s) Form</td>
<td>Complete form as instructed</td>
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<tr>
<td>Research &amp; Related Subaward Budget Attachment(s) Form, if applicable</td>
<td>Complete form as instructed</td>
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## APPENDIX I: ACRONYM LIST

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACOS/R&amp;D</td>
<td>Associate Chief of Staff for Research and Development</td>
</tr>
<tr>
<td>ACURO</td>
<td>Animal Care and Use Review Office</td>
</tr>
<tr>
<td>ARRIVE</td>
<td>Animal Research: Reporting <em>In Vivo</em> Experiments</td>
</tr>
<tr>
<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
</tr>
<tr>
<td>CDE</td>
<td>Common Data Elements</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>DHA</td>
<td>Defense Health Agency</td>
</tr>
<tr>
<td>DHP</td>
<td>Defense Health Program</td>
</tr>
<tr>
<td>DoD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>DoDGARs</td>
<td>Department of Defense Grant and Agreement Regulations</td>
</tr>
<tr>
<td>DUNs</td>
<td>Data Universal Numbering System</td>
</tr>
<tr>
<td>eBRAP</td>
<td>Electronic Biomedical Research Application Portal</td>
</tr>
<tr>
<td>EC</td>
<td>Ethics Committee</td>
</tr>
<tr>
<td>ET</td>
<td>Eastern Time</td>
</tr>
<tr>
<td>FAD</td>
<td>Funding Authorization Document</td>
</tr>
<tr>
<td>FAPIIS</td>
<td>Federal Awardee Performance and Integrity Information System</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>FY</td>
<td>Fiscal Year</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practices</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practices</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
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<tr>
<td>HRPO</td>
<td>Human Research Protection Office</td>
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<tr>
<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
</tr>
<tr>
<td>IDE</td>
<td>Investigational Device Exemption</td>
</tr>
<tr>
<td>IND</td>
<td>Investigational New Drug</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>M</td>
<td>Million</td>
</tr>
<tr>
<td>MIPR</td>
<td>Military Interdepartmental Purchase Request</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>NINDS</td>
<td>National Institute of Neurological Disorders and Stroke</td>
</tr>
<tr>
<td>NPC</td>
<td>Non-Profit Corporation</td>
</tr>
<tr>
<td>OASD(HA)</td>
<td>Office of the Assistant Secretary of Defense for Health Affairs</td>
</tr>
<tr>
<td>ORCID</td>
<td>Open Researcher and Contributor ID, Inc.</td>
</tr>
<tr>
<td>ORP</td>
<td>Office of Research Protections</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test, and Evaluation</td>
</tr>
<tr>
<td>SAM</td>
<td>System for Award Management</td>
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<tr>
<td>SCI</td>
<td>Spinal Cord Injury</td>
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<tr>
<td>SCIRP</td>
<td>Spinal Cord Injury Research Program</td>
</tr>
<tr>
<td>SOW</td>
<td>Statement of Work</td>
</tr>
<tr>
<td>STEM</td>
<td>Science, Technology, Engineering, and/or Mathematics</td>
</tr>
<tr>
<td>TRA</td>
<td>Translational Research Award</td>
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<tr>
<td>USAMRAA</td>
<td>U.S. Army Medical Research Acquisition Activity</td>
</tr>
<tr>
<td>USAMRMC</td>
<td>U.S. Army Medical Research and Materiel Command</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
</tr>
<tr>
<td>VA</td>
<td>U.S. Department of Veterans</td>
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</table>
APPENDIX II: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD and/or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration.

<table>
<thead>
<tr>
<th>Website</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Force Office of Scientific Research</td>
<td>Military Infectious Diseases Research Program</td>
</tr>
<tr>
<td>Air Force Research Laboratory</td>
<td>Military Operational Medicine Research Program</td>
</tr>
<tr>
<td>Armed Forces Radiobiology Research Institute</td>
<td>Naval Health Research Center</td>
</tr>
<tr>
<td>Clinical and Rehabilitative Medicine Research Program</td>
<td>Navy Bureau of Medicine</td>
</tr>
<tr>
<td>Combat Casualty Care Research Program</td>
<td>Naval Medical Research and Development</td>
</tr>
<tr>
<td>Congressionally Directed Medical Research Programs</td>
<td>Navy and Marine Corps Public Health Center</td>
</tr>
<tr>
<td>Defense Advanced Research Projects Agency</td>
<td>Office of Naval Research</td>
</tr>
<tr>
<td>Defense Health Agency</td>
<td>Office of the Under Secretary of Defense for Acquisition, Technology and Logistics</td>
</tr>
<tr>
<td>Defense Technical Information Center</td>
<td>Telemedicine and Advanced Technology Research Center</td>
</tr>
<tr>
<td>Defense Threat Reduction Agency</td>
<td>Unformed Services University of the Health Sciences</td>
</tr>
<tr>
<td><a href="https://www.dtra.mil">https://www.dtra.mil</a></td>
<td><a href="https://www.usuhs.edu/research">https://www.usuhs.edu/research</a></td>
</tr>
<tr>
<td>Military Health System Research Symposium</td>
<td>U.S. Air Force 59th Medical Wing</td>
</tr>
<tr>
<td>Agency</td>
<td>Website</td>
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<tr>
<td>-----------------------------------------------------------------------</td>
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<tr>
<td>U.S. Army Aeromedical Research Laboratory</td>
<td><a href="https://www.usaarl.army.mil">https://www.usaarl.army.mil</a></td>
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<tr>
<td>U.S. Army Center for Environmental Health Research</td>
<td><a href="https://usacehr.amedd.army.mil">https://usacehr.amedd.army.mil</a></td>
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<tr>
<td>U.S. Army Institute of Surgical Research</td>
<td><a href="https://www.usaisr.amedd.army.mil">https://www.usaisr.amedd.army.mil</a></td>
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<tr>
<td>U.S. Army Research Institute of Environmental Medicine</td>
<td><a href="https://www.usariem.army.mil">https://www.usariem.army.mil</a></td>
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<tr>
<td>U.S. Army Medical Research Institute of Infectious Diseases</td>
<td><a href="https://www.usamriid.army.mil">https://www.usamriid.army.mil</a></td>
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<tr>
<td>U.S. Army Medical Research and Materiel Command</td>
<td><a href="https://mrmc.amedd.army.mil">https://mrmc.amedd.army.mil</a></td>
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<tr>
<td>U.S. Army Research Laboratory</td>
<td><a href="https://www.arl.army.mil">https://www.arl.army.mil</a></td>
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<tr>
<td>U.S. Department of Veterans Affairs, Office of Research and Development</td>
<td><a href="https://www.research.va.gov">https://www.research.va.gov</a></td>
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<tr>
<td>U.S. Naval Research Laboratory</td>
<td><a href="https://www.nrl.navy.mil">https://www.nrl.navy.mil</a></td>
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<td>Walter Reed Army Institute of Research</td>
<td><a href="https://www.wrair.army.mil">https://www.wrair.army.mil</a></td>
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