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-20-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 21, 2020
- **Invitation to Submit an Application:** June 30, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, August 25, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, August 31, 2020
- **Peer Review:** October 2020
- **Programmatic Review:** January 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) 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 FY19 totaled $277.85 million (M). The FY20 Defense Appropriations Act provides $40M to the SCIRP through the appropriation for peer-reviewed spinal cord research.

The FY20 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. FY20 SCIRP Translational Research Award (TRA) Focus Areas

Applications must address at least one of the FY20 SCIRP TRA Focus Areas. Applications may address more than one Focus Area. In particular, applications combining biomarker studies with studies in one or more of the other FY20 SCIRP Focus Areas are encouraged. Applications using clinically relevant combinations of interventions within or across Focus Areas are also encouraged. The FY20 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 FY20 SCIRP TRA biomarkers Focus Area; however, ancillary biomarker studies with existing clinical trials are allowed and encouraged.

- **Bowel, genitourinary, cardiopulmonary dysfunction, and neuropathic pain:**

  - Includes studies of the mechanisms of dysfunction specific to SCI, where the application demonstrates a clear path from increased understanding to advancing treatments.

  - 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 people with SCI, their families, and/or their care partners:**

  - Applications should directly address, or show clear relevance to, the needs of Service members and Veterans.

  - Studies of depression, resilience, or self-efficacy are especially encouraged.

  - Studies may address the causes of psychosocial issues, diagnosis, 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, 149 TRA applications have been received, and 30 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, applicants 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.

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.

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.

Applications to the FY20 SCIRP TRA may include preclinical animal studies and clinical research involving human subjects and human anatomical substances. ***Applications including animal studies must include a clear justification for the animal model chosen including relevance to human SCI.***

The FY20 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 FY20 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 include a pilot clinical trial as part of the proposed research will have additional submission requirements and review criteria.

Applications that consist entirely of a clinical trial do not meet the intent of the FY20 SCIRP TRA and should utilize the FY20 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number: W81XWH-20-SCIRP-CTA). A clinical trial is defined as 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.

Applications requesting support for a basic, early study relevant to SCI may better fit the intent of the FY20 SCIRP Investigator-Initiated Research Award mechanism (Funding Opportunity Number: W81XWH-20-SCIRP-IIRA).

SCI Lived Experience Consultation: The research team ***must*** include at least one person with lived SCI experience who will provide advice and consultation throughout the planning and implementation of the research project. Interactions with other team members should be well integrated and ongoing. SCI Lived Experience Consultants include individuals with an SCI, their family members, or care partners. These individuals should provide an independent voice and objective input on the research and its potential impact for people living with SCI.

The types of awards made under the Program Announcement will be assistance agreements. An assistance 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. 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. 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, but is not limited to, 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.

The anticipated direct costs budgeted for the entire period of performance for an FY20 SCIRP TRA award will not exceed **$1,250,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $10M to fund approximately five (5) Translational Research Award 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 FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP) Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

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 USAMRDC 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Funded studies that contain a clinical trial are required to post a copy of the IRB approved informed consent form used to enroll subjects on a publicly available Federal website in accordance with Federal requirements described in Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

Funded studies that contain a clinical trial are required to register the study in the National Institutes of Health (NIH) clinical trials registry, www.clinicaltrials.gov prior to initiation of the study. Refer to the General Application Instructions, Appendix 1, Section D, for further details.

Use of DoD or VA Resources: If the proposed research involves access to active duty military or Veteran patient populations and/or DoD or VA 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. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. 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 https://commondataelements.ninds.nih.gov/Spinal%20Cord%20Injury is strongly encouraged for all human subjects' research.

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

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 Principal Investigator (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:

- 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 Submission:

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

- Full application packages must be accessed and submitted at eBRAP.org

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

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.

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

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1. Full Application Guidelines).

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 PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

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. 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, and key personnel associated with the application.

  One SCI Lived Experience Consultant must also be named, failure to do so may result in administrative withdrawal of the application. The SCI Lived Experience Consultants' role in

the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application.

FY20 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**

  List all individuals other than collaborators and key personnel who may have a conflict of interest 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 FY20 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 care partners.
- **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. Biographical sketches should be included for the SCI Lived Experience Consultant(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 FY20 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 care partners.

- **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.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-20-SCIRP-TRA from Grants.gov (https://www.grants.gov) 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.	Download application package components for W81XWH-20-SCIRP-TRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable)	**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: • Attachments • Key Personnel • Budget • Performance Sites **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.

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** 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. **Note:** 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. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **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. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
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 & 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 & 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.

Extramural Submissions	Intramural DoD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. 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.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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. ***It is important to include the attachment name as a header on each page of the attachment files.***

  - **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 scientific evidence to support the proposed stage of research, including preliminary and/or published data. 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. Outline whether researchers, subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias. 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 collected.

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. Outline whether researchers, subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias. 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). 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. If applicable, describe the SCI CDEs to be collected.

- **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.

    - Describe the type of clinical trial to be performed and outline the proposed methodology in sufficient detail to show a clear course of action. Briefly, identify the intervention to be tested, projected outcomes, study variables, controls, and endpoints. Describe potential challenges and alternative strategies where appropriate.

    - Describe how the pilot clinical trial is clearly linked to the 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 FY20 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 SOW (Attachment 5), and will be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement.

    - 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 articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- SCI Lived Experience Consultation Letters of Commitment: Provide a letter signed by each SCI Lived Experience Consultant confirming their role and commitment to participate on the research team.

- 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.

- Commercial Entity Letters of Commitment (if applicable): If the proposed study involves use of a commercially produced investigational drug, device, or biologic,

provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- Intellectual Property: Information can be found in 2 CFR 200.315, "Intangible Property."

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

- 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. Describe the SCI CDEs to be collected, if applicable. 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 Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation 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 reasoning behind the proposed research project, including sufficient evidence to support the proposed stage of research.

- **Hypothesis or Objective:** State the hypothesis(es)/objective(s) to be tested. Provide evidence or rationale that supports the hypothesis(es)/objective(s).

- **Specific Aims:** State the specific aims of the proposed research project. Identify which aims relate to a pilot clinical trial (if applicable).

- **Study Design:** Briefly describe the study design, including appropriate controls.

- **Impact:** Briefly describe the short- or long-term 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 FY20 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.

- **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 SCI 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 and impact of the research.

    - What populations 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 will this 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 FY20 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/IDE applications) by the FDA or other Government agency (e.g., USAMRDC ORP).

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe the short- and long-term impact of this study on the field of SCI research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed research project will lead to a practical application in individuals living with SCI. Address the impact on one or more of the FY20 SCIRP TRA Focus Areas. This attachment should be written with a broad audience in mind including readers without a background in science or medicine.

- **Attachment 7: Translation Statement (one-page limit): Upload as "Translation.pdf".** 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 pilot clinical trial aims are 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 care partners. 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 (*applicable only if proposing a pilot clinical trial*; three-page limit): Upload as "ClinTrialPlan.pdf".**

  - Identify the intervention to be tested and describe the projected outcomes. Demonstrate the availability of the intervention, including IND/IDE status (or other FDA approvals), as applicable.

  - Summarize the procedures to be conducted. Describe the interaction with the human subject, including the study intervention that they will experience. Describe how the study will be controlled.

  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested, including SCI CDEs if applicable.

  - Identify the study population and 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.

  - 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.

  - Outline whether subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.

- **Attachment 11: Regulatory Strategy (*applicable 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 FY20 SCIRP TRA, if an IND or IDE is required to initiate the proposed research project, it must be submitted to the FDA prior to the FY20 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: SCI Lived Experience Consultation Plan (one-page limit): Upload as "SCILivedExperience.pdf"**. Provide the name(s) of the SCI Lived Experience Consultant(s) and their affiliation (if applicable) with a SCI advocacy organization(s).

  - Describe the roles that the SCI Lived Experience Consultant(s) will play in the planning, design, implementation, and evaluation of the research.

  - Explain how the consultants' unique perspective and input will be captured and integrated into the research project.

  - Describe how the SCI Lived Experience Consultant(s) will be integrated into the research team.

  The SCI Lived Experience Consultants' role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application.

- **Attachment 13: Transition Plan (two-page limit): Upload as "Transition.pdf".** Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application **after successful completion of the award.** Describe the projected regulatory strategy, if applicable. The post-award transition plan should include the components listed below.

  - The development and/or commercialization strategy with sufficient detail for evaluation of feasibility.

  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the projected FDA regulatory strategy, to include considerations for compliance with GMP, GLP, and GCP guidelines, if appropriate.

  - Details of the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).

  - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development. 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 schedule and milestones for transitioning the anticipated research outcomes to the next level of development (e.g., next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, 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.

- **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: Suggested Collaborating DoD Military Facility Budget Format, 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 a separate budget, using **Suggested Collaborating DoD Military Facility Budget Format**, 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 "Suggested Collaborating DoD Military Facility Budget Format" 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.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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

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. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** 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.

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 must be requested for:

- Travel costs for the PI to present project information or disseminate project results at a DoD SCIRP In-progress Review meeting during the period of performance. For planning purposes, it should be assumed that the meeting will occur within the second year of the award and be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for travel including:

- Travel in support of multi-institutional collaborations.
- Travel and lodging costs for research subjects to participate in the study.

- 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 FY20 SCIRP TRA.

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.***

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 move an observation forward into clinical application and accelerate the introduction of healthcare products, technologies, or practice guidelines for clinical use.
    - 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.
    - Whether the anticipated research outcome(s) are realistic given the state of the field now and the proposed research approach.

- **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 designed to achieve the objectives, including the endpoints/outcome measures to be used and how well the animal model chosen reproduces the human injury.
    - If applicable, how well the human subjects, data, or samples are chosen to achieve the study objectives.
    - 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.
- **Clinical Strategy (for applications including a pilot clinical trial)**
    - How well the proposed pilot clinical trial meets the requirements of the FY20 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 or clinical 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, endpoints and data analysis plan.
    - 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 FY20 SCIRP TRA Focus Areas.
- **Transition Plan and Regulatory Strategy**
    - To what extent the proposed plan for the next level of development or commercialization is feasible.
    - Whether the funding strategy described to bring the anticipated research outcomes to the next level of development is reasonable and realistic.
    - How the future regulatory strategy and the development plan to support the proposed product label, if applicable, are appropriate and well described.
    - To what degree the proposed collaborations and other resources for providing continuity of development are established and/or achievable.
    - Whether the schedule and milestones for bringing the anticipated research outcomes to the next level of development are achievable.
    - Whether the application demonstrates access to all intellectual property rights necessary for the next level of development or commercialization, and, if not, whether a plan for management of intellectual property is in place, including the Government's ability to access such products or technologies in the future.
    - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- **For applications including a pilot clinical trial:**
    - 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).
    - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or that the IND or IDE application (and/or international equivalent) has been submitted to the FDA and/or relevant international regulatory agency, as appropriate.
    - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.

- **Personnel**
    - To what extent the backgrounds and expertise of the PI and key personnel are appropriate to accomplish the proposed research project.
    - To what extent the levels of effort by the PI and key personnel are appropriate to ensure the success of this project.
    - How well the application describes how the SCI Lived Experience Consultant will be integrated into the research team. How well the application describes to what extent the input from the SCI Lived Experience Consultant will impact the research project.
    - How well the PI's record of accomplishments demonstrates their ability to accomplish the proposed research project.

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

- **Budget**
    - Whether the direct costs exceed the allowable direct costs as published in the Program Announcement.
    - Whether the budget is appropriate for the proposed research.
- **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.
- **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 FY20 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, USAMRDC, 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. An information paper describing the funding recommendations and review process for the award mechanisms for the 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 FY20 funds are anticipated to be made no later than September 30, 2021. 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.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

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.

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.

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 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 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.

The Award Terms and Conditions will specify if more frequent reporting is required.

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 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 501c. The Program Announcement numeric version code will match the General Application Instructions version code 501.

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.
- SCI Lived Experience Consultation Plan (Attachment 12) is missing.
- Translation Statement (Attachment 7) is missing.
- 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 FY20 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 FY20 SCIRP Programmatic Panel members can be found at https://cdmrp.army.mil/scirp/panels/panels20***

- 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 FY20, 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.
- An SCI Lived Experience Consultant is not included on the research team as required by this Program Announcement.
- The PI does not meet the eligibility criteria.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Translation Statement: Upload as Attachment 7 with file name "Translation.pdf"	
	Relevance to Military Health Statement: Upload as Attachment 8 with file name "Military.pdf"	
	Animal Research Plan: Upload as Attachment 9 with file name "AnimalResPlan.pdf" if applicable	
	Pilot Clinical Trial Plan: Upload as Attachment 10 with file name "ClinTrialPlan.pdf" if applicable	
	Regulatory Strategy: Upload as Attachment 11 with file name "Regulatory.pdf" if applicable	
	SCI Lived Experience Consultation Statement: Upload as Attachment 12 with file name "SCILivedExperience.pdf"	
	Transition Plan: Upload as Attachment 13 with file name "Transition.pdf"	

Application Components	Action	Completed
	Representations (extramural submissions only): Upload as Attachment 14 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 15 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person, including SCI Lived Experience Consultant to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DoD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDE	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator

RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SCI	Spinal Cord Injury
SCIRP	Spinal Cord Injury Research Program
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TRA	Translational Research Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs