Program Announcement for the Defense Health Agency

Spinal Cord Injury Research Program Clinical Trial Award

Funding Opportunity Number: HT942526SCIRPCTA

Pre-Application Due: August 03, 2026

Application Due: November 12, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Spinal Cord Injury Research Program (SCIRP) Clinical Trial Award (CTA) supports the rapid implementation of clinical trials with the potential to have a significant impact on the treatment or management of spinal cord injury (SCI).

Distinctive Features: This funding opportunity contains an **Early-Career Partnership Option**, which allows for two Principal Investigators (PIs). If this option is selected, at least one of the named PIs must be an early-career investigator. Only the Initiating PI will submit a pre-application, but all PIs will need to submit full applications. The Partnering PI's application is an abbreviated package specific to their distinct portion of the research project. If recommended for funding, each PI will be named on a separate award to the recipient organization(s). Be advised, all associated applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.

Applications to this funding opportunity must name at least two spinal cord injury (SCI) community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) who will provide advice and consultation throughout the planning and implementation of the research project.

****NEW for FY26**** An investigator may be named on only **one** FY26 SCIRP Clinical Trial Award application as a PI.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly **$9.76M** to fund approximately **2** Clinical Trial Award applications with total cost caps of **$4.8M** for a Single PI, or **$4.96M** for the Early-Career Partnership Option, per award. The maximum period of performance is **4** years. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 03, 2026
- **Invitation to Submit an Application:** September 18, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, November 12, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, November 16, 2026
- **Peer Review:** January 2027
- **Programmatic Review:** March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526SCIRPCTA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities*.**

2.1.2. Principal Investigator

Investigators affiliated with an eligible organization are eligible to be named as Principal Investigator (PI) on the application, regardless of ethnicity, nationality or citizenship status.

An investigator may be named on only **one** fiscal year 2026 (FY26) Spinal Cord Injury Research Program (SCIRP) Clinical Trial Award (CTA) application as a PI.

Single PI Option: Independent investigators at all career levels may be named by the organization as the PI on the application.

Early-Career Partnership Option: If this option is selected, ***at least one*** of the named PIs (Initiating or Partnering) must be an investigator with **at least three** years' research experience (independent or non-independent) beyond a terminal degree but **no more than seven** years within their first faculty appointment, or equivalent independent research position (excluding time spent on family medical leave). Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application. ***The other PI*** (Initiating or Partnering) may be an independent investigator at any career level.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Spinal Cord Injury Research Program (SCIRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the SCIRP in 2009 to provide support for traumatic spinal cord injury (SCI)-related research of exceptional scientific merit that has the potential to make a significant impact on improving the health and well-being of military Service Members, Veterans, and other individuals living with SCI. Appropriations for the SCIRP from FY09 through FY25 totaled $477.85 million (M). The FY26 appropriation is $33M.

Mission of the SCIRP: To fund research and encourage interdisciplinary collaborations for the development and translation of more effective strategies to improve the health and well-being of Service Members, Veterans, and other individuals with spinal cord injury

Vision of the SCIRP: Advance the treatment and management of spinal cord injury and ameliorate its consequences

The FY26 SCIRP challenges the scientific community to design research that will advance the development, translation, and ultimate adoption of health care solutions for people living with SCI, their families and/or care partners. The SCIRP encourages impactful and well-reasoned research across the continuum of care, at time of injury and throughout the lifespan. Additionally, to ensure alignment with current program priorities, applicants to SCIRP funding opportunities should consider the following:

- Innovative research that investigates new directions or addresses neglected issues in the field of traumatic SCI is supported, although studies focused exclusively on identifying intervention targets are discouraged.
- Mechanism-focused studies must be specific to SCI and demonstrate a clear path from increased understanding to advancing treatments.
- Applications proposing interventions must demonstrate a clinically feasible window for treatment and more than incremental improvement over existing therapies.
- Studies addressing critical questions essential for advancing research toward clinical use, such as study population selection, dosing and safety are allowable.
- Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is significant to Service Members, Veterans, their Families and the American public.

3.1. Program Priority Areas With Programmatic Goals

For FY26, the SCIRP identified near-term and long-term programmatic goals for program-supported research outcomes and products, which align to four key priority areas within the SCI field. ***Research supported by the FY26 SCIRP must address at least one of the program priority areas and undertake an associated near-team programmatic goal listed below.***

Additionally, applicants will be asked to describe the steps the research team will take to further advance the project's outcome(s)/product(s) in accordance with the long-term programmatic goal of the same priority area.

Priority Area: Acute Injury Intervention

- **Near-Term Goal:** Develop and/or test interventions, e.g., surgical, device, pharmacologic, that protect spinal cord tissue from further damage shortly after injury and can be administered on a timeline suitable for acute trauma care in both battlefield and civilian settings.
- **Long-Term Goal:** Adoption of management/stabilization practices into the standard of care for acute spinal cord injury, leading to meaningfully improved outcomes within the prehospital, hospital or deployed environments.

Priority Area: Secondary Health Effects

- **Near-Term Goal:** Develop and/or test interventions to prevent or manage the secondary health effects of spinal cord injury that impact injury survivors throughout their lifespan.
- **Long-Term Goal:** Adoption of interventions into the standard of care that significantly reduce the burden of secondary health effects and improve the lifelong health of SCI survivors.

Priority Area: Psychosocial Well-Being

- **Near-Term Goal:** Develop and/or test psychosocial interventions that are specifically tailored to the unique needs of individuals with SCI, their families and/or care partners.
- **Long-Term Goal:** Adoption of interventions into the standard of care that promote psychosocial well-being for people with SCI, their families and/or care partners.

Priority Area: Rehabilitation and Regeneration

- **Near-Term Goal:** Develop and/or test rehabilitation, regenerative or neuroplastic interventions for individuals with spinal cord injury that can be implemented at any stage of life post-injury.
- **Long-Term Goal:** Adoption of validated rehabilitation and regenerative therapies into the standard of care that meaningfully improve function, independence and quality of life after SCI.

3.2. Award History

The SCIRP Clinical Trial Award mechanism was first offered in FY09. Since then, 306 Clinical Trial Award applications were received, and 62 were recommended for funding.

3.3. Intent of the Clinical Trial Award

The SCIRP Clinical Trial Award mechanism supports the rapid execution and analysis of clinical trials with the potential to have a significant impact on the treatment or management of SCI. Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs, biologics or medical devices), clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (i.e., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant patient populations.

Alternative trial designs to traditional randomized clinical trials are allowed but should be appropriate to the objective of the trial. ***Utilization of decentralized clinical trial strategies that leverage virtual elements/tools for participant enrollment, communication, and data collection is especially encouraged.***

3.3.1. Key Elements for the CTA

- **Impact:** Applications must articulate how the proposed research will advance at least one of the FY26 SCIRP priority areas and help achieve its associated near-term programmatic goal identified in Section 3.1.
- **Early-Career Partnership Option:** To promote enhanced research capacity within the SCI field, the FY26 CTA includes an option specifically for partnership with or among early-career investigators. The Partnership Option is structured to accommodate two PIs who will work together on a single research project. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. At least one of the PIs (Initiating or Partnering) must be an early-career investigator. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on a separate award to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PIs, refer to Section 5.3, Submission Instructions.
- **Community-Informed Research:** Research funded by the FY26 SCIRP CTA must be responsive to the needs of people with SCI, their families and/or their care partners. To this end, applicants are encouraged to leverage patient perspectives research to inform the research question or study design of the proposed trial.

  Furthermore, research teams are also required to establish and utilize effective and equitable partnerships with SCI lived-experience community members to maximize the translation and impact potential of the proposed research. ***Applications to the FY26 SCIRP CTA are expected to name at least two community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) who will provide advice and consultation throughout the planning and implementation of the research project.*** For additional resources, see Community Collaboration below.

3.3.2. Other Important Considerations for the CTA

Allowable Research: Funding from this award mechanism must support a clinical trial. ***Preclinical research is not supported in this funding opportunity.*** Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 SCIRP funding opportunities that may be more appropriate for such research.

If the proposed research relies on access to unique 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.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

Project Timeline: The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the U.S. Food and Drug Administration (FDA) or any equivalent international regulatory agency.

If an Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or equivalent, is required, a regulatory application ***must be submitted to the relevant regulatory agency by the Clinical Trial Award application submission deadline.*** The regulatory application should be specific to the product and indication to be tested in the proposed clinical trial.

Use of Common Data Elements (CDEs): Use of the National Institute of Neurological Disorders and Stroke SCI CDEs is strongly encouraged for all human subject research.

Relevance to Military Health: To help elucidate the realities of treating and managing SCIs while in a deployed environment, a resource document is now available that outlines Spinal Cord Injury Management within the Military Health System (MHS). Applicants are encouraged to read and consider this document before preparing applications. Furthermore, applicants are encouraged to integrate and/or align their research projects with DOW and/or VA research laboratories and programs. Collaboration with the DOW and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI.

Community Collaboration: Collaborative research approaches, such as community-based participatory research, participatory action research, and integrated knowledge transition create partnerships between scientific researchers and community members to create knowledge useable by both sets of stakeholders. Recognizing the strengths of each partner, scientific researchers and community members ***collaborate and contribute equitably*** on all aspects of the project, which may include needs assessment, planning, research intervention design, implementation, evaluation and dissemination. ***Collaborative research approaches feature shared responsibility and ownership for the research project to ensure non-tokenistic involvement of community members within the research team.*** Research results are jointly interpreted, disseminated, fed back to affected communities, and may be translated into interventions or policy. These methods are critically important for community-level interventions and can also have important impacts on translational research and prototype development to identify and augment the potential impact of a research program on people living with SCI, their families and/or their care partners.

Collaborative relationships with consumers and the lived-experience community are often established through integrating community members into research teams as co-researchers, advisors and/or consultants. Some examples for implementing collaborative research approaches include:

- **Lived-Experience Consultation:** The research team includes at least one project advisor with lived SCI experience who will provide advice and consultation throughout the planning and implementation of the research project. Lived-Experience Consultants may include individuals with SCI, their family members and/or their care partners.
- **Partnership With a Community-Based Organization:** The research team establishes partnerships with at least one community-based organization that provides advice and

consultation throughout the planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policymakers or other formal organizational stakeholders.

- **Community Advisory Board Utilization:** A community advisory board is composed of multiple community stakeholders and can take many forms, from a board of Lived-Experience Consultants to a coalition of community-based organizations or any combination thereof. As with Lived-Experience Consultants and organizational partners, the community advisory board provides advice and consultation throughout planning and implementation of the research project.

Additional information on collaborative research approaches can be found here:

- Wallerstein, N. and Duran B. 2010. Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity. *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.
- Gainforth, H.L., F. Hoekstra, R. McKay, et al. 2021. Integrated knowledge translation guiding principles for conducting and disseminating spinal cord injury research in partnership. *Archives of Physical Medicine and Rehabilitation* 102(4):656-663. doi: 10.1016/j.apmr.2020.09.393.

3.4. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

3.5. Funding Details

Period of Performance: The maximum period of performance is **4** years.

3.5.1. Application Submissions With a Single PI

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$4.8M**.

3.5.2. Application Submissions With the Early-Career Partnership Option

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$4.96M**.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Any application that requests the higher level of funding and that does not include an eligible early-career PI will have its budget reduced as appropriate.

3.5.3. For Both Options Within This Award Mechanism

If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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 **4** years.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Costs for sharing data and research resources.
- Costs associated with collaborative research approach (e.g., consultant costs, equitable participation training, capacity-building activities).
- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving and resources/equipment to enable participation).
- Travel in support of multi-institutional collaborations.
- Costs for one investigator, per award, to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 SCIRP CTA.

Must not be requested for:

- Preclinical research costs.
- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Pre-Application Components

The PI, or Initiating PI if selecting the **Early-Career Partnership Option**, must submit the following pre-application components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

- **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/Rationale:** State the scientific rationale on which the proposed research project is based. Clearly demonstrate that there is sufficient rationale, background data and readiness to support the initiation of the proposed clinical trial. ***Indicate how the research question or study design is informed by the lived-experience community and/or patient perspectives research.***
  - **Specific Aims and Study Design:** Concisely state the specific aims for the clinical trial and describe the scientific approach to address them. Indicate whether alternative trial designs to traditional randomized clinical trials will be utilized and how the approach is appropriate to the objective of the trial. If applicable, describe the decentralized clinical trial strategies to be leveraged, including virtual elements/tools for participant enrollment, communication and data collection. It should be evident that the proposed study meets the definition of a clinical trial.
  - **Impact:** Describe the potential impact of the proposed research on at least one of the FY26 priority areas. Indicate how the proposed research will address a near-term programmatic goal identified in Section 3.1.
  - **Relevance to Military Health:** Describe whether/how the proposed research project is applicable to spinal cord-injured military Service Members, Veterans, and/or their Family members and care partners. Applicants are encouraged to review the Relevance to Military Health section of this program announcement prior to preparing this section.

- **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.

4.3. Full Application Components

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

Early-Career Partnership Option: The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

4.3.1. Full Application Components for the PI or Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

***IMPORTANT*: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.**

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below. It should be evident that the proposed study meets the definition of a clinical trial.

  - **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature and completed/ongoing studies relevant to the proposed clinical trial. This section should establish the relevance of the study and explain the applicability of the proposed findings to the SCI community and at least one of the FY26 SCIRP Program Priorities and associated near-term goal.
    - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial. Include community/patient perspectives data to support the rationale and study design.

- Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.
- Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs.

If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source(s) of prior funding. Identify the specific portions of the study that will be supported with funds from this award.

– **Intervention:** Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, behavioral, surgical, etc.), complete name and composition, source, general concept of design, administration route. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation, demonstrating the study team's access to the intervention(s) for the duration of the clinical trial. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.

– **Objectives, Specific Aims and Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question. Only describe aims that the SCIRP award would fund.

– **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations for what study participants will experience. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

- Describe the type of study to be performed. Alternatives to traditional randomized clinical trial designs are supported by this funding mechanism. Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person not involved in the study to understand what the study participant will experience. If applicable, describe the decentralized clinical trial strategies to be leveraged, including virtual elements/tools for participant recruitment/enrollment, intervention administration/delivery and/or outcome data acquisition.
- Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected along with the collection schedule and amount. Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number

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

- Define all endpoints/outcome measures relevant to the objectives of the study; explain why they were chosen, and describe how, when, and where they will be measured. Where applicable, describe the SCI CDEs to be collected. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include a copy of them in Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoints/outcome measures and evaluations, along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).
- Briefly describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Additional details should be provided in Attachment 6: Study Population Recruitment and Safety Plan.
- Explain how the study design is appropriate to achieve the objectives of the trial.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information
- For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.

– **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).

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; include any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized 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.

Letters of Support (two-page limit per letter is recommended): Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.

Research Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

Do not submit a copy of the National Institutes of Health Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

Questionnaires and Other Research Data Collection Instruments: Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides or other instruments. This should include any drafts that are currently in use or underdevelopment.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the ideas and rationale behind the proposed clinical trial.
- **Hypothesis/Objective(s):** State the objective of the proposed clinical trial and the hypothesis/research question to be addressed.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Briefly describe the impact of this study on one or more FY26 SCIRP priority areas. Indicate how the proposed research will address a near-term programmatic goal identified in Section 3.1.
- **Military Relevance:** Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

- Summarize the objectives and rationale for the proposed clinical trial.
- Describe the intervention(s).
- What population will the research help, and how will it help them?
- What are the expected clinical applications and potential risks of the anticipated outcomes?
- Describe how the proposed study will directly address an FY26 SCIRP priority area and contribute to the associated near-term programmatic goal identified in Section 3.1.
- Describe the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or their Families.

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

Include the name(s) of the key personnel and contact information for each study site/ subaward site. The contributions of the key personnel, including the PI or Initiating PI,

Partnering PI (if applicable), and SCI Lived-Experience Consultants or community partners, should be noted for each task.

Early-Career Partnership Option: Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 6: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.

  Enrollment Distribution: Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.

  Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history or physical examination) that are required to determine eligibility/ suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.

  Study Population Availability: Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, Appendix 4, for additional considerations.

  Recruitment and Retention Process: Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to

clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.

Women and Minorities Recruitment/Retention Strategy: Describe the strategy for recruitment, enrollment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.

Informed Consent Process: Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the GAI contains additional considerations unique to DOW-sponsored research.

Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
- **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the Institutional Review Board (IRB) and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the costs of such care.
- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 7: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Follow the instructions and provide supporting documentation as applicable.

  State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

  Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information about this attachment is required.

  For products that require regulation by a Regulatory Agency:

  Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the regulatory application submission strategy.

- 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.
- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 SCIRP Clinical Trial Award 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 include an indication to be tested in the proposed clinical trial. Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.
- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research; include key outcomes, action items and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If the 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).

- **Attachment 8: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.

  Organizational Chart: Provide an organizational chart that identifies key members of the study team and an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers, and/or departments, and name each person's position on the project; include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s) and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.

  Study Personnel Description: Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial. ***Highlight how the study team composition provides military-relevant subject matter expertise to the proposed research, if applicable.***

  - **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than

one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens, and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Partnership Statement *(Early-Career Partnership Option only):*** Describe the experience of the Initiating and Partnering PIs, and indicate how the award will help to enhance research capacity within the SCI field. Describe the contribution and the time commitment of each PI toward the proposed research project. Describe how the partners' combined experience will better address the research question, and explain why the work should be done together rather than through separate efforts.

- **Attachment 9: Impact Statement (two-page limit): Upload as "Impact.pdf".** The impact statement summarizes the potential short- and long-term impact of the proposed clinical trial for the SCI lived-experience community and for the broader SCI research field. The statement should address the points outlined below written ***in a manner that will be readily understood by readers without a background in science or medicine*.**

  Detail the anticipated research outcome(s) that will be directly attributed to the results of the proposed clinical trial and describe the anticipated benefits of these outcomes for individuals with SCI and the broader SCI research field. Explain how the proposed project will advance at least one of the FY26 SCIRP priority areas and help achieve its associated near-term programmatic goal, as identified in Section 3.1.

  To demonstrate how the study is grounded in the needs of the SCI community, describe how the lived-experience community and/or patient perspectives research informed the research question or study design. Describe any relevant controversies, treatment issues or health disparities that will be addressed by the proposed clinical trial.

  Explain how the implementation or dissemination of research outcomes and findings will directly improve patient care and/or the quality of life for individuals with SCI. Describe how the intervention is an improvement over currently available interventions or standards of care.

  If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

  Describe whether/how the proposed research project is applicable to the unique health care needs and quality of life concerns of spinal cord-injured military Service Members, Veterans, and/or their Family members and care partners. Applicants are encouraged to review the Relevance to Military Health section of this program announcement prior to preparing this section.

- **Attachment 10: Long-Term Goal (two-page limit): Upload as "Longterm.pdf".** The purpose of this attachment is to create a high-level roadmap detailing the steps needed to eventually translate outcomes of SCIRP-funded research into the standard of care, consistent with the long-term programmatic goals of the FY26 SCIRP. The long-term goal attachment should include the points listed below.

  Near-term Action: Outline the immediate next steps to be taken by the research team upon successful completion of the proposed research project, including plans for dissemination of results, further outcome validation if applicable, and engagement with end-users (e.g., patients, clinicians).

Intermediate Objectives: Discuss the unresolved questions that must be answered for the outcome to be adopted within the standard of care in enough detail to demonstrate a realistic understanding of the primary barriers to adoption. Consider the following questions as a starting place:

- What additional research is necessary?
- What is the likely regulatory pathway?
- What is the commercial potential of the outcome?
- What is the intellectual property strategy? If the intellectual property rights are not owned by the study team, how will the final product become accessible to the SCI community?

Long-Term Strategy: Describe the long-term implementation and adoption strategy for the research outcome, outlining key milestones on the path to adoption.

Identify the key collaborations (e.g., clinical partners, commercial entities, patient groups, professional societies) required to execute the strategy. Be specific about the types of partners needed, and name them if possible.

Concisely explain how successfully executing this strategy will lead to the integration of the research outcome into the standard of care and directly fulfill the specific long-term programmatic goal for the relevant FY26 SCIRP priority area.

- **Attachment 11: Community Collaboration Plan: Upload as "Collaboration.pdf".**

Community Collaboration Statement (four-page limit recommended): For the FY26 SCIRP CTA, research teams are required to establish and utilize effective and equitable collaborations and partnerships with the SCI lived-experience community to maximize the translational and impact potential of proposed research. More detailed description and expectations of these collaborations/partnerships is included in Section 3.3.2.

Include the names of at least two community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) who will provide advice and consultation throughout the planning and implementation of the research project. The individuals' role in the project should be independent of their employment.

Describe the collaborative research approach that will be used (e.g., lived-experience consultation, partnership with community-based organization, community advisory board, co-researcher model), including a justification for the approach as well as when the approach will be used within the research project.

Detail the community partner's contributions to the research process thus far, as well as the framework for capturing future input. Explain how this input will be meaningfully integrated to inform each phase of the research lifecycle, including needs assessment, planning, design, execution, analysis and dissemination.

Detail the resource allocation and decision-making processes to be employed.

Describe any training that will be provided to both scientific researchers and community members on collaborative research approaches, decision-making and equitable participation.

Describe co-learning and capacity-building activities among all partners.

Outline the process measures to assess the effectiveness of the chosen collaborative research approach.

Letters of Community Collaboration (two-page limit per letter recommended): Provide a letter signed by each community partner (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) confirming their role and commitment to participate on the research team. If a community-based organization will be engaged, the letter of commitment should be signed by BOTH the organization's point of contact leading the engagement and the organization's leadership endorsing the collaboration, if different from the point of contact. The letter should include the qualifications and background of the individual and describe the relevance of those qualifications to the individual's role within the team and to the proposed research project.

- **Attachment 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org

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

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*:

(b) Attachments:

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Additional Application Materials:

The following are additional application materials for application submission. Follow the instructions specific to the submission portal found within the GAI.

Grants.gov	eBRAP.org

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

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed *budget information.*

iii. Project/Performance Site Location(s) Form

iv. Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526SCIRPCTA from Grants.gov or eBRAP, depending on which submission portal will be used.

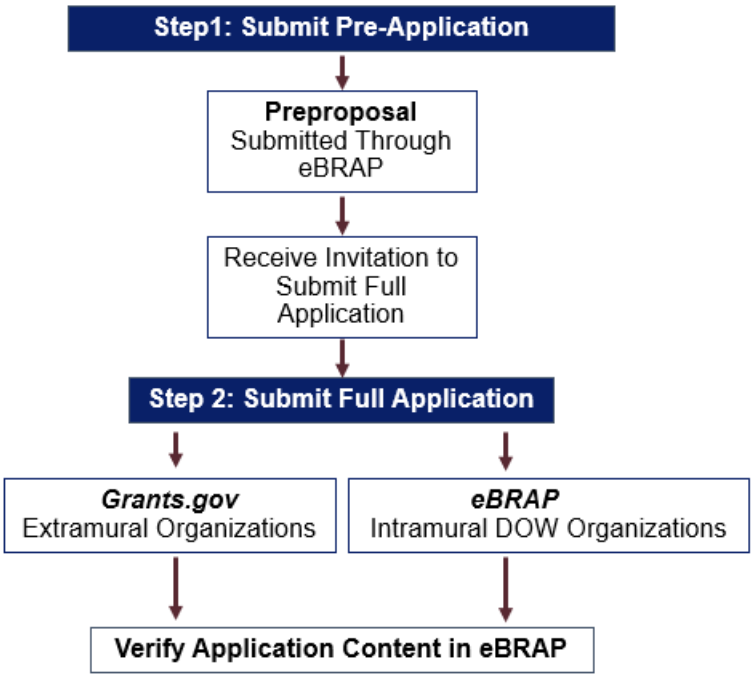
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting the Early-Career Partnership Option.

At least two community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) must be named as part of the pre-application submission. The community partners' roles in the project should be independent of their employment. For administrative purposes, select "Consumer" when assigning the community partners' roles in eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, 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. Contact the eBRAP Help Desk if any changes need to be made.

Early-Career Partnership Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.
- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Single PI	No Option
Early-Career PI and other PI	CTA With Early-Career Partnership Option

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the***

application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

Submitting applications that 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).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal.

Members of the FY26 SCIRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic Panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 SCIRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the SCIRP, pre-applications will be screened based on the following criteria:

- **Funding Mechanism:** How well the clinical trial adheres to the intent of the funding mechanism.
- **Background/Rationale:** How well the background and scientific rationale demonstrate sufficient evidence to support the proposed clinical trial. To what extent the research question or study design is informed by the lived-experience community and/or patient perspectives research.
- **Specific Aims and Study Design:** How well the specific aims are stated and supported through scientific rationale and how well the proposed research project's approach will address these aims. To what extent decentralized clinical trial strategies will be leveraged within the study.
- **Impact:** How well the proposed research project addresses one or more FY26 SCIRP Priority Areas and will make important contributions toward achieving a near-term programmatic goal.

- **Relevance to Military Health:** To what extent the proposed research project will directly or indirectly benefit spinal cord-injured military Service Members, Veterans, and/or their Family members and care partners.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, listed in decreasing order of importance***:***

- **Study Design**
  - How well the scientific rationale for the proposed clinical trial is supported by the review and analysis of the available literature and completed/ongoing studies.
  - How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures and evaluations are designed to address the clinical objective and purpose of the study.
  - How well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - To what extent the strategy for recruitment and retention of women and minorities in the clinical trial is appropriate to the objectives of the study.
  - Whether the distribution of the proposed enrollment on the basis of age, sex, race, and/or ethnicity is appropriate for the proposed research.
  - If applicable, whether the justification for limiting inclusion of any demographic group, including sex, is sufficiently strong.
  - If applicable, whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).
  - If applicable, how well the clinical trial will leverage alternative trial designs to traditional randomized clinical trials, including but not limited to decentralized clinical trial strategies such as virtual elements/tools for participant recruitment/enrollment, intervention administration/delivery, and/or outcome data acquisition.
  - If applicable, how well the application demonstrates utilization of the SCI CDEs.
- **Feasibility**
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - To what degree the planned route and schedule of study intervention(s), evaluation(s), and follow-up procedures are reasonable for study participants to experience.
  - Whether there is evidence indicating availability of the intervention from its source for the duration of the proposed clinical trial (if applicable).
  - To what degree the plan for recruiting, enrolling, and retaining study participants is reasonable to meet the needs of the proposed clinical trial.
  - To what degree the number of study participants to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/exclusion criteria, and planned efforts to achieve accrual goals.
  - To what extent potential challenges and alternative strategies for the study are discussed and planned for, including slow/low enrollment, and poor retention.

- **Clinical Impact**
  - To what extent the anticipated outcomes of the proposed clinical trial would benefit the SCI community with regard to at least one FY26 SCIRP Priority Area and help achieve its associated near-term programmatic goal.
  - To what extent the study addresses current clinical need(s), improves upon available interventions and/or standards of care, or addresses controversies, treatment issues or health disparities within the field.
  - To what degree the lived-experience community, including community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations), and/or patient perspectives research informed the research question or study design.
  - How well the Community Collaboration Plan is designed to meaningfully integrate input from the community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) into the needs assessment, planning, design, execution, analysis and/or dissemination of the research.
  - To what degree the proposed research project is applicable to the unique health care needs and quality of life concerns of injured military Service Members, Veterans, and/or their Family members and care partners.
  - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power for the study, and as applicable, any subgroup analysis.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study, or whether the justification for a single-sex study is sufficiently strong.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race, and/or ethnicity are appropriate for the proposed research.
- **Long-Term Goal**
  - To what extent the application provides a credible and comprehensive strategy to eventually translate outcomes of the research into the standard of care, consistent with the long-term programmatic goals of the FY26 SCIRP.
  - Whether immediate next steps to be taken by the research team upon successful completion of the proposed research project are articulated and appropriate.
  - To what degree the discussion of unresolved questions that must be answered for the research outcome to be adopted within the standard of care demonstrates a realistic understanding of the primary barriers to adoption.
  - How well the implementation and adoption strategy details a clear, logical, and feasible roadmap with high potential to translate the research outcome into a product or clinical practice within the standard of care; and to what extent key collaborations are identified and appropriate to the plan.

- **Personnel and Communication**
  - To what degree the composition of the study team, including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate, military-relevant subject matter expert), is appropriate to accomplish the proposed work.
  - To what degree the levels of effort by the PI, Partnering PI (if applicable), and other key personnel are appropriate for successful conduct of the proposed trial.
  - To what degree the qualifications and background of the community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) are relevant to their roles within the team and to the proposed research project.
  - To what degree the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional structure governing the research protocol[s]) are appropriate and meet the needs of the proposed study.
  - **Early-Career Partnership Option:** How the partners' combined expertise will better address the research question, and to what extent the award will help to enhance research capacity within the SCI field.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - How the level of risk to human subjects is minimized, and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree the process of seeking informed consent is appropriate, and whether safeguards are in place for vulnerable populations.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
  - If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.
- **Regulatory Strategy**
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, or that the IND or IDE application (and/or international equivalent) has been submitted to the 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.
- **Research Sharing Plan**
  - To what extent the plan for sharing project data and research resources is appropriate and reasonable, and includes dissemination to affected communities, study participants and the scientific community. If applicable, which specific repository(ies) were designated for storing project data and research resources?

- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

6.2.3. 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 peer reviewers
- Relevance to the priorities of the FY26 SCIRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Relative impact
  - Program portfolio composition
  - Relevance to military health

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs and Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information About the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full 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.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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.

6.4. Risk, 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 200.1, 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 SAM.

An applicant organization may review the SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the SCIRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website. After all awards are made, the CDMRP includes individual award information in a searchable database.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed DHACA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intragovernmental obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOW organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD) or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOW investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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.

8. Post-Award Requirements

8.1. 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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review.

8.2. Reporting

Quarterly reports, annual technical reports and quad charts, as well as a final technical report and quad chart, will be required. Technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

Enrollment reporting on the basis of sex, race and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available in eBRAP.

An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Awards resulting from this program announcement may entail 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 $10M are required to provide information to the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil and administrative proceedings as specified in the applicable Representations.

8.3. Additional Requirements

PIs are expected to participate in at least one Interim Progress Review (IPR) for the funded project. For planning purposes, PIs can expect that the IPR will last no longer than one day and will be hosted virtually by the SCIRP. The invitation and format for the IPR will be provided by the Grants Officer's Representative at least 90 days prior to the scheduled IPR date.

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, 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.

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the full application:

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not issued.
- Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- Regulatory Strategy (Attachment 7) is missing.
- Study Personnel and Organization (Attachment 8) is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY26 SCIRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.

- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The invited application proposes a different research project than that described in the pre-application.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The proposed research is not a clinical trial.
- The proposed project includes preclinical research.
- An IND or IDE application and/or international equivalent has not been submitted prior to the application submission deadline for a study regulated by a relevant regulatory agency.
- The PI is named on more than one FY26 SCIRP Clinical Trial Award application.
- The PI, Initiating PI, or Partnering PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- Two community partners (e.g., SCI Lived-Experience Consultants, representatives of community-based organizations) are not included on the research team as required by this program announcement.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP submissions only)***	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Study Population Recruitment and Safety Plan – Attachment 6, upload as "StudyPopPlan.pdf"	☐	
Regulatory Strategy – Attachment 7, upload as "Regulatory.pdf"	☐	
Study Personnel and Organization – Attachment 8, upload as "Personnel.pdf"	☐	
Impact Statement – Attachment 9, upload as "Impact.pdf"	☐	
Long-Term Goal – Attachment 10, upload as "Longterm.pdf"	☐	
Community Collaboration Plan – Attachment 11, upload as "Collaboration.pdf"	☐	
Representations ***(Grants.gov submissions only)*** **– Attachment 12, upload as "RequiredReps.pdf"**	☐	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 13, upload as "IGBudget.pdf"**	☐	☐
Additional Application Materials		
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐	☐
Research & Related Budget	☐	☐
Project/Performance Site Location(s)	☐	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting of In Vivo Experiments
CDE	Common Data Elements
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTA	Clinical Trial Award
CONSORT	Consolidated Standards of Reporting Trials
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	Interim Progress Review
IRB	Institutional Review Board
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management

SCI	Spinal Cord Injury
SCIRP	Spinal Cord Injury Research Program
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs