I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Clinical Trial Award

Announcement Type: Initial

Funding Opportunity Number: HT942524SCIRPCTA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 20, 2024
- **Invitation to Submit an Application:** July 5, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 30, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, September 4, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the Fiscal Year 2024 (FY24) Spinal Cord Injury Research Program (SCIRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. 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 FY23 totaled $437.85 million (M). The FY24 Defense Appropriations Act provides $40M to the SCIRP through the appropriation for peer-reviewed spinal cord research.

The vision of the SCIRP is to advance the treatment and management of SCI and ameliorate its consequences. The FY24 SCIRP challenges the scientific community to design research that will advance the development or translation of health care solutions for people living with SCI. Innovative research that fosters new directions or addresses neglected issues in the field of traumatic SCI is also supported, although studies focused exclusively on target identification are discouraged. ***The SCIRP encourages impactful research across the continuum of care from time of injury and across the life span that is well reasoned and scientifically supported.***

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. 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 of significance to Service Members, Veterans, their Families and/or care partners.

II.A.1. FY24 SCIRP Focus Areas

To meet the intent of the funding opportunity, applications to the FY24 SCIRP Clinical Trial Award (CTA) must address at least one of the Focus Areas listed below. Applications may address more than one Focus Area. In particular, applications combining biomarker studies with studies in one or more of the other Focus Areas are encouraged. Applications using clinically relevant combinations of interventions within or across Focus Areas are also encouraged. The FY24 SCIRP Focus Areas are:

- **Preserving and protecting spinal cord tissue at time of injury for improved neurologic outcomes**
    - Responsive projects may include surgical and acute care management of SCI, especially within the battlefield/deployed environment.

- Therapeutics (devices and pharmacologic interventions) to stabilize SCI in the prehospital environment and during transport are encouraged.

- Applications proposing neuroprotective interventions need to demonstrate a clinically feasible window for treatment and more than an incremental improvement over existing therapies.

- **Identifying and validating biomarkers for diagnosis, prognosis, and evaluation of treatment efficacies**

  - To be responsive to this Focus Area, biomarker identification or validation must be the primary focus of the proposed research.

  - Biomarkers must focus on diagnosis, prognosis, progression, and/or recovery of SCI.

  - Projects with a clear link between a biomarker and underlying physiology are encouraged. Projects can include imaging and other modalities.

  - Applications should demonstrate a clear path to clinical use.

  - Biomarker studies directed at identifying the best single or combination of treatments for individuals (personalized medicine) are encouraged.

- **Developing, testing, and validating promising interventions to address bowel, genitourinary, neuropathic pain, cardiopulmonary or autonomic dysfunction across the life span of people with SCI**

  - Mechanism-focused studies must be specific to SCI and demonstrate a clear path from increased understanding to advancing treatments.

  - Studies addressing the needs of and treatments for individuals with SCI across the full life span from acute to chronic injury are encouraged.

- **Investigating psychosocial issues relevant to people with SCI, their families, and/or their care partners across the life span**

  - To be responsive to this Focus Area, psychosocial issues must be the primary focus of the research.

  - Projects should provide an understanding of critical factors promoting psychosocial well-being leading to implementation of potential treatments and interventions.

  - Studies addressing social isolation, loneliness, and depression, as well as resilience, self-efficacy, sexuality and intimacy, and interactions between people living with SCI and their care partners, are especially encouraged.

  - Applications should consider or directly address the needs of Service Members and Veterans across the life span.

- Preclinical animal studies are not responsive to this Focus Area.

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

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

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

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

II.A.2. Award History

The SCIRP CTA mechanism was first offered in FY12. Since then, 274 CTA applications have been received, and 56 have been recommended for funding.

II.B. Award Information

The SCIRP CTA supports the rapid implementation of clinical trials with the potential to have a significant impact on the treatment or management of SCI. Applications should articulate both the short- and long-term impact of the proposed research on individuals with SCI and/or their care partners. The proposed intervention(s) to be tested should offer significant potential impact for individuals affected by SCI within the context of one or more of the FY24 SCIRP Focus Areas.

Clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies. Proposed projects may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate feasibility or inform the design of more advanced trials through large-scale trials to determine efficacy in relevant 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.***

The proposed research must be relevant to active-duty Service Members, their Families, Veterans, and/or the American public. To help elucidate the realities of treating and managing SCIs while deployed, a resource document is now available on the CDMRP website that outlines **Spinal Cord Injury Management Within the Military Health System (MHS).** Applicants are encouraged to read and consider this document before preparing their applications. The resource can be accessed at https://cdmrp.health.mil/scirp/pdfs/Beginner's%20Guide%20to%20Military%20Health%20System.pdf.

Employing community collaborations to optimize research impact is required. Research funded by the FY24 SCIRP CTA should be responsive to the needs of people with SCI, their families, and/or their care partners. Research teams are therefore required to establish and utilize effective and equitable collaborations and partnerships with community members to maximize the translational and impact potential of the proposed research. Applications to the FY24 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 (see Attachment 5, Collaborative Research Plan).

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 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 HL, Hoekstra F, McKay R, 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.

Early-Career Partnership Option: The FY24 SCIRP encourages applications that include meaningful and productive collaborations between investigators. To promote enhanced research capacity within the SCI field, the FY24 CTA includes an option specifically for Partnership with an Early-Career investigator. 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.*** The PIs may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. 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 separate awards to the recipient organization(s). For individual submission requirements for the Initiating PI and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

Funding from this award mechanism must support a clinical trial. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Applications proposing work that does not meet the definition of a clinical trial may be more suited to one of the other FY24 SCIRP program announcements being offered: FY24 Investigator-Initiated Research Award (Funding Opportunity Number HT942524SCIRPIIRA), FY24 Translational Research Award (Funding Opportunity Number HT942524SCIRPTRA), or FY24 Clinical Translation Research Award (Funding Opportunity Number HT942524SCIRPCTRA).

For more information, a Human Subject Resource Document is provided at https://cdmrp.health.mil/pubs/pdf/Human%20Subjects%20Resource%20Document_DEC2022.pdf.

Key aspects of the SCIRP CTA Mechanism:

- **Clinical Trial Start Date:** 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 a Regulatory Agency.

- **Preliminary Data Are Required:** Inclusion of preliminary data relevant to the proposed clinical trial is required.

- **Study Population:** The application should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study. The application should include a discussion of how accrual goals will be achieved, as well as the strategy for inclusion of women and minorities in the clinical trial appropriate to the objectives of the study. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Intervention Availability:** The application should demonstrate the documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate, for the proposed duration of the study.

- **Personnel and Environment:** The application should demonstrate the study team's expertise and experience in all aspects of conducting clinical trials, including appropriate statistical analysis, knowledge of Food and Drug Administration (FDA) processes (if applicable), and data management. The application should include a study coordinator(s) who will guide the clinical protocol through the local IRB of record and other federal agency regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual. The application should show strong institutional support and, if applicable, a commitment to serve as the FDA regulatory sponsor, ensuring all sponsor responsibilities described in the 21 CFR 312, Subpart D, are fulfilled.

- **Statistical Analysis and Data Management Plans:** The application should include a clearly articulated statistical analysis plan, a power analysis reflecting sample size projections that will answer the objectives of the study, and a data management plan that includes use of an appropriate database to safeguard and maintain the integrity of the data. If required by a Regulatory Agency, the trial must use a 21 CFR 11-compliant database and appropriate data standards.

- **Use of Common Data Elements (CDEs):** Use of the SCI CDEs developed through the collaboration of the International Spinal Cord Society, the American Spinal Injury Association, and the National Institute of Neurological Disorders and Stroke CDE team, as referenced at https://commondataelements.ninds.nih.gov/Spinal%20Cord%20Injury is strongly encouraged for all human subjects research.

- **Nuclear Medicine:** Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve

diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

- **Women's Health:** CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

For the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.

If the proposed clinical trial involves the use of a drug that has not been approved by the relevant Regulatory Agency for the country where the research will be conducted, then submission of an Investigational New Drug (IND) application, or equivalent, that meets all requirements under 21 CFR 312 may be required. It is the responsibility of the applicant to provide evidence from the IRB of record or the relevant Regulatory Agency if an IND, or equivalent, is not required. If an IND, or equivalent, is required, the regulatory application ***must be submitted to the relevant regulatory agency by the FY24 CTA application submission deadline.*** The IND, or equivalent, should be specific for the product and indication to be tested in the proposed clinical trial. For more information on IND applications specifically, the FDA has provided guidance at https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application.

If the investigational product is a device, then submission of an Investigational Device Exemption (IDE), or equivalent, application that meets all requirements under 21 CFR 812 may be required. It is the responsibility of the applicant to provide evidence if an IDE, or equivalent, is not required. If an IDE, or equivalent, is required, the IDE application, or equivalent, ***must be submitted to the relevant Regulatory Agency by the CTA application submission deadline.*** The IDE, or equivalent, should be specific for the device and indication to be tested in the proposed clinical trial.

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 SCIRP CTA should not exceed **$3,000,000 or $3,100,000** for the Early-Career Partnership Option. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $14.56M to fund approximately three CTA applications. 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. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization:

Extramural and Intramural organizations are eligible to apply, including foreign or domestic institutions, for-profit and nonprofit organizations, and public entities.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

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

II.C.1.b.i. Single PI Option

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

II.C.1.b.ii. Early-Career Partnership Option

If exercising the Early-Career Partnership Option, ***at least one*** of the named PIs (Initiating or Partnering) must be an investigator with **at least 3** years research experience (independent or non-independent) beyond a terminal degree but **no more than 7** 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.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

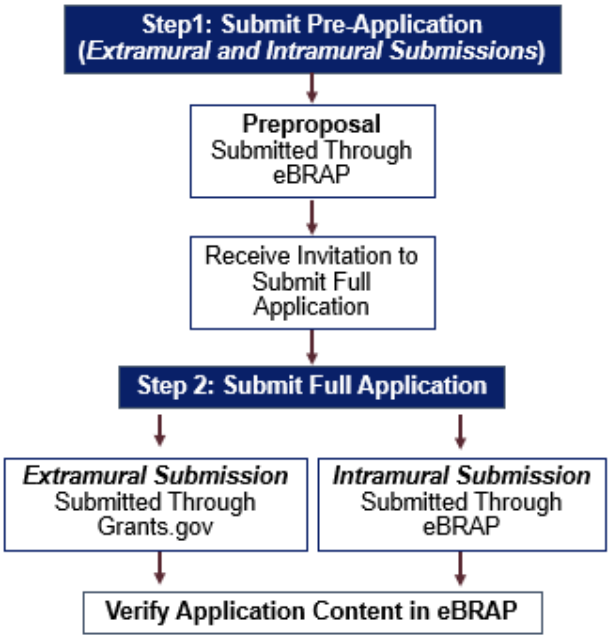
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524SCIRPCTA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524SCIRPCTA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

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).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

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. Refer to the General Application Instructions Appendix 7, Section B.

FY24 SCIRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI if exercising the **Early-Career Partnership Option**.

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

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 link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

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 complete these steps as soon as possible. If they are not completed:

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

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

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

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (three-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. Specify the intervention to be investigated and indicate the phase of the study and/or class of device, as appropriate.

  - **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. Describe plans for subject recruitment and retention.

  - **Impact:** Describe the impact of this study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY24 SCIRP Focus Areas.

- **Relevance to Military Health:** Describe how the proposed research project is applicable to spinal cord-injured military Service Members, Veterans, and/or their Family members and care partners. Applicants are encouraged to read and consider the resource document Spinal Cord Injury Management Within the Military Health System (MHS) when 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.

  - **Key Personnel Biographical Sketches (six-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

    Biographical sketches, or an equivalent document, should also be included for community partners (e.g., SCI Lived Experience Consultants, representatives of community-based organizations) to demonstrate background and experience relevant to their role in the proposed research project. ***At least two community partners (e.g., SCI Lived Experience Consultants, representatives of community-based organizations) must be named on the pre-application***; failure to do so may result in administrative withdrawal of the application. The community partners' roles in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. (For administrative purposes, please use the label "Consumer" when assigning the community partners' roles in eBRAP.)

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the SCIRP, pre-applications will be screened based on the following criteria:

- **Background/Rationale:** How well the background and scientific rationale demonstrate sufficient evidence to support the proposed clinical trial.

- **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.

- **Impact:** How well the proposed research project addresses one or more FY24 SCIRP Focus Areas and will make important contributions toward the goals of advancing SCI research, patient care, and/or improving quality of life.

- **Relevance to Military Health:** How well the proposed research project directly or indirectly benefits spinal cord-injured military Service Members, Veterans, and/or their Family members and care partners.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, 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 I, Overview of 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.

II.D.2.b. Step 2: Full Application Submission

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components for the PI or Initiating PI

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. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. ***All***

associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B., for detailed information.

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 7-11 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

  Describe the proposed project in detail using the outline below.

  - **Background:** Describe in detail the scientific rationale for the study. Provide a literature review and analysis. Describe the preliminary studies and/or preclinical data that led to the development of the proposed clinical trial. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings to at least one of the FY24 SCIRP Focus Areas.

    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 of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.

- **Study Design:** Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Alternative trial designs to traditional randomized clinical trials are supported by this funding mechanism. Explain how the study design 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 recruitment/enrollment, intervention administration/delivery, and/or outcome data acquisition. Outline the proposed methodology in sufficient detail to show a clear course of action.

    - Identify the intervention to be tested and describe the projected results. Additional details should be provided in Attachment 7: Intervention.

    - Define the primary and any secondary or interim endpoints/outcome measures, outline why they were chosen, and describe how and when they will be measured. Include a description of appropriate controls. Where applicable, describe the SCI CDEs to be collected. Outline the timing and procedures planned during the follow-up period.

    - Briefly describe and justify the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial.

    - Briefly describe the methods that will be used to recruit a sample of human subjects from the accessible population. Additional details should be provided in Attachment 8: Human Subject Recruitment and Safety Procedures. If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD 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. Refer to the General Application Instructions, Appendix 4, for additional considerations.

    - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

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

    - If using psychometric measures, describe their reliability and validity.

    - Describe potential challenge areas and discuss alternative methods/approaches that may be employed to overcome them. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. For phase 3 clinical trials, describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

  - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

  - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

  - **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming that each PI meets eligibility criteria and has access to laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program

announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)***: Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Commercial Entity Letters of Commitment *(if applicable)*:** If the proposed study involves use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the proposed clinical trial, support for the proposed phase of research, and support for the indication to be tested.

- **Inclusion Enrollment Plan:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Quad Chart:** Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at https://ebrap.org/eBRAP/public/Program.htm.

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

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

- **Attachment 3: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only

characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- Describe the ultimate applicability and impact of the research to the SCI community.
- Summarize the objectives and rationale for the proposed study and intervention.
- What population will the research help, and how will it help them?
- What are the potential clinical applications, benefits, and risks of the anticipated outcomes?
- What is the projected time it may take to achieve a person-related outcome?
- What are the likely contributions of the proposed research project to advancing the field of SCI research, patient care, and/or quality of life?

- **Attachment 4: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the Lay Abstract.***

  Technical abstracts should be written 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 hypothesis to be tested and/or objective(s) to be reached. Provide evidence or rationale that supports the hypothesis/objective(s).
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design, including appropriate controls.
  - **Impact:** Briefly describe the short- and/or long-term impact of this study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the FY24 SCIRP Focus Areas.

- **Attachment 5: Collaborative Research Plan: Upload as "Collaboration.pdf".**

  Collaborative Research Statement (four-page limit): For the FY24 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 II.B.

- 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, and they cannot be employees of any of the organizations participating in the application.

- 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.

- Indicate the input from the community partner that has already and/or will be captured and how this input has and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.

- 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): 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 point of contact leading the engagement along with 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 6: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

For the CTA mechanism, refer to the ***"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"*** for guidance on preparing the SOW. Use the ***"Suggested SOW Format"*** to develop the SOW for the proposed research. Submit as a PDF.

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

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

- Indicate the number (and type, if applicable) of research subjects projected or required for each task and at each site. Allocate time within the period of performance to obtain local IRB and USAMRDC Office of Human and Animal Research Oversight (OHARO) approvals. Refer to the General Application Instructions, Appendix 6, for additional information regarding regulatory requirements.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets at all sites.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND/IDE applications) by the FDA or other government agency.

Early-Career Partnership Option: ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.***

- **Attachment 7: Intervention (no page limit): Upload as "Intervention.pdf".** The Intervention attachment should include the components listed below.

  - **Description of the Intervention:** Identify the intervention to be tested and describe the particular outcomes. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care. As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include general concept of design, detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial. Summarize key preclinical pharmacological findings, dosage studies,

and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

- **Study Procedures:** Describe the interaction with the human subject, including the study intervention that they will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Address any 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). Describe measures to ensure consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions). Clearly delineate research procedures from routine clinical procedures. 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. Discuss how compliance with current Good Laboratory Practice (GLP) and Good Manufacturing Practices (GMP) guidelines and other regulatory considerations will be established, monitored, and maintained, as applicable.

- **Laboratory Evaluations:** State the biospecimen that will be collected along with the collection schedule and amount. Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects). Describe the specimen storage plan, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the actions to be taken to allow the use of stored specimens in future research studies, if applicable. Identify the laboratory performing each evaluation, the applicable quality standard, and any special precautions that should be taken in handling the samples. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **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. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

- **Clinical Monitoring Plan:** Describe how the study will be conducted by and monitored for current International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practices (GCP) compliance by an independent clinical trial monitor (or clinical research associate). The monitoring plan should describe the types of monitoring visits to be conducted, the intervals (based on level of risk), how corrective actions will be reported to the Sponsor and PI, and how they will be corrected and prevented by the clinical trial site/PI.

- **Attachment 8: Human Subject Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf".** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. ***Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals.*** Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For clinical trials proposing inclusion of military populations, refer to the General Application Instructions, Appendix 4 for more information.***

  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. Provide detailed justification for exclusions.

  - **Women and Minorities in the Study:** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

  - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification, internet/web-based). Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them. Address the availability of human subjects for the clinical trial for each enrollment site. If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan. Describe the recruitment and advertisement materials. Discuss past efforts in recruiting human subjects from the target population 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. Identify ongoing clinical trials that may

compete for the same patient population and how they may impact enrollment progress.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

  - ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.

  - Include information regarding the timing and location of the consent process.

  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.

  - Address how privacy and time for decision-making will be provided and whether the potential human subject will be allowed to discuss the study with anyone before making a decision.

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.

  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. ***Note:*** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial.

  - ***Assent:*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

- **Screening Procedures:** 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.

- **Risks/Benefits Assessment:**

  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. If applicable, any potential risk to the study personnel should be identified.

  - **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the 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. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values. 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 cost 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 9: Data Management and Sharing (no page limit): Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below.

  - **Data Management:** Describe the data to be gathered and all methods used for collection, including the following:

    - **Data:** The types of data, software, or other materials to be produced.

    - **Acquisition and processing:** How the data will be acquired, including the time and location of data acquisition, if scientifically pertinent. If use of existing data resources is proposed, describe the origin of the dataset. Provide an account of the standards to be used for data and metadata format and content. Explain how the data will be processed.

    - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

    - **Confidentiality:** Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed. Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DOD are eligible to review study records. Address requirements for reporting sensitive information to state or local authorities.

- **Data capture, verification, and disposition:** Describe how data will be captured and verified, including the quality assurance and quality control measures taken during collection, analysis, and processing. Describe where data (both electronic and hard copy) will be stored; who will keep the data; how the data will be stored, if applicable; the file formats and the naming conventions that will be used; the process for locking the database at study completion; and the length of time that data will be stored, along with a justification for the time frame of preservation, which may include considerations related to the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden of data storage. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. Describe the database lock process. For studies requiring Regulatory Agency oversight, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) is required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with a Regulatory Agency, if applicable.

– **Data and Research Resources Sharing Plan:** Describe the type of data or research resources to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. ***Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable.*** If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. In cases of national security or controlled unclassified information concerns, include a statement that the data cannot be made available to the public (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09."). Refer to CDMRP's Policy on Data & Resources Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

- **Attachment 10: 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".** Answer the following questions 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. No further information for this attachment is required.

  For products that require regulation by a Regulatory Agency:

  - State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States.

  - If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

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

  - For the FY24 SCIRP CTA, ***if an IND or IDE is required, the application must be submitted to the FDA prior to the FY24 SCIRP CTA application submission deadline.*** The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed clinical trial. Provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. If there are any existing cross-references in place, provide the application number(s) and associated sponsor(s). Provide an explanation of the status of the application (e.g., past the critical 30-day period, pending response to questions raised by the FDA, on clinical hold, on partial clinical hold). If the IND or IDE application has been placed on clinical hold or partial hold, explain the conditions that must be met for release of the hold. Provide a summary of any previous meetings with the FDA on development of this product. A copy of the Regulatory Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.

- If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- If an active IND or IDE for the investigational product is in effect, but an amendment is needed to include the proposed trial, describe the type and nature of the amendment(s) and the timeline for submission. Indicate whether the amendment increases the risk of the intervention.

- 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).

- Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), nonclinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of Regulatory Agency meetings that will be held/planned, and the submission filing strategy. Include considerations for compliance with current GMP, GLP, and GCP guidelines.

- **Attachment 11: 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 provides 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. Identify and provide justification for the inclusion of international sites, as appropriate. 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. ***Note:*** This item may be made available for programmatic review.

  - **Study Personnel Description:** Briefly describe the composition of the study team, including roles of the individuals listed in the organizational chart on the project 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 research. Describe relevant background and qualifications that demonstrate appropriate expertise to accomplish the proposed work, including previous interactions with the relevant Regulatory Agency, if applicable. ***Highlight how the study team composition provides military-relevant subject matter expertise to the proposed research, if applicable.***

- **Study Management Plan:** 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. Provide a regulatory submission plan for the master protocol and master consent form by the lead institution. If the research involves more than one institution, a single IRB is required for all institutions located in the United States. 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.

- **Partnership Statement** ***(only applicable and required for applications submitted under the Early-Career Partnership Option):*** 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 12: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the product into the next phase of development. ***The post-award transition plan should include the components listed below:***

  - The project's anticipated research outcomes including knowledge products, clinical products for development, etc.

  - An outline of the necessary next logical steps to advance the research outcome to the next stage of clinical development/implementation. Include steps regarding Regulatory Agency approval as appropriate.

  - A timeline with defined milestones and deliverables describing the expected post-award progress of the research outcome. This timeline should include the necessary

next steps to move the research outcome to the next stage of clinical development/implementation as outlined above.

- A description of collaborations and other resources that are in place or will be established to execute the next steps to advance the research outcome to the next stage of development/implementation (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources).

- Details of the funding strategy to transition to the next level of investigation, development, and/or commercialization. This may include commercial sponsorship, venture capital, federal or non-federal funding opportunities, etc.

- A milestone plan to distribute the findings or intervention to the SCI community.

- An assessment of the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcome into clinical practice.

- A discussion of ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award including a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the SCI community.

- **Attachment 13: Impact and Relevance to Military Health Statement (two-page limit): Upload as "Impact.pdf".**

  - **Impact (one-page limit):** Describe the short- and long-term impact of this study on the field of SCI research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed research project will lead to a practical application in individuals living with SCI. Indicate how the study's sample population represents the targeted patient population that might benefit from the proposed intervention. Describe how the intervention represents an improvement over currently available interventions and/or standards of care. Address the impact on one or more of the FY24 SCIRP Focus Areas. This should be written with a broad audience in mind, including readers without a background in science or medicine.

  - **Relevance to Military Health (one-page limit):** Describe 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 read and consider the resource document Spinal Cord Injury Management Within the Military Health System (MHS) when preparing this section. If active-duty military, Veteran, or military Family population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If a non-military population will be used

for the proposed research project, explain how the results will be relevant to Service Members, Veterans, and/or their Families or care partners.

- **Attachment 14: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B.

- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form" available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".

- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Key Personnel Biographical Sketches (six-page limit each):** Upload as "Biosketch_LastName.pdf".

  Biographical sketches, or an equivalent document, should also be included for community partners (e.g., SCI Lived Experience Consultants, representatives of community-based organizations) to demonstrate background and experience relevant to their role in the proposed research project.

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

Early-Career Partnership Option: 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 II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 15.

II.D.2.b.iii. Full Application Submission Components for the Partnering PI if Applying Under the Early-Career Partnership Option

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

- **Attachment 6: Statement of Work (five-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 14: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**

- **Attachment 15: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (six-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (six-page limit each):** Upload as "Biosketch_LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

- **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

The Initiating and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, (via eBRAP), refer to General Application Instructions, Section V.A.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 15.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

II.D.5.a. Application Submissions with a Single PI

The application's direct costs budgeted for the entire period of performance should not exceed **$3,000,000**. 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.

II.D.5.b. Application Submissions with the Early-Career Partnership Option

The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$3,100,000**. 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.

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

The PIs are expected to be partners in the research and may divide budgetary costs across the two awards as appropriate for their separate efforts towards the proposed research project.

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

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.

II.D.5.c. For Both Options Within This Award Mechanism, Direct Costs:

Must be requested for:

- ***Interim (In-Progress) Review (IPR):*** Travel costs for the PI or Initiating PI to present project information or disseminate project results at a DOD SCIRP IPR must be requested. For planning purposes, it should be assumed that the meeting will occur within the second year of the award and be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Data and research resource sharing costs
- Costs associated with collaborative research approach (e.g., consultant costs, equitable participation training, capacity-building activities)
- Travel in support of multi-institutional collaborations.
- Travel and lodging costs for research subjects to participate in the study.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings

should be to present project information or disseminate project results from the FY24 SCIRP CTA.

Must not be requested for:

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

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Study Design and Feasibility**
    - How well the scientific rationale for the proposed clinical trial is supported by the preliminary studies, preclinical data, critical review and analysis of the literature, and/or relevant ongoing, planned, or complete clinical trials.
    - How well the study questions, specific aims, hypotheses and/or objective(s), experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective and purpose.
    - 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.
    - How well the inclusion/exclusion criteria and group assignment process meet the needs of the proposed clinical trial.
    - How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
    - To what degree the data collection instruments, if applicable, are appropriate to the proposed study.

- How well the application demonstrates utilization of the SCI CDEs, if applicable.
- How well potential challenges and alternative strategies are discussed.

- **Patient Impact**
  - To what extent a successful outcome of the proposed research project will make important contributions toward the goals of advancing patient care and quality of life.
  - How likely a successful outcome of the proposed research project will lead to a practical application in individuals living with SCI.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - To what degree the proposed intervention represents an improvement over currently available interventions and/or standards of care.
  - How well the input of the community partners (e.g., SCI Lived Experience Consultants, representatives of community-based organizations) has already and/or will be captured and to what extent this input has and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
- **Scientific Impact**
  - To what extent a successful outcome of the proposed research project will make important contributions toward advancing SCI research.
  - To what degree a successful outcome of the proposed research project will impact at least one of the FY24 SCIRP Focus Areas.
- **Intervention**
  - Whether there is evidence of support, indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - To what degree the intervention addresses the clinical need(s) described.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well research procedures are clearly delineated from routine clinical procedures.
  - Whether measures are described to ensure the consistency of dosing (e.g., active ingredients for nutritional supplements, rehabilitation interventions).

- **Recruitment, Accrual, and Feasibility**
    - To what degree the number of human subjects to be enrolled within the study is reasonable based upon the proposed timeline, study procedures, study population, inclusion/exclusion criteria, and planned efforts to achieve accrual goals.
    - How well the application addresses the availability of human subjects for the clinical trial, access to the proposed human subject population, and the prospect of their participation.
    - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
    - How well the application identifies possible delays (e.g., low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
    - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.
    - Whether the strategy for the inclusion of women and minorities is appropriate to the objectives of the study.
    - Whether the distribution of the proposed enrollment on the basis of sex/gender, race, and/or ethnicity is appropriate for the proposed research.
- **Regulatory Strategy and Transition Plan**
    - How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.
    - Whether the application includes documentation that the study is exempt from the FDA or other international regulatory agency, 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.
    - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support.
    - Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.
    - To what degree the next logical steps and planned immediate next steps for the research team to take upon successful completion of the project are realistic and appropriate to bring the research outcome(s)/product(s) to the next stage of clinical development/implementation.

- Whether the timeline for expected post-award progress is reasonable and contains appropriate milestones and deliverables for advancing the study results toward clinical impact.

- To what degree the proposed collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/ execution committees, training providers/resources) to execute the next steps to advance the research outcome to the next phase of development and eventual clinical implementation are established and/or achievable.

- Whether the funding strategy described to transition the anticipated research outcomes to the next level of investigation, development, and/or commercialization is reasonable and achievable.

- To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.

- How well available opportunities and potential barriers that could impact the progress of commercializing and/or translating the study results into clinical practice are assessed.

- **Statistical Plan and Data Analysis**

  - To what degree the statistical model and data analysis plan are suitable for the planned study.

  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.

  - If applicable, whether the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.

  - If applicable, whether the plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity for phase 3 clinical trials are appropriate for the proposed research.

- **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.

  - Whether the levels of effort of the study team members 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.

- How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.

- For clinical trials that involve more than one institution, to what degree the multi-institutional structure governing the research protocol(s) across all participating institutions and regulatory submission plan are described and appropriate.

- **Early-Career Partnership Option:** How the partners' combined experience 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 **unscored criteria** will also contribute to the overall evaluation of the application:

- **Ethical Considerations**

  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.

  - If applicable, how well the inclusion of international sites is justified.

  - 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 privacy and confidentiality issues are appropriately considered.

  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

- **Data and Research Resources Sharing Plan**

  - Whether project data and research resources will be shared with the SCI research community.

  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable. If applicable, whether specific repository(ies) are named where scientific data and resources arising from the project will be archived.

  - To what extent data and outcome dissemination activities, with particular focus on feeding back the data to affected communities, are described and appropriate.

- **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.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
    - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 SCIRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Relevance to military health
    - Program portfolio composition
    - Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review***. Additional information about

the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review 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.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. 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 funding recommendation 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.

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 USAMRAA 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).***

Intra-DOD 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 DOD 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 DOD 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D General Terms and Conditions and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trials registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

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

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

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

Inclusion Enrollment Reporting Requirement: Enrollment reporting on the basis of sex/gender, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901Ta. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Collaborative Research Plan (Attachment 5) is missing.
- Intervention (Attachment 7) is missing.
- Human Subject Recruitment and Safety Procedures (Attachment 8) is missing.
- Data Management and Sharing (Attachment 9) is missing.
- Regulatory Strategy (Attachment 10) is missing.
- Study Personnel and Organization (Attachment 11) is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

I.H.2.c. Withdrawal

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

- An FY24 SCIRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 SCIRP Programmatic Panel members can be found at https://cdmrp.health.mil/scirp/panels/panels24***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The proposed research is not a clinical trial.
- The proposed project includes research that does not meet the definition of a clinical trial.
- The invited application proposes a different research project than that described in the pre-application.
- 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.
- 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.
- The application does not include documentation that the study is exempt from the FDA or other international agency regulation, if applicable.
- The application does not include documentation that an IND or IDE application and/or international equivalent has been submitted prior to the *application submission deadline* for an FDA-regulated and/or relevant international regulatory agency study.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Single or Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary and Application Contacts *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Lay Abstract – Attachment 3, upload as "LayAbs.pdf"	☐	
Technical Abstract – Attachment 4, upload as "TechAbs.pdf"	☐	
Collaborative Research Plan – Attachment 5, upload as "Collaboration.pdf"	☐	
Statement of Work – Attachment 6, upload as "SOW.pdf"	☐	☐
Intervention – Attachment 7, upload as "Intervention.pdf"	☐	
Human Subject Recruitment and Safety Procedures – Attachment 8, upload as "HumSubProc.pdf"	☐	
Data Management and Sharing – Attachment 9, upload as "Data_Manage.pdf"	☐	
Regulatory Strategy – Attachment 10, upload as "Regulatory.pdf"	☐	
Study Personnel and Organization – Attachment 11, upload as "Personnel.pdf"	☐	
Post-Award Transition Plan – Attachment 12, upload as "Transition.pdf"	☐	
Impact Statement – Attachment 13, upload as "Impact.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 14**,** upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 15**,** upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐

Full Application Components	Single or Initiating PI	Partnering PI
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CTA	Clinical Trial Award
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
ICH E6	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
LAR	Legally Authorized Representative
M	Million
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
SAM	System for Award Management
SCI	Spinal Cord Injury
SCIRP	Spinal Cord Injury Research Program

SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs