I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Translational Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524SCIRPTRA

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."

TABLE OF CONTENTS

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 Translational Research Award (TRA) 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 TRA mechanism was first offered in FY12. Since then, 262 TRA applications have been received, and 53 have been recommended for funding.

II.B. Award Information

The SCIRP TRA is intended to support translational research that will accelerate the movement of promising ideas in SCI research into clinical applications. Although not all-inclusive, some examples include demonstration studies of pharmaceuticals and medical devices in preclinical systems and/or clinical research on therapeutics, devices, or practice using human tissues or resources.

The ultimate goal of translational research is to move an observation forward into clinical application and accelerate the clinical introduction of health care products, technologies, or practice guidelines. Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data. However, applicants should not view translational research as a one-way continuum from bench to bedside. The research plan is encouraged to involve a reciprocal flow of ideas and information between basic and clinical science.

Applicants need to clearly articulate three points along the translational research spectrum:

- Where the field is now;

- Where the field will be after the successful completion of the proposed research project; and

- What the next step will be after completion of the proposed project.

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

Applications to the FY24 SCIRP TRA may include preclinical animal studies (except where otherwise specified) and/or clinical research involving human subjects and human anatomical substances. ***Proposal of animal studies is not a required element of this mechanism, though applications including animal studies must include a clear justification for the animal model chosen including relevance to human SCI.*** The FY24 SCIRP TRA may also support ancillary studies that are associated with an ongoing or completed clinical trial and projects that optimize the design of future clinical trials.

The FY24 SCIRP TRA also allows funding for a pilot clinical trial as PART of the funded research project where limited clinical testing of a novel intervention or device is necessary to inform the next step in the continuum of translational research. Such pilot clinical trial studies should be small, make up only a portion of the proposed Statement of Work (SOW), and be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement. Alternative trial designs to traditional randomized clinical trials are allowed but should be appropriate to the objective of the trial. ***If a pilot clinical trial is proposed, utilization of decentralized clinical trial strategies that leverage virtual elements/tools for participant enrollment, communication, and data collection is especially encouraged.*** Applications that include a pilot clinical trial as part of the proposed research will have additional submission requirements and review criteria. ***Applications that consist entirely of a clinical trial or multiple pilot clinical trials may be administratively withdrawn.***

Applications that consist entirely of a clinical trial, including pilot clinical trials, do not meet the intent of the FY24 SCIRP TRA and should utilize either the FY24 SCRIP Clinical Translation Research Award mechanism (Funding Opportunity Number HT942524SCIRPCTRA) or the FY24 SCIRP Clinical Trial Award mechanism (Funding Opportunity Number HT942524SCIRPCTA).

Applications requesting support for a discovery or early-stage study relevant to SCI may better fit the intent of the FY24 SCIRP Investigator-Initiated Research Award mechanism (Funding Opportunity Number HT942524SCIRPIIRA).

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.

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.

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.

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.

Employing community collaborations to optimize research impact is required. Research funded by the FY24 SCIRP TRA 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 TRA are expected to name at least one community partner (e.g., SCI Lived Experience Consultant, representative of community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project (see Collaborative Research Plan, Attachment 8).

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 TRA 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 and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

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.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

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 TRA should not exceed **$1,250,000 or $1,350,000** 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 $10.32M to fund approximately five TRA 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 organizations, 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

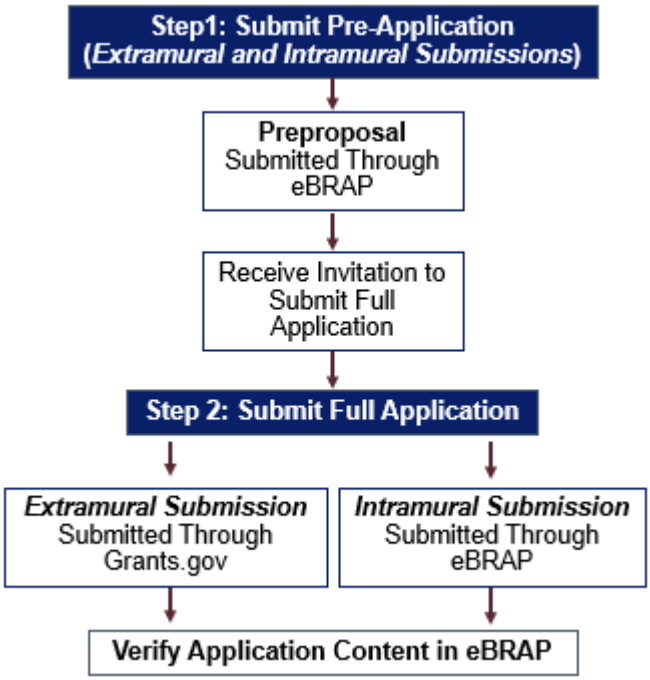
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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 HT942524SCIRPTRA 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

HT942524SCIRPTRA 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 and NO Pilot Clinical Trial	No Option
Single PI and Pilot Clinical Trial	TRA – Pilot Clinical Trial
Early-Career PI and other PI but NO Pilot Clinical Trial	TRA with Early-Career Partnership Option
Early-Career PI and other PI AND Pilot Clinical Trial	TRA with Early-Career Partnership Option – Pilot Clinical Trial

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 (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

- **Background/Rationale:** State the scientific rationale on which the proposed research project is based. Clearly demonstrate that there is sufficient rationale for the proposed research.

- **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the scientific approach. Include the animal model proposed, if applicable, along with its relevance to human SCI. If applicable, clearly identify which aims describe the proposed preclinical or clinical studies and which describe the pilot clinical trial. Describe how the outcome of the pilot clinical trial will optimize the design of future clinical trials or inform the next step in the continuum of translational research.

- **Translational Potential:** Explain how the project will accelerate promising laboratory research findings into clinical applications. Where applicable, describe how the proposed research will allow for a reciprocal flow of ideas between basic and clinical science.

  Clearly articulate three points along the translational research spectrum. Any specific regulatory milestones, e.g., submission of an application for an Investigational New Drug/Investigational Device Exemption (IND/IDE), should be included.

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

- **Impact:** Describe the impact of this study on the field of SCI research, patient care, and/or quality of life, including the impact on one or more of the 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 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 one community partner (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 research project.

- **Specific Aims and Study Design:** How well the specific aims are stated and addressed in the outlined research project. If applicable, how well the outcome of the pilot clinical trial will optimize the design of future clinical trials or inform the next step in the continuum of translational research.

- **Translational Potential:** How well the project will accelerate promising research findings into clinical applications and move the field forward from where it is now to where it will be at the completion of the research project. Whether the next steps after completion of the work are articulated and reasonable.

- **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 (12-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (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.

  Describe the proposed project in detail using ***one*** of the two outlines below, depending on whether or not a pilot clinical trial is included in the proposed research. ***The Project Narrative must include preliminary or published data that are relevant to SCI and the proposed research project. All applications must address at least one of the FY24 SCIRP Focus Areas.***

  Outline for projects without a pilot clinical trial:

  - **Background/Readiness:** Present the ideas and scientific rationale behind the proposed research project. Clearly demonstrate that there is sufficient scientific evidence to support the proposed stage of research, including preliminary and/or published data. Cite relevant literature. Describe previous experience most pertinent to this project.

  - **Hypothesis or Objective(s):** State the hypothesis to be tested or the objective(s) to be reached.

  - **Specific Aims:** Concisely explain the project's specific aims. If the proposed research project is part of a larger study, present only tasks that this SCIRP award would fund.

  - **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Describe the statistical plan as appropriate for the proposed research. Address potential problem areas and present alternative methods and approaches. If applicable, briefly describe the relevance of the animal model chosen to human SCI – full details will be required in the Animal Research Plan (Attachment 11).

For human subjects or human anatomical samples or data, provide a detailed plan for the recruitment of subjects or the acquisition of samples or data, including evidence that the research team has access to subjects, samples, and/or data. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, 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 Institutional Review Board [IRB] review) are exempt from this requirement. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2).

- **Study Personnel Description:** Briefly describe the composition of the study team 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). 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.***

Outline for projects <u>with</u> a pilot clinical trial:

(Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested during award negotiation.)

- **Background/Readiness:** Present the ideas and scientific rationale behind the proposed research project, and clearly demonstrate that there is sufficient evidence, including preliminary data, to support the proposed stage of research. Cite relevant literature. Describe previous experience most pertinent to this project.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective(s) to be reached.

- **Specific Aims:** Concisely explain the project's specific aims. If the proposed research project is part of a larger study, present only tasks that the SCIRP award would fund. Clearly identify which aims comprise the preclinical or clinical studies and which aims comprise the pilot clinical trial portions of the research.

- **Study Design and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Briefly, describe the statistical plan as appropriate for the proposed research. Address potential problem areas and present alternative methods and approaches. For studies using animals, briefly describe the relevance of the animal model chosen to human SCI – full details will be required in the Animal Research Plan (Attachment 11).

For human subjects or human anatomical samples or data, provide a detailed plan for the recruitment of subjects or the acquisition of samples or data, including evidence that the research team has access to subjects, samples, and/or data. 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. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2).

- **Pilot Clinical Trial:** Provide plans for initiating and conducting the pilot clinical trial during the course of this award. Further details of the pilot clinical trial will be required in Attachment 13.

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

  - Describe how the pilot clinical trial is clearly linked to the preclinical or clinical research studies that will also be performed through this award.

  - Include a description of how the proposed work is responsive to the intent of the FY24 SCIRP TRA and includes only exploratory clinical testing of a novel intervention or device necessary to inform the next step in the continuum of translational research. Describe how the pilot clinical study is small, represents only a portion of the proposed SOW (Attachment 5), and will be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement.

- **Study Personnel Description:** Briefly describe the composition of the study team 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). 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***

- **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 the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and 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 availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- **Regulatory Documentation *(if applicable)*:** For the purposes of this funding opportunity, Regulatory Agency refers to the Food and Drug Administration (FDA) or any relevant international regulatory agency unless otherwise noted.

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

    Provide evidence that the pilot 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:***

    If the product is not currently FDA-approved, -licensed, or -cleared, and requires an IND/IDE or equivalent, the application must be submitted to the appropriate Regulatory Agency prior to the FY24 SCIRP TRA application submission deadline. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed study.

    Provide documentation that indicates the date of Regulatory Agency submission, application number, and sponsor for any existing FDA applications in place. If available, provide documentation that supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) for the product. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource 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. Refer to CDMRP's Policy on Data & Resource 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.

- **Inclusion Enrollment Plan** ***(only required if clinical research and/or a pilot clinical trial is proposed)*****:** 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 U.S. Department of Veterans Affairs (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 use 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?

- If the proposed research includes a pilot clinical trial, how will this advance the research findings along the translational spectrum?
- What is the projected time it may take to achieve a person-related outcome?
- If the research is too basic for immediate clinical applicability, describe the interim outcomes.
- What are the likely contributions of the proposed research project to advancing the field of SCI research, patient care, and/or quality of life?

- **Attachment 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 reasoning behind the proposed research project, including sufficient evidence to support the proposed stage of research.
  - **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 proposed research project. Identify which aims relate to a pilot clinical trial (if applicable).
  - **Study Design:** Briefly describe the study design, including appropriate controls.
  - **Impact:** Briefly describe the short- 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.
  - **Translation:** Briefly describe how the proposed research project will translate promising, well-founded research findings into clinical applications for SCI. If a pilot clinical trial is included as part of the proposed research, explain how this is necessary to inform the next step on the translational spectrum.

- **Attachment 5: Statement of Work (three-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 TRA, refer to either the ***"Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work"*** or ***"Example: Assembling a Generic Statement of Work",*** whichever example is most appropriate for the proposed effort, 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 Consultant or community partner, should be noted for each task.

- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Allocate time within the period of performance to obtain local Institutional Animal Care and Use Committee (IACUC)/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.

- Identify cell line(s) and commercial or organizational source(s) to be used.

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

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 6: Translation Statement (one-page limit): Upload as "Translation.pdf".** The ultimate goal of translational research is to move an observation forward into clinical application and accelerate the introduction of health care products, technologies, or practice guidelines for clinical use. State explicitly how the proposed research project is translational in nature and describe how it will help to move an observation forward into clinical practice and/or allow for the reciprocal transfer of ideas between basic and clinical science. Clearly articulate three points along the translational research spectrum:

  - Where the field is now including the current state of knowledge or practice;

  - Where the field will be after the successful completion of the proposed research project; and

- What the next step will be after completion of the proposed project.

If the proposed research includes a pilot clinical trial as part of the study, explain how the pilot clinical trial aims are necessary to advance the anticipated research outcomes toward clinical implementation.

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe the short- and long-term impact of this study on the field of SCI research, patient care, and/or quality of life, including an assessment of the likelihood that a successful outcome of the proposed research project will lead to a practical application in individuals living with SCI. If applicable, describe how the study's sample population represents the targeted patient population that might benefit from the proposed intervention. If applicable, state whether/how the proposed project builds off of previous research efforts to advance a product, outcome, or finding closer to clinical utility. Address the impact on one or more of the FY24 SCIRP Focus Areas. This attachment should be written with a broad audience in mind including readers without a background in science or medicine.

- **Attachment 8: Collaborative Research Plan: Upload as "Collaboration.pdf".**

  Collaborative Research Statement (three-page limit): For the FY24 SCIRP TRA, 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 name of at least one community partner (e.g., SCI Lived Experience Consultant, representative of community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project. The individual's 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 Consultant; representative of community-based organization) 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 9: Relevance to Military Health Statement (one-page limit): Upload as "Military.pdf".** 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 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 population simulates the relevant military population.

- **Attachment 10: 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 description of the planned immediate next steps to be taken ***by the research team*** to bring the research outcomes to the next stage of clinical development/implementation.

- 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 11: Animal Research Plan (three-page limit): Upload as "AnimalResPlan.pdf".** ***(Attachment 11 is only applicable and required for applications proposing animal studies.)*** If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the IACUC. The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

  - Describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology. ***Be specific as to why an animal model is necessary to address the study aims, why the specific animal SCI model was chosen over other models including any relevance of the model specific to military health, and how it is optimal for addressing the study aims. The model's relevance to human SCI should also be detailed.***

- Summarize the procedures to be conducted and the outcome measures to be collected. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

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

- **Attachment 12: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 12 is 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 13: Pilot Clinical Trial Plan (five-page limit): Upload as "ClinTrialPlan.pdf".** ***(Attachment 13 is only applicable and required for applications proposing a pilot clinical trial.)***

  - Identify the intervention to be tested and describe the particular outcomes. Describe how the intervention addresses the clinical needs and how it compares with currently available interventions and/or standards of care.

  - Demonstrate the availability of the intervention, including IND/IDE status (or other Regulatory Agency approvals), as applicable. Regulatory documentation should be provided as part of the application's Supporting Documentation (Attachment 2). 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 pilot clinical trial.

  - Summarize the procedures to be conducted. 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. Outline the timing and procedures planned during the follow-up period.

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

- Identify the study population and describe the methods that will be used to recruit a sample of human subjects from the accessible population. ***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.*** List the inclusion and exclusion criteria for the proposed pilot clinical trial.

- As appropriate for the proposed pilot clinical trial, describe the statistical model and data analysis plan with respect to the study objectives. If applicable, include power analysis calculations.

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

- **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, Representations.

- **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 instructions. 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 instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload 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 5: Statement of Work (three-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, 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 **3** 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 **$1,250,000**. 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 3 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 **$1,350,000**. 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 **3** 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 TRA.

Must not be requested for:

- 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:

- **Translational Potential**
    - How well the application describes where the field is now, including the current state of knowledge or practice.
    - How well the application describes and justifies how the proposed work will move the field closer to a clinical application by the end of the study and how likely the project will move an observation forward into clinical application and accelerate the introduction of health care products, technologies, or practice guidelines for clinical use.
    - How well the application describes feasible next steps to be taken after the end of the proposed study toward a clinical application for individuals with SCI.

- How well the project allows for the reciprocal transfer of ideas between basic and clinical science, as applicable.

- Whether the anticipated research outcome(s) are realistic given the state of the field now and the proposed research approach.

- **Study Design and Feasibility**

  - How well the preliminary data and scientific rationale support the proposed research project and demonstrate sufficient evidence to support moving into the proposed stage of research.

  - How well the hypothesis/hypotheses or objective(s), specific aims, research strategy, methods, and analyses are developed and support successful completion of the project aims.

  - To what extent the proposed research project is feasible as described.

  - How well the application acknowledges potential problems and addresses alternative approaches.

  - If applicable, how well-justified the chosen animal SCI model is over other models, including its relevance to human SCI.

  - If applicable, whether the application includes sufficient evidence to support successful recruitment of and access to human subjects, data, and samples and whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. 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.

  - If applicable, whether the application includes documentation that the study is exempt from Regulatory Agency review, or that the IND/IDE application (and/or international equivalent) has been submitted to the appropriate Regulatory Agency. If documentation is provided, how well that documentation supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) for the regulated product.

  - If applicable, how well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

  - If applicable, whether the application describes SCI CDEs to be collected.

- **Clinical Strategy (for applications including a pilot clinical trial)**

  - How well the trial is designed to achieve the research objectives including the procedures human subject will experience, study variables to be measured, use of appropriate controls and study endpoints.

- How well the proposed pilot clinical trial meets the requirements of the FY24 SCIRP TRA with regard to being small, representing only a portion of the proposed SOW, and being utilized to establish feasibility of a potential approach or aiding in device, intervention, or future clinical trial design refinement.

- How clearly linked the proposed pilot clinical trial is to the preclinical or clinical research studies that will also be performed through this award.

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

- If applicable, how well the pilot clinical trial will leverage decentralized clinical trial strategies including virtual elements/tools for participant recruitment/enrollment, intervention administration/delivery, and/or outcome data acquisition.

- How well the application demonstrates availability of the intervention, access to the study population, and ability to achieve recruitment goals.

- **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.

  - If applicable, to what extent the proposed project builds off of previous research efforts to advance a product, outcome, or finding closer to clinical utility.

- **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 input of the community partner (e.g., SCI Lived Experience Consultant, representative of community-based organization) has been and/or will be captured and to what extent this input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.

- **Transition Plan**

  - 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 stage 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.

- **Personnel**

  - To what degree the composition of the study team including any external consultants or advisors (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate, military-relevant subject matter expert) is appropriate to accomplish the proposed research project.

  - To what degree the levels of effort by the PI, Partnering PI (if applicable), and other key personnel are appropriate to ensure successful conduct of the proposed work.

  - To what degree the qualifications and background of the community partner (e.g., SCI Lived Experience Consultant, representative of community-based organization) are relevant to their role within the team and to the proposed research project.

  - **Early-Career Partnership Option:** How the PIs' 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:

- **Budget**

  - Whether the budget is appropriate for the proposed research.

- **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.
    - Whether data and outcome dissemination activities, with particular focus on feeding back the data to affected communities, is described and appropriate.
- **Environment**
    - To what extent the scientific environment is appropriate for the proposed research project.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
    - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the 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
    - Translation potential

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 or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

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 Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

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 IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded clinical trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded clinical trials are required to register the study in the NIH 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.

II.F.4. Reporting

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

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 ***(only required for clinical research studies and pilot clinical trials)***: Enrollment reporting on the basis of sex/gender, race, and/or 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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of pre-applications 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.
- Translation Statement (Attachment 6) is missing.
- Collaborative Research Plan (Attachment 8) is missing.
- For the **Early-Career Partnership Option**, Partnership Statement (Attachment 12) is missing.
- For the **Pilot Clinical Trial Option**, Pilot Clinical Trial Plan (Attachment 13) 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.

II.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 invited application proposes a different research project than that described in the pre-application.
- One community partner (e.g., SCI Lived Experience Consultant, representative of community-based organization) is 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.
- Proposed project consists entirely of a pilot clinical trial or multiple pilot clinical trials.

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"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Translation Statement – Attachment 6, upload as "Translation.pdf"	☐	
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐	
Collaborative Research Plan – Attachment 8, upload as "Collaboration.pdf"	☐	
Relevance to Military Health Statement – Attachment 9, upload as "Military.pdf"	☐	
Post-Award Transition Plan – Attachment 10, upload as "Transition.pdf"	☐	
Animal Research Plan – Attachment 11, upload as "AnimalResPlan.pdf"	☐	
Partnership Statement – Attachment 12, upload as "Partnership.pdf"	☐	
Pilot Clinical Trial Plan – Attachment 13, upload as "ClinTrialPlan.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)	☐	☐

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
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
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
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
TRA	Translational Research Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity

USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs