

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Translational Research Partnership Award

Funding Opportunity Number: W81XWH-10-SCIRP-TRPA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Spinal Cord Injury Research Program (SCIRP) was established in fiscal year 2009 (FY09) with a \$35 million (M) congressional appropriation. The FY10 appropriation is \$11.25M to promote research into regenerating damaged spinal cords, arthritis research, and improving rehabilitation therapies that offer real promise for enhancing long-term care of wounded soldiers. The SCIRP focuses its funding on innovative projects that have the potential to make a significant impact on improving the function, wellness, and overall quality of life for military Service Members as well as their caregivers, families, and the American public.

The FY10 SCIRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the fields of spinal cord injury (SCI) focused research. Proposals from investigators within the military Services and proposals involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

B. FY10 SCIRP Areas of Encouragement

The FY10 SCIRP encourages proposals that specifically address prevention, alleviation, or acute care of medical complications from SCI (e.g., autonomic dysreflexia, spasticity, sensory dysfunction or deficit, pain, skin care issues, bladder and bowel dysfunction, sexual dysfunction, and adjustment to disability).

The SCIRP seeks applications from the wide spectrum of basic, translational, and clinical research that are responsive to the Areas of Encouragement. Of particular interest to the program are projects focused on developing, testing, and translating novel interventions in SCI, and moving them into clinical practice. Since few advancements have impacted the standard of care in SCI, the SCIRP is giving special consideration to projects focused on implementation research (i.e. the development of methods or approaches that would enable the translation of research findings into SCI clinical practice) and/or the development of new clinical practice guidelines or the modification of current guidelines.

C. Encouraged DOD Collaboration and Alignment

Alignment with current Department of Defense (DOD) research and collaboration with military researchers and clinicians is encouraged. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY10 SCIRP Areas of Encouragement:

Defense Technical Information Center
<http://www.dtic.mil>

Congressionally Directed Medical
Research Programs
<http://cdmrp.army.mil>

U.S. Army Medical Research and
Materiel Command
<https://mrmc.amedd.army.mil>

Air Force Research Laboratory
<http://www.wpafb.af.mil/afrl>

Navy and Marine Corps Public Health
Center
<http://www-nehc.med.navy.mil/>

U.S. Department of Veterans Affairs,
Office of Research and Development
www.research.va.gov

Office of Naval Research
<http://www.onr.navy.mil/>

U.S. Army Research Laboratory
<http://www.arl.army.mil>

U.S. Naval Research Laboratory
www.nrl.navy.mil

Defense Advanced Research Projects
Agency
<http://www.darpa.mil/>

U.S. Army Medical Research
Acquisition Activity
<http://www.usamraa.army.mil>

Naval Health Research Center
<http://www.nhrc.navy.mil/>

Office of the Under Secretary of Defense
for Acquisition, Technology and
Logistics
<http://www.acq.osd.mil/>

D. Award Description

The SCIRP Translational Research Partnership Award mechanism was first offered in FY09. Since then, 13 Translational Research Partnership Award applications have been received, and 5 have been recommended for funding.

The intent of the Translational Research Partnership Award (TRPA) is to promote *multi-institutional, multi-disciplinary* partnerships among clinicians and laboratory scientists that accelerate the movement of promising ideas in spinal cord injury research into clinical applications. This award is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to have a major impact on spinal cord injury research. Training of the next generation of scientists and clinicians is encouraged; therefore, graduate and medical students, residents, postdoctoral fellows, and clinician-scientists are encouraged to be part of the application.

The TRPA supports the development of translational research partnerships among **two or three** independent investigators (known as partners). Proposals should address one of the Areas of Encouragement in spinal cord injury research in a manner that would be less readily achievable through separate efforts. *At least one partner must be a clinician*, and *at least one partner must have experience in spinal cord injury laboratory research*. A clinician is defined as an individual who is credentialed (possesses the necessary degrees, licenses, and other certifications) as a care provider in any relevant capacity at the institution of record. Biosketches should include appropriate documentation of credentials. It should be clear that all partners have substantial intellectual input into the design of the research project. A proposed project in which

one of the partners merely supplies tissue samples or access to patients will not meet the intent of this mechanism.

Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and preliminary data. While the ultimate goal of translational research is to move an observation forward into clinical application, members of the partnership should view translational research as a two-way continuum between bench and bedside. Developing the research plan must involve a reciprocal flow of ideas and information within the partnership. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at (<http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals>).

The Translational Research Partnership Award does not support clinical trials. The SCIRP encourages clinical trials with a focus on rehabilitation through the Clinical Trial Award – Rehabilitation (for information about this mechanism, see <http://cdmrp.army.mil>). Principal Investigators (PIs) wishing to apply for funding for a clinical trial focused on Rehabilitative Medicine should utilize this mechanism. A ***clinical trial*** is defined as a prospective accrual of patients where an intervention is tested on a human subject for a ***measurable outcome*** for safety and/or efficacy. Clinical trials require informed consent on the subject, and may include identifiable information.

Proposals must include preliminary and/or published data originating from the PI, research team, or partners that is relevant to the topic area and the proposed project.

Important aspects of the Translational Research Partnership Award are as follows:

- 1. Translational:** The application should provide evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.
- 2. Partnership:** The success of the project depends on the unique disciplines, skills, and contributions of each partner. Of the two to three partners, at least one ***must*** be a clinician, and at least one ***must*** have experience in SCI laboratory research.
- 3. Multi-institutional:** At least two distinct institutions ***must*** be involved.
- 4. Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising ideas in spinal cord injury research into clinical applications.

New for FY10: NESTED NEW INVESTIGATOR OPTION

The SCIRP is offering opportunities for training graduate students, medical students, residents, postdoctoral fellows, and clinician-scientists new to SCI research, as an option for the Translational Research Partnership Award. The intent of the **Nested New Investigator Option** is to provide mentored research opportunities in SCI research. It is expected that the training will provide new investigators with a meaningful and productive experience in SCI research. Only one Nested New Investigator can be requested per proposal. Applications must include the

Nested New Investigator's name, biosketch, and a letter indicating their professional goals, commitment, and intentions in furthering their interest in SCI research. A letter of support is also required from the Mentor.

At the application submission deadline, Nested New Investigators must be either:

- A graduate student, medical student, resident, or post-doctoral fellow participating in a mentored training program, or
- A clinician with clinical duties and/or responsibilities who is new to scientific research (i.e. no history of independent research funding in any scientific discipline), or
- A clinician with clinical duties and/or responsibilities who has research experience but is new to the SCI field (i.e. no history of independent research funding or scientific publications in the field of SCI research).

Use of Human Subjects and Human Biological Substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local Institutional Review Boards (IRBs). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects.

E. Eligibility

Independent investigators at any academic level (or equivalent) are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

F. Funding

Each partner will be a PI, and a separate award will be made to each partner's organization. The PIs are expected to be equal partners in the research, and the direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

- The maximum period of performance is **3** years.
- The maximum allowable direct cost for the entire period of performance is **\$750,000**.
 - An additional \$47,000 is allowed for projects requesting a Nested New Investigator Option with graduate student, medical student, resident, or post-doctoral fellow, bringing the maximum direct cost to **\$797,000**.
 - An additional \$63,000 is allowed for projects requesting a Nested New Investigator Option with clinician or clinician-scientist, bringing the maximum direct cost to **\$813,000**.

More cost-effective studies that do not request the full available funding amount are encouraged.

- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- Salary
- Research Supplies
- Equipment
- Clinical costs (clinical trials not allowed)
- Travel between collaborating organizations
- Training related costs and salary for Nested New Investigator
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

An additional \$1,800 in funding must be requested for the PI to travel to one DOD-sponsored scientific meeting in the Washington, DC/Baltimore, Maryland, area.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.4M of the \$11.25M FY10 SCIRP appropriation to fund approximately 2 Translational Research Partnership Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

G. Award Administration

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), August 5, 2010**
- **Invitation to Submit an Application: September 30, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, December 1, 2010**
- **Scientific Peer Review: January 2011**
- **Programmatic Review: March 2011**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline, and a proposal has been invited.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). *Applications will be invited based on pre-application screening. Do not submit an application unless a letter of invitation has been received.*

The Translational Research Partnership Award mechanism is structured to accommodate at least two, and up to a maximum of three, PIs. One partner 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(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required statements. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will subsequently be notified separately by email. Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, the Initiating PI will receive a letter of invitation via email by the CDMRP eReceipt system. The letter will provide the information necessary to begin application submission through Grants.gov.

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by **5:00 p.m. ET on the deadline**. Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The Initiating PI is responsible for submission of all pre-application components.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs (Refer to the General Application Instructions for additional information on pre-application submission):

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section.

- **Required Files – Tab 4**

Preproposal Narrative (three-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Research Idea:** State the ideas and reasoning on which the *proposed work* is based. Show how the perspective of each team member contributes to the development of the idea. Clearly state the type of study proposed (e.g., discovery, development, animal validation, human validation, etc.)
- **Research Strategy:** Concisely state the project's objectives and specific aims.
- **Translational:** Describe the translational aspect of this proposal, providing evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.
- **Partnership:** Describe how the project incorporates multiple institutions and disciplines, and how it depends on the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
- **Impact:** State explicitly how the proposed research will have an impact on accelerating the movement of promising ideas in SCI into clinical applications, if successful.
- **Military Relevance:** Describe how the proposed work is applicable to the health care needs of military service members, their family members, and/or the U.S. veteran population.
- **Alignment with Areas of Encouragement:** If applicable, explain how the proposed work addresses any of the FY10 SCIRP Areas of Encouragement.

Pre-Application Supporting Documentation: The following items are to be included as supporting documentation for the pre-application:

- References Cited (one-page limit): List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
- Key Personnel Biographical Sketches (four-page limit per individual): Include biographical sketches for the PI and other key collaborators.
- **Submit Pre-application – Tab 5**
- **Other Documents Tab**
Not applicable.

Pre-Application Screening: Pre-applications will be screened by the SCIRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates, based on the following criteria:

- **Research Idea:** How well the described research demonstrates solid judgment and rationale for SCI research.
- **Research Strategy:** How the specific aims support the research idea.
- **Translational:** How the project will translate promising, well-founded research findings into clinical applications in spinal cord injury.
- **Partnership:** Whether the partnership is multi-institutional and multidisciplinary, and includes at least one clinician and one experienced SCI laboratory researcher. How the partners' backgrounds and expertise are appropriate to accomplish the proposed research that could not be accomplished by either a single investigator or through separate efforts. How the disciplines and the levels of effort are appropriate for the proposed research.
- **Impact:** How the study addresses an important problem related to SCI. If successful, how the partnership and the aims of the application are likely to accelerate the movement of promising ideas in SCI into clinical applications.
- **Military Relevance:** How the proposed study may directly or indirectly benefit military service members, their family members, and/or the U.S. veteran population.
- **Alignment with Area of Encouragement:** If applicable, how the proposed study addresses any of the FY10 SCIRP Areas of Encouragement.

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

Applications will not be accepted unless the Initiating PI has received a letter of invitation.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number.

Application Components for the Initiating PI:

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.B., for detailed information.

2. Attachments Form

- **Attachment 1: Project Narrative (15-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below. *The Project Narrative must include preliminary and/or published data that is relevant to SCI and the proposed project.*

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this application. If the proposed work is part of a larger study, present only tasks that the DOD award would fund.
- **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*

- **Partnership:** Describe how the proposed project incorporates the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational research partnership will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide the evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*
 - **References Cited:** List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
 - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - **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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.
 - **Letters of Organizational Support (two-page limit per letter):** Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. If the PI is a practicing clinician, the institution must clearly demonstrate a commitment to the clinician’s research.
 - **Letters of Collaboration (if applicable) (two-page limit per letter):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Mentor Letter of support for Optional Nested New Investigator (if applicable):** Provide a letter signed by the mentor in support of the nested new investigator

reflecting protected time, resources, and training available to investigator, as well as the applicant's current position and/or status.

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

Technical abstracts should be written using the outline below.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Briefly describe how the proposed project will have an impact on SCI research and/or patient care.
- Translation: Briefly describe how the proposed project will translate promising, well-founded research findings into clinical applications in spinal cord injury.

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

Public abstracts should be written using the outline below.

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
 - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
 - What types of patients will it help, and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of SCI research?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.

Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.

- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 8: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Describe the potential impact of this study on the field of research and/or patient care in SCI. Include an assessment of the likelihood that a successful outcome to the research project will lead to a practical application in patients. The following are examples of ways in which proposed studies, if successful, may have an impact. Although not all inclusive, these examples are intended to help PIs frame the impact of the proposed research:
 - Has the potential to advance the field of research in SCI.
 - Has the potential to change the standard of care.
 - Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.
- **Attachment 9: Military Relevance Statement (one-page limit):** Upload as “Military.pdf.” Demonstrate how the proposed study is applicable to the health care needs and quality of life of military service members, their family members, and/or the U.S. veteran population. If active duty military, military families, or veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, 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 targeted population (i.e. Armed Forces, their family members, and/or the U.S. veteran population).
- **Attachment 10: Translation Statement (one-page limit):** Upload as “Translation.pdf.” Describe the translational research that will be performed through this award, and articulate why it could not be achieved through separate efforts. State explicitly how the proposed research is translational in nature, allowing for the reciprocal transfer of ideas between basic and clinical science.
- **Attachment 11: Letter from Nested New Investigator (if applicable, two-page limit):** Upload as “Letter.pdf.” The Nested New Investigator must provide a letter indicating their professional goals, commitment, and intentions in furthering their interest in SCI research by participating in the proposed research project.
- **Attachment 12: Approval for Access to Military and VA Populations (if applicable, one-page limit):** Upload as “ApprovalAccess.pdf.” A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities).

3. Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Include Nested New Investigator Biographical Sketch (if applicable)
- Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

4. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

Application Components for Each Partnering PI:

Each Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. SF 424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI (s) should be noted for each task.*
- **Attachment 6: Detailed Budget and Justification:** Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Upload as “Budget.pdf.” *Initiating and Partnering PIs must each submit a unique and separate detailed budget and justification.*
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.”

3. Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance:

- **Translational Potential**
 - How the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for patients with, or populations at risk for, SCI.
- **Research Strategy and Feasibility (preliminary and/or published data are required)**
 - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data, and logical reasoning.
 - How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the partners acknowledge potential problem areas and consider alternative approaches.

- **Partnership**
 - How the partnership between the clinician(s) and SCI laboratory researcher(s) is likely to result in a level of productivity greater than that achievable by each PI working independently.
 - How the proposal addresses an Areas of Encouragement in a way that could not be accomplished by a single investigator.
 - How well the evidence supports that all partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.
 - How the multiple disciplines and multiple institutions within the partnership support the proposed project
 - How the partners' background, expertise, and levels of effort support the proposed project.
 - **Nested New Investigator applicants (if applicable):**
 - How the qualifications of the Nested New Investigator will add to the project.
 - How the Nested New Investigator will benefit from participation in this project.
- **Impact**
 - If successful, how the partnership and the aims of the study will eventually move a clinical observation, a laboratory discovery, or population-based study into clinical application.
 - How the proposed research will have an impact on the concepts or methods that drive the field of SCI research.
 - How the proposed research will make original and important contributions towards the goal of advancing SCI research or patient care.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Environment**
 - How the evidence indicates an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the clinical trial at each participating center or institution (including collaborative arrangements).
 - How well the evidence supports appropriate institutional commitment from each participating institution.
 - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations.

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Program portfolio composition, with consideration of the Areas of Encouragement,
- Relative impact,
- Adherence to the intent of the award mechanism, and
- Military relevance

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not received.
- Initiating or Partnering PI(s) application is not submitted by the deadline.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 SCIRP IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY10 SCIRP IP members may be found at <http://cdmrp.army.mil/scirp/panels/panel10>.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The proposed research is or contains a clinical trial.
- At least one partner is not a clinician, or at least one partner does not have experience in SCI research or SCI patient care.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1		Not Applicable (N/A)
	Upload Supporting Documentation (Support.pdf) as Attachment 2		N/A
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3		N/A
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4		N/A
	Upload Statement of Work (SOW.pdf) as Attachment 5		
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6		
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7		
	Upload Impact Statement (Impact.pdf) as Attachment 8		N/A
	Upload Military Relevance Statement (Military.pdf) as Attachment 9		N/A
	Upload Translation Statement (Translation.pdf) as Attachment 10		N/A
	Upload Letter from Nested New Investigator (Letter.pdf), if applicable, as Attachment 11		N/A
	Upload Approval for Access to Military and VA Populations (ApprovalAccess.pdf), if applicable, as Attachment 12		N/A

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		N/A
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field		N/A
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		N/A
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field		N/A
Project/Performance Site Location(s) Form	Complete form as instructed		N/A