

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-09-SCIRP-EHDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Background

1. Program Objectives

The Spinal Cord Injury Research Program (SCIRP) was established in fiscal year 2009 (FY09) to promote research into regenerating/repairing damaged spinal cords 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. Approximately \$35 million (M) of the FY09 supplemental appropriations bill, Public Law 110-329, was made available to support spinal cord injury (SCI) research. The Government reserves the right to increase or decrease the SCIRP funding of \$35M to execute the program.

The FY09 SCIRP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of SCI-focused research. Proposals involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs, and other Federal Government agencies are highly encouraged. Though the SCIRP supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

2. Areas of Encouragement

The FY09 SCIRP encourages proposals that specifically address the critical needs of the SCI community in the following areas:

- Neuro-protection and repair
- Rehabilitation and complications of chronic SCI
- Outcome measures to include development and validation

Several areas are of particular interest to the program; **however, all areas may not be applicable to each mechanism.** These areas include:

- The identification, refinement, and validation of outcome measures and devices to allow improved assessment of interventions in animal models and humans.
- A bio-physiological understanding of the mechanism of injury and repair throughout the progression of the injury from acute to subacute to chronic.
- Understanding the relationship between animal models and clinical/human application, including an understanding of the scaling issues between animals and humans as well as the pathobiological and behavioral relevance of animal models.
- Understanding and leveraging the clinical characteristics of injury and repair that can translate back to and guide priorities for basic research.
- Predictors of poor clinical outcomes and associated maladaptive plasticity.

- Comparative clinical trials that assess the differences between rehabilitation methods.
- Understanding the physiological basis (neuroplasticity) for rehabilitation therapies and evaluating whether there are quantitative benefits of activity-dependent rehabilitation training.
- Development and refinement of assistive and rehabilitation strategies and technologies to deliver improved functional capacity for people living with SCI.
- Research into advanced rehabilitation technologies including their contribution to neuroplasticity (e.g., tele-rehabilitation, simulation, virtual reality, functional electrical stimulation, exoskeleton movement systems, and robotics).
- Prevention of medical complications from SCI (e.g., cardiac disease, autonomic dysreflexia, spasticity, pain, skin care issues, bladder and bowel dysfunction, sexual dysfunction, and bone fractures).
- Utilization of existing clinical trials infrastructure and resources of established collaborations to enable rapid initiation of research that leverages available systems for structured data collection, analysis, and/or outcomes assessment.

B. Award Description

The SCIRP Exploration – Hypothesis Development Award (EHDA) supports the initial exploration of innovative, untested, high-risk, high-gain, and potentially groundbreaking concepts in the SCI research field. Results of studies conducted through this award may provide the scientific rationale upon which a new hypothesis can be based, or they should provide initial principles of an innovative hypothesis. This award is designed to provide investigators with the opportunity to pursue serendipitous observations. Some gaps in supporting rationale may exist due to a lack of available information. *The presentation of preliminary data is allowed, but not required.*

Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are either exempt under Title 32, Code of Federal Regulations (CFR), Part 219, Section 101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Studies that do not qualify for either exempt or expedited status during review at any level will be administratively withdrawn and will not be funded.

Investigators should consult with their local Institutional Review Board (IRB) if these regulations are unclear. If a study is not exempt or eligible for expedited review, applicants may be able to apply utilizing the Investigator-Initiated Research Award mechanism.

For studies using only commercially available or de-identified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the U.S. Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphrpo.asp>).

C. Eligibility

Investigators at all academic levels (or equivalent) are eligible to submit applications. Refer to Application Instructions & General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 2 years.
- The maximum allowable funding for the entire performance period is **\$100,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 2-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 institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs (*no clinical trials allowed*)
- Travel between collaborating institutions
- Travel to scientific/technical meetings, including travel to one Department of Defense-sponsored scientific meeting.

The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.6M of the \$35M FY09 SCIRP appropriation to fund approximately 10 EHDA applications, depending upon the quality and number of proposals received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

No changes in institution will be allowed once the proposal has been awarded. Refer to the Application Instructions & General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Submission is a two step process consisting of (1) pre-application submission and (2) application submission. *Pre-application submission is a required first step.*

Pre-application Submission Deadline:	October 30, 2009, 5:00 p.m. Eastern Time (ET)
Application Submission Deadline:	November 20, 2009, 11:59 p.m. ET
Scientific Peer Review:	January-February, 2010
Programmatic Review:	March 2010

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

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

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. ET on the deadline date**. Refer to the Application Instructions & General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the

Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each application submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for this U.S. Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

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

2. Attachments Form

- **Attachment 1: Project Narrative (two-page limit)**
- Describe the proposed project in detail using the outline below. *Presentation of preliminary data is allowed, but not required.*
 - **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this proposal.
 - **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 Department of Defense award would fund.
 - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials or studies that are not either exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).*
- **Attachment 2: Supporting Documentation**
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publications and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support (two-page limit per letter)
 - Letters of Collaboration (if applicable, two-page limit per letter)
 - Intellectual and Material Property Plan (if applicable)

- **Attachment 3: Technical Abstract (one-page limit)**
- **Attachment 4: Public Abstract (one-page limit)**
- **Attachment 5: Statement of Work (SOW) (three-page limit)**
- **Attachment 6: Detailed Budget and Justification**
- **Attachment 7: Impact Statement (one-page limit)**

Explain how the expected results of the study will make an original and important contribution to the goal of advancing SCI research and its impact on patient care. Describe the potential clinical applications, benefits, and risks.

- **Attachment 8: Innovation Statement (one-page limit)**

Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

Although not all-inclusive, the following examples are ways in which the proposed work may be innovative, and are intended to help PIs frame the innovative features:

- Study concept – Investigation of a novel idea and/or research question.
 - Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.
 - Novel method or technology – Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.
 - Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- **Attachment 9: Approval for Access to Military and Department of Veterans Affairs Populations (if applicable, one page limit)**
- 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).
- **Attachment 10: Federal Agency Financial Plan (if applicable)**
 - **Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)**

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

4. Research & Related 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 proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, military relevance, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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 correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions 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).

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement, Impact Statement, etc.).

B. Review Criteria

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

- **Innovation**
 - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.
 - How the proposed research represents more than an incremental advance upon published data.
 - How the potential gain justifies the perceived risk. **Impact**
- ○ How the proposed study addresses a critical problem in SCI research or patient care.
- How the proposed research will make original and important contributions toward

the goal of advancing SCI research or patient care.

- **Research Strategy and Feasibility** (*preliminary data allowed but not required*)
 - How well the scientific rationale and feasibility of the project supports the hypotheses or objectives as demonstrated by a critical review and analysis of the literature and logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How the intended results should give rise to a testable hypothesis.

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

- **Personnel**
 - The PI's potential for contributing to the SCI research field.
 - How the PI's record of accomplishment demonstrates his/her ability to accomplish the proposed work.
 - Appropriateness of the levels of effort for successful conduct of the proposed work.
- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that create the program's broad portfolio:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Program portfolio balance, with consideration of the Areas of Encouragement.
- Relative innovation and impact, and

- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur.

A. Rejection

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).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW FOR FY09:** Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 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 FY09 IP members may be found at <http://cdmrp.army.mil/09scirppanel>
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.
- Inclusion of studies that do not qualify for either exempt status under 32 CFR 219.101(b) or expedited review (32 CFR 219.110 or 21 CFR 56.110).

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 USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. 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
 Fax: 301-619-7792
 Email: cdmrp.pa@amedd.army.mil

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

Phone: 301-682-5507
 Website: <https://cdmrp.org>
 Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

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

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.