Program Announcement

Department Of Defense Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program (SCIRP)

Translational Research Partnership Award

Funding Opportunity Number: W81XWH-09-SCIRP-TRPA

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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 fields of SCI-focused research. 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.

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 intent of the SCIRP Translational Research Partnership Award is to encourage ***multi-institutional, multidisciplinary*** partnerships among clinicians and laboratory scientists that accelerate the movement of promising ideas in SCI research into clinical applications. Proposals that focus on research outcome measures are encouraged. This award is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to make a major impact on SCI research.

The SCIRP Translational Research Partnership Award supports the development of translational research partnerships among **two to three** independent investigators. Proposals are to address one of the areas of encouragement in SCI experimental 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 SCI laboratory research. It should be clear that all partners have equal 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 the 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). These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials. Please be aware that the ***Translational Research Partnership Award does not support clinical trials***, but may support correlative studies that are

associated with an existing clinical trial and projects that develop clinical endpoints for clinical trials. Refer to the Application Instructions & General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research. Research projects may also include preclinical studies in animal models and human subjects and human anatomical substances.

Proposals must include preliminary data (originating from the PI, research team or collaborator) and/or published data relevant to the topic area and the proposed project.

Important aspects of the SCIRP 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 skills and contributions of each partner. Of the two to three partners, at least one partner must be a clinician, and at least one partner 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 SCI research into clinical applications.

5. **Transition Plan:** Each PI must provide a transition plan (including funding and resources) showing how the product will progress to clinical trials and/or delivery to the military or commercial market after the successful completion of this SCIRP award.

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 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 by the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects. Refer to the Application Instructions & General Information, Appendix 6, for additional information.

Encouraged Department of Defense (DOD) Collaboration and alignment: Military relevance is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DOD areas of research interest within the FY09 SCI Research Program topic areas:

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/

C. Eligibility

Independent investigators at any academic level or equivalent are eligible to submit applications. Refer to the Application Instructions & General Information, Appendix 1, for general eligibility information. Partnering PI(s) must be independent investigators.

D. Funding

Each partner will be a PI, and a separate award will be made to each partner's institution. 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 combined total maximum allowable funding for one award is **$750,000** in direct costs, regardless of whether there are two or three PIs. While Initiating and Partnering PIs are expected to each contribute significantly to the execution of the proposed research, direct cost funding should reflect the tasks performed by each PI.
- 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 institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs (clinical trials not allowed)
- Travel between collaborating institutions
- Travel to scientific/technical meetings, including travel to one DOD-sponsored scientific meeting.

The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $6M of the $35M FY09 SCIRP monies to fund approximately five Translational Research Partnership Award applications, depending on 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

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:	**August 27, 2009, 5:00 p.m. Eastern Time (ET)**
Invitations to Submit Full Proposals Sent:	**No Later than October 2009**
Application Submission Deadline:	**December 10, 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/) and (2) an application submission through

Grants.gov (http://www.grants.gov/). ***Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.***

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 Translational Research Partnership Award is structured to accommodate two or three PIs. 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 PIs will be identified as the Partnering PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute to the preparation of the proposal. ***The Initiating PI must complete the pre-application process and submit contact information for each Partnering PI.***

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP e-Receipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting his/her application to Grants.gov, each Partnering PI must associate him- or her-self with the Initiating PIs application by accepting the link sent by the CDMRP eReceipt system. ***All PIs must submit an identical copy of a jointly created Statement of Work (SOW).***

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, Submission, and Screening

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. ET on the pre-application deadline***. Refer to the Application Instructions & General Information for detailed information.

- **Proposal Information:** The Initiating PI must enter the Application Information before continuing the pre-application.
- **Proposal Contacts:** The Initiating PI must enter his/her contact information.
- **Partners and Conflicts of Interest (COI):** The Initiating PI must enter the contact information for the collaborating PIs in the "Partnering PIs" section.
- **Preproposal Narrative:** The Preproposal Narrative has a ***three-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the pre-application. The preproposal narrative must be outlined as follows:
    - **Research Idea:** State the ideas and reasoning on which proposed research is based. Show how the perspective of each team member contributes to the development of the idea.

- **Research Strategy:** Concisely state the project's objective and specific aim.
- **Translational:** Describe the translational aspect of this proposal.
- **Partnership:** Describe how the project incorporates multiple disciplines and how it depends on the unique skills of each partner. Provide the time commitment for each partner as well**.** 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 a promising idea in SCI into clinical applications.
- **Military Relevance:** Describe how the proposed work is responsive to the health care needs of the 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 one or more of the FY09 SCIRP Areas of Encouragement.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
  - **References Cited:** One-page limit.
  - **Biographical Sketches:** Include biographical sketches for all partners and other key partners.

Pre-Application Screening

Pre-applications will be screened by the SCIRP Integration Panel, composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** Whether 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:** 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. Appropriateness of the proposed disciplines and the levels of effort.
- **Impact:** How the study addresses an important problem related to one of the areas of encouragement in spinal cord injury research. If successful, how the partnership and the aims of the application are likely to accelerate the movement of promising ideas in spinal cord injury into clinical applications.
- **Military Relevance:** How the proposed study may directly or indirectly benefit the identified military population, family member, or veteran, if successful.
- **Alignment with Areas of Encouragement:** If applicable, how the proposed study addresses at least one of the FY09 SCIRP Areas of Encouragement.

B. Step 2 – Application Components and Submission

PIs will receive notification of invitation to submit an application for the Translational Research Partnership Award. Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless the Initiating and Partnering PIs receive a letter of invitation. If invited to submit an application, the Partnering PIs will be contacted via e-mail by the CDMRP eReceipt system and provided the information necessary to begin application submission through Grants.gov. Please note that the Partnering PIs 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.

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 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 & General Information for detailed requirements of each component.

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting their application to Grants.gov, each Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system. ***Each PI also must submit an identical copy of a jointly created SOW.***

Failure by the Initiating PI or any Partnering PI to submit his or her required application components will result in administrative rejection of all applications associated with the proposed research project.

Application Submission Components for the Initiating PI

The Initiating PI must submit all Grants.gov application package components as listed in items 1-4 below.

The package includes:

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (15-page limit)**

     Describe the proposed project in detail using the outline below. ***The project narrative must include preliminary 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.***
  - Observations may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and preliminary data. Translational research should be viewed as a two-way continuum between bench and bedside. The process of moving an observation forward into clinical application should involve a reciprocal flow of ideas and information within the partnership. ***The Translational Research Partnership Award does not support clinical trials***, but may support correlative studies that are associated with an existing clinical trial and projects that develop clinical endpoints for clinical trials.
- **Partnership:** Describe how the project incorporates the unique skills of each partner. Provide the time commitment for each partner as well. 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 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**
  - References Cited
  - Acronyms & Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publication URLs and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support

    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)
- 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 (three-page limit)**
- **Attachment 6: Detailed Budget and Justification**
- **Attachment 7: Impact Statement (one-page limit)**

  Explain how the proposed research will have an impact on the concepts or methods that drive the field of SCI research. Describe how the proposed research will make original and important contributions towards the goal of advancing SCI research or SCI patient care.

- **Attachment 8: Military Relevance Statement (one-page limit)**

  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). Show how the proposed study complements ongoing DOD areas of research interest identified in the FY09 SCI Areas of Encouragement.

- **Attachment 9: Translation Statement**

  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 will translate promising, well-founded research findings into clinical applications in SCI.

- **Attachment 10: Approval for Access to Military and VA 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 11: Federal Agency Financial Plan (if applicable)**
- **Attachments 12-15: 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**

Application Components for Each Partnering PI

Before submitting the proposal application to Grants.gov, each Partnering PI must associate him- or herself with the proposal by accepting the link sent by the CDMRP eReceipt system. The CDMRP eReceipt system assigns a unique and separate log number, which must be used when submitting the Grants.gov application package.

The application submission process for the Partnering PIs uses an abbreviated application package of forms and attachments from Grants.gov. Each Partnering PI will be contacted via email by the CDMRP eReceipt system and provided with the information necessary to begin application submission through Grants.gov. 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.

Each Partnering PI package includes only the following from the list above:

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

2. **Attachments Form**

   - Attachment 5: Statement of Work: Three-page limit.

     The Initiating and Partnering PIs must each submit an identical, jointly created SOW.
   - Attachment 6: Detailed Budget and Justification
   - Attachment 11: Federal Agency Financial Plan (if applicable)
   - Attachments 12-15: Subaward Detailed Budget and Justification (if applicable)

3. **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 applications 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, overall goals of the program, the specific intent of the award mechanism, and military relevance. 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 program review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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. 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 applications based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Military Relevance Statement, Translatability Statement, etc.).

B. Review Criteria

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

- **Translational Potential**
  - How the project will translate promising, well-founded experimental laboratory or clinical research findings into clinical applications for patients with or populations at risk for SCI.
- **Research Strategy and Feasibility**
  - 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 hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How the partners acknowledge potential problems and address alternative approaches.
  - How well the proposal demonstrates access to military, family member, or veteran populations that will provide an appropriate sample for the study. How well the proposal documents power analyses or other method of determining adequate sample size for the proposed research. The viability of the alternatives proposed should the planned population become unavailable due to deployment or other exigent conditions.

- **Partnership**
    - Whether all PIs meet the eligibility requirements.
    - How the proposal addresses one of the 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.
- **Impact**
    - If successful, how the partnership and the aims of the study project will eventually move from a clinical observation, a laboratory discovery, or population-based study into clinical applications.
    - 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 toward the goal of advancing SCI research or SCI patient care.

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

- **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 impact

- Adherence to the intent of the award mechanism, and
- Military relevance

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, U.S. Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding.

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from 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 all applications associated with the proposed research project:

- Initiating or Partnering PI(s) application is missing.
- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Initiating or Partnering PI(s) 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:

- The proposed research is or contains a clinical trial.
- 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.
- At least one partner is not a clinician, or at least one partner does not have experience either in SCI research or SCI patient care.

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/) portal should be directed to the Grants.gov help desk, which is available Monday through Friday from 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 the CDMRP help desk is unable to answer questions regarding Grants.gov submissions.

Phone: 800-518-4726

Email: ***support@grants.gov***

Grants.gov will notify Principal Investigators (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.