Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Spinal Cord Injury Research Program

Advanced Technology/Therapeutic Development Award

Funding Opportunity Number: W81XWH-09-SCIRP-ATTDA

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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 (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 Advanced Technology/Therapeutic Development Award (AT/TDA) is intended to support demonstration studies of pharmaceuticals (drugs, biologics, and vaccines) and medical devices in preclinical systems and/or the testing of therapeutics and devices in clinical studies. The intent of the Advanced Technology/Therapeutic Development Award is to assess therapeutics and devices for the treatment, prevention, detection, and diagnosis of SCI.

The overall goal of this award mechanism is to accelerate the introduction of improved therapies, treatments, devices, or technologies for SCI into the clinical setting by supporting (1) cognitive/behavioral clinical studies, (2) clinical interventions, (3) the generation of the preclinical data (e.g., Good Laboratory Practice [GLP] animal safety and toxicity, identifying endpoints of clinical efficacy or its surrogate in animal models, and data collection sufficient to support an Investigational New Drug [IND] or Investigational Device Exemption [IDE] application) necessary to conduct clinical trials after completion of the proposed research. The proposed studies are expected to be empirical in nature and product-driven and are expected to be at or beyond Biomedical Technology Readiness Level (TRL) 4 (for descriptions of TRL(s) please see pages 126-138 of the document located at http://www.darpa.mil/STO/solicitations/sn07-44/pdf/TRA_Desktop.pdf).

All applications must specifically and clearly address the military relevance of the proposed research. Therefore, Principal Investigators (PIs) are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs. 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 market after the successful completion of this award.

Applications must include relevant data to support the rationale for the proposed study. These data may be unpublished and/or from the published literature.

Awards may support human studies but ***may not*** be used to support clinical trials of medical products to support regulatory submissions for new or expanded indications (i.e., Phase I-IV clinical trials). Awards ***may not*** be used to support fundamental basic research. Proposals must include preliminary and/or published data relevant to the hypothesis/aims of the proposed research project.

Awards may support human studies but ***may not be used to support clinical trials*** of medical products to support regulatory submissions for new or expanded indications (i.e., Phase 1–4 clinical trials). Awards may not be used to support fundamental basic research. Proposals must include preliminary and/or published data relevant to the hypothesis/aims of the proposed research project. Refer to the Application Instructions & General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research. PIs seeking funding for a clinical trial should apply to the FY09 SCIRP Clinical Trial Award –Rehabilitation mechanism (for information about this mechanism, see ***http://cdmrp.army.mil***).

Partnering PI Option: To foster collaboration and facilitate progress in the SCI research field by combined effort, the FY09 SCIRP is offering a Partnering PI option for this award mechanism. Development of the research plan should involve a reciprocal flow of ideas and information with equal intellectual input from all partners into the design of a single research project. For example, a proposed project in which a partner merely supplies support services, tissue samples, or access to patients will not meet the intent of this option.

This award is structured to accommodate **up to three PIs**. One member of the team will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with application submission. The other member(s) will be identified as the Partnering PI(s) and will need to complete administrative tasks associated with application submission. Separate awards will be made to each PI's institution. **One Initiating and up to two Partnering PIs may be designated.** Additional collaborators may be included, but they will not be designated PIs. Multidisciplinary and multi-institutional projects are allowed. If the project is multi-institutional, PIs should include plans for communication between investigators at each institution. Additionally, participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of this 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 SCIRP 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 all academic levels (or equivalent) are eligible to submit applications. Refer to Application Instructions & General Information, Appendix 1, for general eligibility information. Partnering PI(s) must be independent investigators.

D. Funding

- The maximum period of performance is **3** years.
- The combined total maximum allowable funding for one award is **$1.4M** in direct costs, regardless of whether there are one, 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.
- More cost-effective studies that do not request the full available funding amount are encouraged. The applicant may also 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 research costs ***(no clinical trials 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 $6.72M of the $35M FY09 SCIRP appropriation to fund approximately three AT/TDA 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 Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

Partnering PI Option

This award is structured to accommodate up to three PIs. One PI will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with proposal 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 the Partnering PIs.***

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 herself with the Initiating PI's 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).***

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 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)
- **Preproposal Narrative:** The Preproposal Narrative has a ***two-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preproposal. The preproposal narrative must be outlined as follows:
    - **Research Idea:** State the ideas and reasoning on which ***proposed work*** is based.
    - **Research Strategy:** Concisely state the project's objectives and specific aims.
    - **Impact:** State explicitly how the proposed work will have an impact on the prevention, detection, diagnosis, and treatment of military-relevant SCI.

- **Partnering PI:** If applicable, describe the partnerships and their contribution to the project.
- **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 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:** One-page limit.
  - **Biographical Sketches:** Include biographical sketches for the PI and other key collaborators.

Partnering PI Option: The Initiating PI must complete the pre-application components listed above and must enter the contact information for each Partnering PI in the "Partnering PI" section.

Pre-Application Screening: Pre-applications will be screened by the SCIRP Integration Panel (IP), 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 rational for SCI research.
- **Research Strategy:** How well the specific aims support the research idea.
- **Impact:** How the study addresses an important problem related to SCI. If successful, how the study will improve the prevention, detection, diagnosis, and treatment of military-relevant SCI.
- **Partnering PI:** If applicable, how the partnership fosters collaboration and facilitates progress in the SCI research field
- **Military Relevance:** How the proposed study may directly or indirectly benefit the identified military population, family member, or U.S. 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

Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless a letter of invitation has been received. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

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 and separate log number to each PI (Initiating and Partnering) that must be used when submitting the 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/her required application components will result in administrative rejection of all applications associated with the proposed research project.

Application Components for Single PIs or for Initiating PIs under the Partnering PI Option

The PI or 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.***

- **Partnership (if applicable):** 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 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 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)

    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)**

  Describe the potential impact of this study on the field of research and/or patient care of 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 for SCI.
  - Contributes to the development or validation of evidence-based policy or guidelines for patient evaluation and care.

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

  Demonstrate how the proposed study is responsive 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 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: Transition Plan (one-page limit)**

  Provide information on how the methods and strategies proposed will progress the outcome to the next clinical trial phase and/or delivery to the military and/or civilian marketplace after the successful completion of the SCIRP award. The plan should include details of potential funding sources, collaborations, other resources that will be used to provide this continuity of development, a potential timeline for deployment into the clinical setting, the involvement of appropriate intellectual property, licensing and/or business professionals, and plans for the further development and successful transition of the product.

- **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:

The application submission process for each Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov. Each Partnering PI will be contacted via email through the CDMRP eReceipt system and provided with 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 items from the list above:

1. **SF-424 (R&R) Application for Federal Assistance Form**
2. **Attachments Form**
   - Attachment 5: Statement of Work (SOW): 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, 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 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 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 proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Military Relevance Statement, Transition Plan, 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.

- **Research Strategy and Feasibility**
  - How well the preliminary data and scientific rationale supports the research project.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How the PI acknowledges potential problems and addresses 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. What alternatives are proposed should the planned population become unavailable due to deployment or other exigent conditions?
- **Transition Plan**
  - How the transition plan describes deployment of the product, device, and/or emerging technology to the clinical environment.
  - Whether there is evidence that the PI has or can secure additional funding, or whether the PI clearly described potential options to secure the additional funding needed to bring the product, device, and/or emerging technology to clinical trial phase and/or deployment to the clinical setting.
  - How the proposed resources to bring the product to delivery support the likelihood of success.
  - How appropriate intellectual property, licensing, and/or business professionals have been included or engaged.
  - How well the plans are described for further development of the product, device and/or emerging technology and how well the plan completes development of the product to ensure a successful transition.
- **Impact**
  - How the proposed study addresses a critical problem in SCI research or patient care.
  - The potential contribution of the proposed study to research and/or patient care in SCI.
- **Personnel**
  - How the background and expertise of the PI and other key personnel are appropriate to accomplish the proposed work.

- How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
- **Partnering PI Option (if applicable)**
  - How well the evidence supports that the Initiating PI and all Partnering PIs contributed substantially to the development and implementation of the study design.
  - How well the evidence supports that the Initiating PI and Partnering PIs demonstrate their ability to accomplish the proposed work.
  - How well the proposal demonstrates a partnership among the PIs that will foster collaboration and facilitate progress in the SCI field by combined effort

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

- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported adequately 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 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 the by 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 and objectives of the program.

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 CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within by 5:00 p.m. ET on the second full business day following the date 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.
- 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 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, 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***

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