Program Announcement

Department of Defense Congressionally Directed Medical Research Programs (CDMRP)

Peer Reviewed Orthopaedic Research Program (PRORP)

Career Development Award

Funding Opportunity Number: W81XWH-09-PRORP-CDA

Table of Contents

I. FUNDING OPPORTUNITY DESCRIPTION

A. Background Information

1. Program Objectives

The Peer Reviewed Orthopaedic Research Program (PRORP) was established in Fiscal Year 2009 (FY09) to address the leading burden of injury and loss of fitness for military duty by funding innovative, high-impact, clinically relevant research to advance treatment and rapid rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities. The FY09 congressional appropriations bills, Public Law 110-329 and 111-32, provided $61 million (M) and $51M, respectively, for a total appropriation of $112M to support military-relevant, peer-reviewed orthopaedic research. The Government reserves the right to increase or decrease the PRORP funding to execute the program.

The FY09 PRORP challenges the scientific community to design innovative research that will foster new directions for and address neglected issues in the field of medical research focused on combat-relevant orthopaedic problems. Though the program emphasizes funding groundbreaking research, all projects must demonstrate appropriate judgment and sound rationale. The program highly encourages the submission of applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies.

2. Priority Research Areas

The FY09 PRORP priority research areas relevant to musculoskeletal injury are provided below. This award mechanism seeks applications from all areas of basic, preclinical, translational, and clinical research (excluding clinical trials) as they relate to ***any*** of the PRORP-identified priority research areas listed below. ***All applications for PRORP funding must specifically and clearly address at least one PRORP-identified priority research area.***

The FY09 PRORP priority research areas are:

- Acute Care of Battle Injuries (**Roles II and III**)
  - Enhancement of the tissue environment for healing
    - Optimal indicators of viability for soft tissue and bone
    - Methods of enhancing viability
    - Modulators of local inflammatory processes
    - Optimal indicators for limb salvage vs. amputation
    - Optimal timing and materials for vascular, nerve, and other soft tissue repair
  - Prevention of complications
    - Preventing, identifying, and treating compartment syndrome
    - Early intervention strategies for acute management of pain
    - Methods of early bone or soft tissue stabilization

        - Early prevention strategies for infection
    - Development of in vivo translational models for the acute injury environment
- Definitive Care of Battle Injuries
    - Restoration of joint function
        - Optimal materials and clinical care for joint reconstruction
        - Treatment of articular cartilage injury
        - Regeneration of bone, muscle, and cartilage
        - Development of *in vivo* translational models
    - Treatment of orthopaedic injuries (and sequelae) of the spine not related to spinal cord injury (e.g., spinal fractures, acute herniated disks, infection of the spinal column, acute instabilities)
    - Restoration of Function
        - Clinical studies of motor and sensory reinnervation
        - Development of a functional innervated muscle for soft tissue injury
    - Acceleration of healing
        - Clinical efficacy of new and existing products
        - Modulation of systemic responses to injury/healing
        - Clinical care for segmental bone loss
- Rehabilitation
    - Evaluation of clinical efficacy of new technologies
        - New and novel approaches to rehabilitation, prosthetics, and orthotics
    - Evaluation of clinical outcomes of rehabilitation strategies, prosthetics, and/or orthotics
    - Evidence-based rehabilitation strategies for warriors in transition with orthopaedic-related injuries
- Prosthetics and Orthotics
    - Maintenance/enhancement of long-term socket performance/fit
        - Design and development of flexible socket suspension systems
        - Evaluation of socket performance
        - Maintenance of limb volume/mass
        - Clinical applications of new technologies
    - Solution of critical issues in osseointegration
        - Translational investigation of skin/prosthesis interface for osseointegrated sockets
        - Reduction of infection risk of osseointegrated limb interfaces

B. Award Description

The PRORP Career Development Award is being offered for the first time in FY09. This award supports a mentored research experience to prepare military investigators without significant experience in orthopaedic research for a productive, independent career in this field. This award supports individuals in the early stages of their careers by providing the experience necessary to pursue career opportunities at the forefront of orthopaedic research and make significant contributions to combat-relevant orthopaedic research and/or clinical care.

Key elements of this award include:

- **Principal Investigator:** PIs must be an active-duty researcher- or active-duty physician-scientist at the early-career stage, and located at a Department of Defense (DOD) research or clinical site. PIs must have less than a total of 8 years of postdoctoral clinical or research experience (excluding clinical residency or fellowship training), and received less than $500,000 in direct costs in aggregate as a PI of Federally or privately funded, non-mentored, peer reviewed grants.

- **Orthopaedic Research Mentorship:** A designated mentor is required. This mentor must be an established, independent orthopaedic researcher, have a history of orthopaedic research funding, and have a record of orthopaedic research publications in peer-reviewed journals. In addition, the mentor must demonstrate a commitment to developing and sustaining the PI's research career in orthopaedic research. ***To promote collaboration between military and non-military institutions, it is encouraged, but not required, that the mentor be from an academic, VA, or other non-military institution.***

- **Career Development:** A career development plan should be prepared with guidance from the mentor. A clearly articulated strategy for acquiring the necessary skills, competence, and expertise to have a career at the forefront of orthopaedic research should be included. The plan should outline how the PI will gain experience and training in orthopaedic research. Because career development is the focus of this award, the institution must demonstrate a commitment to the PI through a minimum of 30% protected time, though more protected time is highly desirable.

- **Priority Research Areas:** This award mechanism seeks applications from all areas of basic, preclinical, translational, and clinical research (excluding clinical trials) as they relate to ***any*** of the PRORP-identified priority research areas listed under Section A above. ***If the proposed project is not relevant to at least one PRORP-identified priority research area, the Government reserves the right to administratively withdraw the application.*** All applications must have a direct relevance to orthopaedic injuries sustained during military combat or combat-related activities.

- **Military Benefit:** The proposed research should provide a significant benefit for the field of military combat-relevant orthopaedic injuries research. The proposed research is expected to make an important and original contribution to advancing combat-relevant orthopaedic research or orthopaedic medicine.

Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive.

Clinical trials are not allowed under this award mechanism, but clinical research and correlative studies associated with an existing clinical trial may be proposed. Refer to the Application Instructions & General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

Encouraged 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 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:

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

Congressionally Directed Medical Research Programs (CDMRP)
http://cdmrp.army.mil

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

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

Naval Health Research Center
http://www.med.navy.mil/sites/nhrc

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

Office of Naval Research
http://www.med.navy.mil/

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

U.S. Army Medical Research Acquisition Activity (USAMRAA)
http://www.usamraa.army.mil

U.S. Army Medical Research and Materiel Command (USAMRMC)
https://mrmc.amedd.army.mil

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

U.S. Naval Research Laboratory
http://www.nrl.navy.mil

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

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 to the local review board. Allow a minimum of 6 months for regulatory

review and approval processes for studies involving human subjects. Refer to Application Instructions & General Information, Appendix 6, for detailed information.

Use of Military Populations: Coordination of access to various military populations is described below.

1. Active Duty, National Guard, Reserve troops, and/or military patient populations (not CENTCOM Area of Responsibility): Access to Active Duty, National Guard, or Reserve troops must be coordinated by the PI. Collaboration with Associate Investigators in military treatment facilities is encouraged as a method for access to patient populations.

2. CENTCOM Area of Responsibility military populations: Access to military populations in the pre-deployment, deployment, and post-deployment window is very limited and will be coordinated through the CDMRP as described above. ***PIs who do not have a previously established study population should not contact unit Commanders at this time or during preparation of the proposal submission. If selected for funding, the PI will be provided guidance on how to obtain access to the appropriate population.***

Research conducted using military populations in Iraq is conducted with oversight by the Multi-National Force - Iraq (MNF-I). PIs who are outside of this system and submit a research proposal designed to recruit patients within MNF-I must coordinate with the in-theatre Deployed Combat Casualty Research Team charged with facilitating an in-theater review, and be approved by the MNF-I Command and the MNF-I designated Institutional Review Board (IRB). The same is true for research conducted in Afghanistan in the US Forces - Afghanistan (USFOR-A) Area of Responsibility. PIs who are outside of this system and submit a research proposal designed to recruit patients within USFOR-A must coordinate with the in-theatre Deployed Combat Casualty Research Team charged with facilitating an in-theater review, and be approved by the USFOR-A Command and the USFOR-A -designated Institutional Review Board (IRB). If selected for funding and if needed, CDMRP will assist with guidance on how to obtain the required in-theater approvals.

Given the constraints of wartime operations, investigators without an ongoing collaboration with an appropriate military investigator should strongly consider alternatives to conducting in-theater research. DOD-supported human subjects research can only be conducted by institutions (including those in-theater) with approved Federal Assurances of Compliance from the Human Research Protection Office. It is strongly suggested that proposals submitted necessitating the use of this population involve civilian and non-deployed military populations as an alternative. Any request for access to these limited populations should be strongly justified, and it must be shown that the proposed study cannot be done on any other population.

3. Department of Veterans Affairs (VA) Medical Centers patient populations: Access to patient populations from the VA Medical Centers or use of information from VA data systems must be coordinated by the PI. PIs who submit a research project designed to recruit patients from a VA Medical Center or use information from VA data systems and

those who do not have an appointment at one of the VA Medical Centers must include a collaborator with a VA appointment. This collaborator must be willing to assume the role of PI for the VA component of the research. IRB approval from all participating VA clinical sites will be required.

C. Eligibility

To be eligible for this award the PI must be an active-duty researcher- or active-duty physician-scientist at an early-career stage, located at a DOD research or clinical site. PIs must have less than a total of 8 years of postdoctoral clinical or research experience (excluding clinical residency or fellowship training), and received less than $500,000 in direct costs in aggregate as a PI of Federally or privately funded, non-mentored, peer reviewed grants. Refer to the Application Instructions & General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is **$225,000** in direct costs.
- 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 your institution's negotiated rate agreement.

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

- Salary of non-government personnel
- Research supplies
- Equipment
- Clinical research costs *(Clinical trials are not allowed)*
- Publication costs
- Tuition for workshops, courses, and/or other educational opportunities
- Consultation with scientific and/or technical experts (e.g., statisticians, editors)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

DOD applicants must develop a plan delineating how all funds provided directly to them by USAMRAA will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include a funding mechanism(s) that will be used to carry over funds between fiscal years, such as through current/active agreements

with foundations, non-federal institutions, and universities. Please see Section II.B in the Application Instructions for information regarding the Federal Entity Financial Plan.

The CDMRP expects to allot approximately $1.75M of the $112M FY09 PRORP appropriation to fund approximately 5 Career Development Award applications, depending on the quality and number received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

A change in PI is not allowed for the Career Development Award mechanism, except under extreme circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

Refer to the Application Instructions and General Information, Appendix 5, for general award information on changes in award personnel or institution.

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:	**November 20, 2009, 5:00 p.m. Eastern time**
Application Submission Deadline:	**December 9, 2009, 11:59 p.m. Eastern time**
Scientific Peer Review:	**February 2010**
Programmatic Review:	**April 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/).

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.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to administratively withdraw duplicative applications submitted to 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 by ***5:00 p.m. Eastern time on the deadline date***. In addition to award-specific information provided below, refer to the Application Instructions and General Information for detailed information on pre-application components and submission.

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

B. Step 2 – Application Components and Submission

Applications 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).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US 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 (8-page limit)**

     Describe the proposed project in detail using the following outline:

     - **PI's Career Goals:** Explain how the PI meets the eligibility requirements of the award as outlined in Section I.C. Describe qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a researcher and clinician and how the proposed training will promote his or her career in combat-relevant orthopaedic research and/or patient care. Discuss the PI's career plans after the completion of this award.

- **Career Development Plan:** Describe the career development plan, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Provide a timeline for the career development plan. Describe the mentor's background and experience in orthopaedic research and discuss how the mentor will assist the PI in developing his or her career. Explain how the career development plan is supported by the environment; this should include a description of ongoing combat-relevant orthopaedic research at the institution(s). Include information on training or collaborations with other investigators.
- **Research Project:** Identify the PRORP Priority Research Area(s) with which the proposed project aligns. Describe the project, including background, hypothesis or objectives, specific aims, experimental design and methods. ***Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive.*** Address potential problem areas and present alternative methods and approaches. Discuss the relevance of this research to combat-related orthopaedic research. ***This award may not be used to conduct clinical trials.***
- **Integration of Training and Research:** Describe how the career development plan and research project are integrated and how they will contribute to preparing the PI for a career in combat-relevant orthopaedic research and/or patient care.

- **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

    The letter(s) should indicate the level of institutional commitment to fostering the PI's research and clinical career, as reflected by (1) the extent to which the PI will be relieved of clinical or other responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues with establish research careers. **Letters from the PI's immediate supervisor and Commander must be provided that demonstrate a commitment to allow at least a 30% effort on the project by the PI.**
  - Letters of Collaboration (if applicable)
  - Intellectual and Material Property Plan (if applicable)

- **Attachment 3: Technical Abstract (one-page limit)**

  Both the career development program and the research project should be emphasized.

- **Attachment 4: Public Abstract (one-page limit)**

  Both the career development program and the research project should be emphasized.

- **Attachment 5: Statement of Work (SOW; three-page limit)**

- **Attachment 6: Detailed Budget and Justification**

- **Attachment 7: Letter from Designated Mentor (three-page limit)**

  The letter from the designated mentor should describe:

  - The PI's potential as an orthopaedic researcher;
  - How the PI's achievements (as reflected by academic performance, awards, and honors) indicate a potential for a successful career in orthopaedic research:
  - The mentor's proposed interactions with the PI during the PI's career development;
  - The training environment, including ongoing orthopaedic research at the mentor and PI institutions, and how the environment will promote the development of the PI as a orthopaedic researcher;
  - The research training program in which the PI will participate including descriptions of coursework, experience with laboratory techniques, conferences, and journal clubs;
  - Research being performed under the mentor's direction and how this research is relevant to orthopaedic injuries, orthopaedic research, and/or treatment outcomes;
  - The mentor's history of training postdoctoral fellows, residents, and fellows;
  - The resources available to adequately support the PI's project (specific details on existing support should be covered in the Existing/Pending Support section); and
  - The degree to which the PI participated in idea development and application preparation, and the degree to which the PI will participate in the execution of the application if funded.

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

  State explicitly how the proposed work, if successful, will have an impact on the lives of individuals recovering from combat-relevant orthopaedic injuries, orthopaedic research, and/or treatment outcomes. Describe how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of these injuries.

Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces and/or the US veteran population. If active duty military 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 and/or the US veteran population). Show how the proposed study complements ongoing DOD areas of orthopaedic research interest. Describe how the study design will replicate field conditions, if applicable.

- **Attachment 9: Approval for Access to Military Populations (if applicable)**

  If the PI has already established access to a service member population, a letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military; 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 Form)

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

  A biographical sketch of the PI's mentor is required.
- Key Personnel Current/Pending Support

  Current/Pending Support for the PI's mentor is required.

4. 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, the overall goals of the program, 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 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., Innovation Statement or Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria. Of these, Principal Investigator, Mentor, and Training Program and Environment are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Principal Investigator**
  - How well the PI meets the eligibility requirements.
  - How the PI's achievements (as reflected by academic performance, awards, and honors) indicate a potential for successful career in orthopaedic research.
  - How the mentor's letter of support provides evidence for the PI's potential for a productive career in orthopaedic research.
  - To what extent the PI demonstrates the potential to become a successful orthopaedic researcher or clinician.
  - How the PI's stated career goals demonstrate a commitment to pursuing a career as an orthopaedic researcher or clinician.
- **Mentor**
  - How the mentor is appropriately trained and well suited to guide the research project, including the mentor's experience, publications and current funding in orthopaedic research.
  - How the mentor's training achievements, as reflected by his/her previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in orthopaedic research.
  - How the mentor's research experience, research program, committed resources,

and level of effort are appropriate for the proposed career development plan.

- Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.

- **Career Development Plan**
  - How well the career development plan addresses an issue related to orthopaedic research or clinical medicine.
  - How well the PI has outlined an individualized career development plan that augments his/her expertise.
  - How well the training will prepare the PI for an independent career in orthopaedic research and clinical medicine.
- **Environment**
  - How the scientific environment is appropriate for the proposed career development activities, including critical professional interaction with established senior research colleagues.
  - Whether there is a clear institutional commitment to allow protection of at least 30% of the PI's time for research.
  - How the quality and extent of other institutional support are appropriate.
- **Military Benefit**
  - The degree to which the proposed project, if successful, will impact the lives of those affected by combat-relevant orthopaedic injuries.
  - How well the project addresses a critical problem in combat-relevant orthopaedic research or medicine.
  - The degree to which the proposed project, if successful, will advance the research methods, understanding of, and/or treatment of combat-relevant orthopaedic injuries.
- **Research Project, Strategy, and Feasibility**
  - How the research project is appropriate to prepare the PI for a successful career in orthopaedic research and clinical medicine.
  - Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
  - How well the PI acknowledges potential problems and addresses alternative approaches.

- How well the proposed research project responds to one or more of the FY09 PRORP priority research areas.

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

- **Budget**
  - How 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 maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative impact and responsiveness to FY09 PRORP Focus Areas
- Program portfolio balance

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.

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 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 by 5:00 p.m. Eastern time on the second full business day following the date the email was sent. Otherwise, the application will be 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/09prorppanel
- 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 proposed project is not relevant to at least one of the award mechanism-specific focus areas.

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. Eastern time.

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. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time
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.