

Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Peer Reviewed Orthopaedic Research Program (PRORP)

Technology Development Award

Funding Opportunity Number: W81XWH-09-PRORP-TDA

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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. **Not all of the following research areas may be applicable to this Program Announcement/ Funding Opportunity;** some areas are relevant to other mechanisms offered by the FY09 PRORP. Focus areas specific to this award mechanism are provided in Section B, Award Description. ***All applications for PRORP funding must specifically and clearly address a focus area of the specific award mechanism to which the application is being submitted.***

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 Technology Development Award mechanism is being offered for the first time in FY09.

The PRORP recognizes the critical need for improved technologies and resources to advance the field of research focused on military combat-relevant orthopaedic injury and rehabilitative medicine. Consequently, the Technology Development Award has been established to support product-driven research aimed at developing technologies and related resources for use by both the applicant's laboratory and the orthopaedic research community to promote basic and preclinical research on musculoskeletal injuries related to military service. Applicants must clearly articulate how the proposed technology or resource addresses an unmet need in orthopaedic research or clinical care for acute combat-related injury. As applicable, applicants should also explain the advantages of their proposed approach to developing the technology or resource over standard methodologies and techniques.

PRORP Technology Development Award Focus Areas: This award mechanism seeks applications from all areas of basic, preclinical, translational, and clinical research (excluding clinical trials) as they relate to the Technology Development Award focus areas listed below. *If the proposed project is not relevant to the specified PRORP Technology Development Award focus areas, 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 related activities. The focus areas are:

- Development of in vivo translational models for the acute injury environment
- Restoration of joint function
 - Development of in vivo translational models to study restoration of joint function in definitive care
- 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

Although not required, multi-institutional and multidisciplinary research collaborations, especially those with military laboratory scientists and/or clinicians, are encouraged.

Applications for this award should include a plan describing the means by which the fully developed technology/resource will be made available to the scientific community at reasonable or appropriate costs. The Government intends to advertise the technology/resource developed through this award to the scientific community and to provide information on the Congressionally Directed Medical Research Programs (CDMRP) website as to how to acquire the technology/resource.

Important aspects of the Technology Development Award are as follows:

- 1. Military Benefit:** The proposed research is expected to make an important and original contribution to advancing combat-relevant orthopaedic research or clinical care.
- 2. Technology Development Product:** The technology or resource produced by the research should be relevant for a wide range of studies for combat-relevant acute musculoskeletal injuries, and should be able to be made widely available to the military and non-military scientific research community.

Applications must include preliminary and/or published data relevant to the topic area and the proposed project.

This award may not be used to conduct clinical trials. Refer to the Application Instructions & General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research. Principal Investigators (PIs) seeking funding for a clinical trial should apply to the FY09 PRORP Clinical Trial Award mechanism.

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
<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-nmcpbc.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
<http://www.usamraa.army.mil>

U.S. Army Medical Research and Materiel Command
<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: Describe the military population(s) to be used for the proposed study, if applicable. 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): Unless the PI has already established access to a service member population, access to Active Duty, National Guard, or Reserve troops must be coordinated through the CDMRP. Collaboration with Associate Investigators in military treatment facilities is encouraged as a method for access to patient populations. *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.*

2. CENTCOM Area of Responsibility military populations: Access to military populations in these areas is very limited and will be coordinated through the CDMRP as described above.

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, CDMRP will assist with guidance on how to obtain the required in-theatre 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 suggested that proposals submitted necessitating the use of this population involve civilian and non-deployed military populations as an alternative.

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

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

D. Funding

- The maximum period of performance is **4** years.
- The maximum allowable funding for the entire period of performance is **\$2M** in direct costs. However, investigators are encouraged to submit applications for smaller-scale projects that require lower funding levels.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum **4**-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 & General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical research costs (Clinical trials are not allowed.)
- Travel to scientific/technical meetings, including the next CDMRP Military Health Research Forum
- Travel between collaborating institutions
- Other direct costs as described in Application Instructions & General Information for Detailed Budget and Justification.

In addition, travel funds must be requested for the PI to attend one DOD military research-related meeting to be determined by the Office of the Congressionally Directed Medical Research Programs (CDMRP) during the award performance period.

The CDMRP expects to allot approximately \$9.3M of the \$112M FY09 PRORP appropriation to fund approximately three Technology Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/ Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions & General Information, Appendix 5, for general award administration information.

In addition written progress reports, awardees may expect requests for formal progress presentation in clinical symposia to accelerate transition into clinical practice.

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 the required first step.*

Pre-application Submission Deadline:	August 13, 2009, 5:00 p.m. Eastern time
Invitation to Submit an Application:	No later than September 30, 2009
Application Submission Deadline:	November 17, 2009, 11:59 p.m. Eastern time
Scientific Peer Review:	January 2010
Programmatic Review:	March 2010

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

III. SUBMISSION PROCESS

Submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). *Applications will not be accepted unless the 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 administratively withdraw duplicative applications submitted within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by **5:00 p.m. Eastern time (ET) on the pre-application 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 **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 should address the following:
 - **Military Benefit:** Briefly state how the proposed technology or resource will, in the near- and/or far-term, provide a significant benefit to the lives of individuals who have sustained combat-relevant orthopaedic injuries, including concepts and methods that will advance the field of combat-relevant orthopaedic research and/or clinical care.
 - **Technology Development Product:** State the scientific rationale that supports the need for the proposed technology or resource. Describe the range of applicability of the proposed product, with attention to the PRORP Technology Development Award Focus Areas described above.
 - **Research Strategy:** Concisely state the scientific strategy that will be used to develop the technology or resource, including the broad objective and specific aims.

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 key collaborators.

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

- **Military Benefit:** The degree to which the proposed technology or resource, if successful, will accelerate the movement of orthopaedic research or clinical care toward a significant benefit to the health and lives of warfighters who have experienced combat-related orthopaedic injury.
- **Research Idea:** How well a clear technology or resource has been identified. The degree to which the work aligns with the Technology Development Award focus

areas and will address an important problem related to acute combat-relevant orthopaedic injury and/or care.

- **Research Strategy:** How well the specific aims support the technology development.

B. Step 2: Application Components and Submission

PIs will receive notification of invitation to submit an application for the Technology Development Award. Applications 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).

Because the invitation to submit an application is based on the contents of the pre-application, PIs should not change the title, research objectives, or focus area(s).

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 & 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 (25-page limit)**

The Project Narrative is the main body of the application. The inclusion of preliminary data is required.

Describe the proposed project in detail using the following outline:

- **Background:** Present the ideas and reasoning supporting the proposed research, to include relevant literature citations. Describe scientific findings and previous experience most pertinent to this proposal.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If this proposal is part of a larger study, present only aims that this DOD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If

human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***Clinical trials are not allowed under the Technology Development Award mechanism.***

- **Attachment 2: Supporting Documentation**

- References Cited
- Acronyms and 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 clinical physician, the institution must clearly demonstrate a commitment to the clinician's research.
- Letters of Collaboration (If applicable; no page limit)
- Letter(s) from appropriate authority showing approved access to veterans if proposing to study veteran volunteers or use data from veterans (e.g., Defense Manpower Data Center Data Request System, collaborating investigators from the Veterans Administration, etc.) (if applicable)
- Intellectual and Material Property Plan (If applicable)

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

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

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

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

- **Attachment 7: Military Benefit Statement (one-page limit)**

State explicitly how the proposed work, if successful, will have an impact on orthopaedic research and ultimately on the lives of individuals recovering from combat-relevant orthopaedic injuries. 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 U.S. 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 U.S. 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 8: Transition Plan (one-page limit)**

Provide information on the methods and strategies by which the fully developed technology/resource will be made available to the research or clinical community at reasonable or appropriate costs. The plan may include details of funding sources, collaborations, and other resources that will be used to provide this continuity of development.

- **Attachment 9: Approval for Access to Military Populations (if applicable; one-page limit)**

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: Request for Information on Study Population (if applicable)**

If the PI has not yet established access to a service member population, a Request for Information on Study Population form should be submitted. This form is provided in the Application Instructions and General Information for the Program Announcement/Funding Opportunity.

- **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 Form)

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

4. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends applications 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.htm>.

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 nondisclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the nondisclosure 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).

B. Review Criteria

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

- **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.
- **Technology Development Product**
 - How well a clear product has been identified.
 - The degree to which the technology or resource to be developed will provide significant advantages over standard methodologies and techniques.

- **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 and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and support completion of the aims.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - The degree to which the plan to study military populations, if applicable, is appropriate and feasible.

- **Transition Plan**
 - Whether the plan for bringing the product to delivery is feasible and appropriate.
 - Whether there is evidence that the PI has or can secure the additional funding needed to bring the product to delivery (if applicable).
 - How well intellectual property, licensing, and/or business professionals have been included or engaged.
 - How well the resources proposed to bring the product to delivery support the likelihood of success.

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

- **Personnel**
 - Whether the applicant meets the eligibility requirements.
 - The degree to which the research team's background and expertise are appropriate to accomplish the proposed work.
 - Whether there are appropriate levels of effort by the PI and other key personnel to ensure success of the project.

- **Environment**
 - The degree to which the scientific environment is appropriate for the proposed research.
 - The degree to which the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - Whether 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 equally weighted 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 military benefit
- Program portfolio balance, with consideration for the award mechanism focus areas

Scientifically sound applications that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by IP members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command.

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 the application:

- Submission of an application for which a letter of invitation was not received.
- 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by the 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 peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <http://cdmrp.army.mil/09prorppanel.htm>.
- The application includes a clinical trial.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- 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 and Justification 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. ET.

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

C. Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. ET
Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement 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.