

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Peer Reviewed Orthopaedic Research Program**

### **Idea Development Award**

**Funding Opportunity Number: W81XWH-12-PRORP-IDA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 27, 2012
- **Invitation to Submit an Application:** August, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, September 25, 2012
- **Peer Review:** November 2012
- **Programmatic Review:** January 2013

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications for the Peer Reviewed Orthopaedic Research Program (PRORP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PRORP was established in fiscal year 2009 (FY09) to support research focused on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or combat-related duties. Appropriations for the PRORP from FY09 through FY11 totaled \$158.5 million (M). The FY12 appropriation is \$30M.

The FY12 PRORP challenges the scientific community to address the most significant gaps in care for the leading burden of injury and loss of fitness for military duty by funding innovative, high-impact, clinically relevant research to advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities. Applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged.

### B. Award Information

The PRORP Idea Development Award was previously offered in FY09. In that year, 65 applications were received, and 21 were recommended for funding. The Idea Development Award is designed to promote new ideas that are still in the early stages of development and have the potential to yield highly impactful data and new avenues of investigation. This mechanism supports conceptually innovative, high-risk/high-reward research that could lead to critical discoveries or major advancements that will accelerate progress in the clinical care of combat-related orthopaedic injuries. Applications should include a well-formulated, testable hypothesis based on strong scientific rationale.

***Innovation and military benefit are the most important aspects of the Idea Development Award. Applications that demonstrate exceptional scientific merit but lack innovation and high potential military relevance do not meet the intent of the Idea Development Award.***

Presentation of preliminary data is not consistent with the intent of the Idea Development Award mechanism. While the inclusion of preliminary data is not prohibited, the strength of the application should not rely on preliminary data, but on the innovative idea and the potential for impact on wounded Warfighters.

**Innovation:** Research deemed innovative may represent a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. The following list, ***although not all-inclusive***, provides examples of research that is not innovative and will not be considered for funding under this mechanism:

- Exploring a previously tested hypothesis in a different cell line or in a new population.
- Using a published series of in vitro assays to further characterize a model system.
- Investigating the next logical step or continuation of a previous research project.
- Proposing work that would be an incremental advancement of published data.

**Military Benefit:** The proposed research is expected to make an important and original contribution to advancing combat-relevant orthopaedic medicine or research. Projected outcomes should have the potential to impact issues common in or unique to orthopaedic injuries sustained in combat or combat-related activities.

***It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's innovation and its potential impact on military populations. The project's impact to both orthopaedic research and to combat-injured patients should be articulated, even if clinical impact is not an immediate outcome.***

**PRORP Idea Development Award Focus Areas:** All applications must address at least one of the following Focus Areas:

- Improvement of moisture management and residual limb skin care at the prosthetic socket interface.
- Strategies to inhibit neuromas at surgical/amputation sites.
- Improvement of the rate of nerve regeneration.
- Mitigation of the musculoskeletal and physiologic effects of reduced mobility for polytrauma patients, excluding spinal cord injury and behavioral/psychological effects.
- Short-term and long-term outcomes in limb salvage populations. May include retrospective or prospective observational clinical studies.
- Prevention or treatment of post-traumatic joint stiffness and contracture in the ankle, knee, and/or elbow.

In determining the Focus Areas for FY12, the PRORP Integration Panel (IP) strongly considered the research priorities set forth during the Extremity War Injuries VII Symposium held January 18-20, 2012, in Washington, DC.<sup>1</sup>

***Research involving human subjects is permitted under this funding opportunity; however, clinical trials are not allowed.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical research, see Human Subject Resource Document at [https://cdmnp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmnp.org/Program_Announcements_and_Forms/). PIs seeking funding for a clinical trial should utilize the PRORP Clinical Trial Award mechanism.

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<sup>1</sup> Ficke JR, Obremsky WT, Gaines RJ, Pasquina PF, Bosse MJ, Mamczak CN, O'Toole RV, Archer KR, Born CT, Fleming ME, Watson JT, Gordon WT, Stannard JP, Rispoli DM, MacKenzie EJ, Wenke JC, Hsu JR, Pollak AN, and Anderson R. Extremity War Injuries VII – A Decade of War: Reprioritization of Research for Combat Casualty Care. *J Am Acad Orthop Surg* (in press).

## NESTED CAREER DEVELOPMENT OPTION

A nested Career Development opportunity is being offered as an optional addition to the Idea Development Award. The intent of the nested Career Development Option is to support research training opportunities for military investigators pursuing careers in orthopaedic research. This option supports individuals in the early stages of their careers by providing the experience necessary to pursue career opportunities at the forefront of orthopaedic trauma research and make significant contributions to combat-relevant orthopaedic research and clinical care.

- Career Development Principal Investigator: Career Development PIs must be active-duty research- or physician-scientists at either the postdoctoral or early-career level as described under the Eligibility Information section (Section I.C). The Career Development PI may be the PI or a co-PI of the application. Only one Career Development PI may be included within a given Idea Development Award application. “To be named” Career Development PIs are not allowed.
- Orthopaedic Research Mentorship: A designated mentor is required. The mentor may be the PI of the application, a member of the research team, or outside of the research team. This mentor must be an established 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 Career Development PI’s research career in orthopaedic research. The mentor may request salary support, as appropriate to his/her level of effort. ***To promote collaboration between military and non-military organizations, it is encouraged, but not required, that the mentor be from an academic, VA, or other non-military organization.***
- Applications that contain a nested Career Development PI will qualify for a higher level of funding as described under the Funding section (Section I.D).
- Supporting documentation should include a biographical sketch for the Career Development PI, a Career Development Statement, and a letter of support from the Career Development PI’s primary mentor. A biographical sketch must also be provided for the mentor if not already included as a key personnel biographical sketch in the Idea Development Award application.
- ***To qualify for the nested Career Development option, all requirements described above must be included in the application. If these requirements are not met, the Government reserves the right to review the application for a traditional Idea Development Award.***

**Use of Human Subjects and Human Biological Substances:** All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human biological substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the IRB of record. IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB of record.

Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information and resources.

**Use of Military and VA Populations:** If applicable, access to target military or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, veterans, military and/or VA-controlled study materials, and military and/or VA databases.

**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. Although not a comprehensive list, 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>

Clinical and Rehabilitative Medicine  
Research Program

<https://crmrp.amedd.army.mil>

Combat Casualty Care Research Program

<https://ccc.amedd.army.mil>

Congressionally Directed Medical Research  
Programs

<http://cdmrp.army.mil>

Defense Advanced Research Projects  
Agency

<http://www.darpa.mil/>

Defense Medical Research and  
Development Program

<http://dmrdp.fhpr.osd.mil/home.aspx>

Defense Technical Information Center

<http://www.dtic.mil>

Military Infectious Disease Research  
Program

<https://midrp.amedd.army.mil>

Military Operational Medicine Research  
Program

<https://momrp.amedd.army.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

<https://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. Department of Defense Blast Injury  
Research Program

<https://blastinjuryresearch.amedd.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>

Walter Reed Army Institute of Research

<http://wrair-www.army.mil>

***The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities)***

*and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.*

### **C. Eligibility Information**

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Nested Career Development Option: Career Development PIs must be active-duty military and must have at the time of application submission:
  - Completed a doctoral-level degree,
  - A total of less than 8 years of postdoctoral clinical or research experience (excluding clinical residency or fellowship training) at the time of application submission, and
  - Been awarded less than \$500,000 in direct costs in aggregate as a PI of Federal or private, non-mentored, peer reviewed grants.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$500,000** plus indirect costs.
  - If requesting the Nested Career Development Option, the maximum allowable direct costs for the entire period of performance are **\$725,000**, plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel costs of up to \$1,800 for the PI to attend one DoD research-related meeting to be specified by the CDMRP during the award performance period. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary of non-Government personnel
- Research supplies
- Training-related costs for Nested Career Development PI
- Equipment
- Clinical research costs (clinical trials not allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The PRORP expects to allot approximately \$5.6M of the \$30M FY12 PRORP appropriation to fund approximately seven Idea 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.*

## **II. SUBMISSION INFORMATION**

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-12-PRORP-IDA.

### **B. Pre-Application Submission Content and Form**

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507. Requests for a change in PI or organization will be allowed only at the discretion of the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.



The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY12 PRORP IP members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507.

- **Required Files – Tab 4**

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Focus Area:** Explain how the proposed work addresses at least one of the FY12 PRORP Idea Development Award Focus Areas.
- **Research Idea:** Describe the ideas and reasoning on which the proposed work is based; include relevant literature citations.
- **Research Strategy:** Concisely state the project's hypothesis/objectives and specific aims. Briefly describe the experimental approach. If applicable, describe the roles of the Career Development PI and mentor in the project.
- **Military Benefit:** Describe how the proposed research will provide a significant benefit in the near-term and/or long-term to individuals who have sustained combat or combat-related orthopaedic injuries.
- **Innovation:** Describe how the proposed study is innovative.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- **References Cited (one-page limit):** List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
- **Key Personnel Biographical Sketches (four-page limit per individual):** Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-Application – Tab 5**

*This tab must be completed for the pre-application to be accepted and processed by the CDMRP.*

- **Other Documents Tab**

No additional documents are required.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DoD and the PRORP, pre-applications will be screened by the PRORP IP based on the following criteria:

- **Research Idea:** The degree to which the proposed research addresses the intent of the award mechanism and aligns with FY12 PRORP Idea Development Award Focus Areas. How well the rationale supports the research idea.
- **Research Strategy:** How well the specific aims and proposed methodology support the research idea and objectives.
- **Innovation:** To what extent the research is creative and represents more than an incremental advance on published data.
- **Military Benefit:** The degree to which the proposed research, if successful, will advance the field of combat-relevant orthopaedic research and/or orthopaedic injury treatment and ultimately benefit the health and lives of Warfighters.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **C. Application Submission Content and Form**

*Applications will not be accepted unless the PI has received notification of invitation.*

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Grants.gov application package components:** For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

## 2. Attachments Form

- **Attachment 1: Project Narrative (10-page limit):** Upload as “ProjectNarrative.pdf.”

The 10-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the application.

Presentation of preliminary data is not consistent with the intent of the Idea Award mechanism. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of published literature for the application to be competitive. Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work, to include relevant literature citations.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan, if appropriate, for the research proposed. 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 Idea Development Award mechanism.*
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.*
  - **References Cited:** List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. For PI(s) who are practicing clinicians, the institution must clearly demonstrate a commitment to the clinician’s research. *If a Career Development PI is included in the application, letters from the Career Development PI’s immediate supervisor and Commander must be provided that demonstrate a commitment to allow the Career Development PI to participate in the project.*
- Mentor Letter of Support for Optional Nested Career Development PI (if applicable): Provide a letter signed by the primary mentor in support of the nested Career Development PI. Describe the following:
  - How the Career Development PI’s achievements indicate a potential for a successful career in orthopaedic research.
  - How the training environment will promote the development of the Career Development PI as an orthopaedic researcher.
  - The mentor’s qualifications, including how the research being performed under the mentor’s direction is relevant to combat-related orthopaedic injury.
  - The mentor’s proposed interactions with the Career Development PI, and the degree to which the Career Development PI will participate in the execution of the application if funded.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”  
The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects. Technical abstracts should be written using the following outline.

- Background: State the FY12 PRORP Focus Area(s) addressed by the proposed research. Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Describe the overall research goals.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Innovation: Briefly describe how the proposed project is innovative.
- Military Benefit: State briefly how the proposed project, if successful, will have an impact on combat-relevant orthopaedic injury research and/or patient care.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Lay abstracts should be written using the following outline.

- Describe the objectives and rationale for the application in a manner that will be *readily understood by readers without a background in science or medicine*.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
- Briefly describe how the proposed project will benefit military populations and impact combat-relevant orthopaedic research and/or patient care.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
- **Attachment 6: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

Describe how the proposed work is innovative. Research that represents an incremental advancement on published data is not considered innovative.

The following examples of ways in which the proposed work may be innovative, although not all-inclusive, are intended to help the PI frame the innovative features of his/her application:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.

- Novel method or technology: Development of a novel method or technology for prevention, detection, diagnosis, or treatment.
- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- **Attachment 7: Military Benefit Statement (one-page limit):** Upload as “MilBen.pdf.”

Describe the impact of this study on the lives of individuals recovering from combat-relevant orthopaedic injuries, including but not limited to 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: Letters Confirming Access to Target Military or VA Patient Population(s), if applicable:** Upload as “Access.pdf.”

If applicable, provide a letter(s) of support, signed by the lowest ranking person with approval authority, for studies involving active duty military and/or veteran populations, military and/or VA-controlled study materials, and military and/or VA databases.

- **Attachment 9: Career Development Statement, if applicable (three-page limit):** Upload as “CareerDev.pdf.”

The required Career Development Statement from the proposed Career Development PI should:

- Identify the primary mentor. Multiple mentors may be proposed, if appropriate, but one must be identified as primary.
- Describe a Career Development Plan, which may include coursework, hands-on laboratory and clinical techniques, conferences, seminars, teaching responsibilities, and/or clinical responsibilities.
- Describe the research that will be performed by the Career Development PI in the context of the proposed project.
- Articulate career goals and how the proposed research training will promote a career in orthopaedic trauma research.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
  - PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - If applying under the Nested Career Development Option, include biographical sketches of the Career Development PI and mentor
  - Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - If applying under the Nested Career Development Option, include the current/pending support of the Career Development PI and mentor.
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

#### **D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

#### **E. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Office of the Assistant Secretary of Defense for Health Affairs, based on technical merit, the relevance to the mission of the DoD and PRORP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level 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. Organizational personnel and PIs are prohibited from contacting persons involved in the 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 organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

#### **B. Application Review Criteria**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, of which Military Benefit and Innovation are equally most important.
  - **Military Benefit**
    - To what degree the proposed project could, either in the short-term or long-term, make a significant impact on 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.



- **Innovation**
  - How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, clinical interventions.
  - How the proposed research is unique and creative, and not the next logical step or continuation of a previous research project.
  - How well the proposed research represents more than an incremental advance upon published data.
- **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.
- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure the successful conduct of the project.
  - *Nested Career Development applicants (if applicable):*
    - How the qualifications of the Career Development PI will augment the project and study team.
    - How the Career Development PI will benefit from participation in this project.
    - How well the mentor, training environment, and career development plan are suited to providing the Career Development PI with a training experience that will further his/her career at the forefront of orthopaedic research.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **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).
- To what degree the quality and extent of institutional support are appropriate.

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influenced the review.

**2. Programmatic Review:** To determine the application's relevance to the mission of the DoD and PRORP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Program portfolio composition in relation to FY12 PRORP Focus Areas
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative military benefit

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **E. Notification of Application Review Results**

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

#### **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from CDMRP 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.

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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

##### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

##### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- A FY12 PRORP IP member is named as being involved in the research proposed or is found to have assisted 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 FY12 PRORP IP members can be found at <http://cdmrp.army.mil/prorp/default.shtml>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.
- The proposed project is not relevant to at least one of the FY12 PRORP Idea Development Award 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 required to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative and National Policy Requirements**

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

#### **C. Reporting**

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

Quarterly technical progress reports will be required. In addition to written progress reports, oral presentations may be requested.

#### **D. Award Transfers**

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 6.	
	Upload Military Benefit Statement (MilBen.pdf) as Attachment 7.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) if applicable (Access.pdf) as Attachment 8.	
	Upload Career Development Statement, if applicable, (CareerDev.pdf) as Attachment 9.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	