

# **Program Announcement**

**for the**

**Defense Health Program**

**Defense Medical Research and Development Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Peer Reviewed Orthopaedic Research Program**

### **Idea Development Award**

**Funding Opportunity Number: W81XWH-13-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), April 4, 2013
- **Invitation to Submit an Application:** mid-May 2013
- **Application Submission Deadline:** 11:59 p.m. ET, July 18, 2013
- **Peer Review:** To Be Determined
- **Programmatic Review:** To Be Determined

*This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2013 (FY13) Peer Reviewed Orthopaedic Research Program (PRORP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The PRORP was initiated in 2009 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 FY12 total \$188.5 million (M). The executing agent for the PRORP is the Congressionally Directed Medical Research Programs (CDMRP).

The FY13 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.

***Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of FY13 federal funds for this program.*** As of the release of this Program Announcement/Funding Opportunity, the FY13 Defense Appropriations Bill has not been passed and there is no guarantee that any funds will be made available to support this Program Announcement/Funding Opportunity. Funding allotted for this Program Announcement/Funding Opportunity is approximate and subject to change.

### B. Award Information

The PRORP 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 previous work.
- 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-related 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 for both orthopaedic research and combat-injured patients should be articulated, even if clinical impact is not an immediate outcome.

***All applications must address at least one of the following FY13 PRORP Idea Development Award Focus Areas:***

- Strategies to prevent or mitigate post-traumatic osteoarthritis resulting from fracture and/or ligament injury, including novel surgical approaches and interventions for treatment, the effect of weight bearing, and retrospective studies on the impact of prior surgical interventions on the occurrence of post-traumatic osteoarthritis.
- Maintenance/enhancement of long-term socket performance/fit of prosthetics, including the design and development of flexible socket suspension systems, the evaluation of socket performance (comfort, fit, and durability), and the application of new technologies to improve existing prosthetic sockets.
- Studies to improve moisture management and residual limb skin care at the prosthetic socket interface.

***The FY13 PRORP Idea Development Award does not allow clinical trials; however, research involving human anatomical substances or human subjects is permitted under this funding opportunity.*** 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 how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/). PIs seeking funding for a clinical trial should utilize the PRORP Clinical Trial Award or Clinical Trial Development Award mechanisms.

## **NESTED CAREER DEVELOPMENT OPTION**

A nested career development opportunity is being offered as an Idea Development Award option. The intent of the nested Career Development Option is to support research training opportunities for U.S. 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-related orthopaedic research and clinical care.

- Career Development Investigator: The Career Development Investigator must be a U.S. **active-duty military** research- or physician-scientist at either the postdoctoral or early-career level as described in Section I.C., Eligibility Information. Only one Career Development Investigator may be included within a given Idea Development Award application. The Career Development Investigator must be a named individual (“To be named” Career Development PIs are not allowed) and must submit all required supporting documents listed below. Recipients of prior PRORP Career Development Awards or Nested Career Development Option awards are not eligible to apply as a Career Development Investigator to this Program Announcement/Funding Opportunity.
- Orthopaedic Research Mentorship: A designated mentor is required. Multiple mentors may be proposed, if appropriate, but one must be identified as the primary mentor. 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 Investigator’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 Investigator will qualify for a higher level of funding as described in Section I.D., Funding.
- Supporting documentation must include a biographical sketch for the Career Development Investigator, a Career Development Statement, and a letter of support from the Career Development Investigator’s primary mentor. A biographical sketch must also be provided for the mentor(s) if not already included in the Idea Development Award application Key Personnel Biographical Sketches.
- ***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 as a standard Idea Development Award.***

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical 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 CDMRP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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: The Career Development Investigator must be U.S. active-duty military and must have at the time of the application submission deadline:
  - Completed a doctoral-level degree,
  - A total of less than 8 years of postdoctoral clinical or research experience (excluding clinical residency or fellowship training),
  - Been awarded less than \$500,000 in direct costs in aggregate as a PI of federal or private, non-mentored, peer reviewed awards, and
  - Not been the recipient of a prior PRORP Career Development Award or Nested Career Development Option.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- 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.
- Any application that requests the higher level of funding and that does not include an eligible Nested Career Development Investigator will have its budget reduced as appropriate.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget.

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel funds of up to \$1,800 for the PI to attend one DoD-sponsored 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 (includes contract research personnel at Government facilities)
- Research supplies
- Equipment
- Training-related costs for the Nested Career Development Investigator
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meeting described above

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply and are so noted in Section II.C.4. of the General Application Instructions.*** As required of all applicants to this Program Announcement, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

***The PRORP expects to allot approximately \$5.2M of the FY13 PRORP appropriation to fund approximately 7 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 two-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 applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

## 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-13-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 pre-application should be the same as those intended for the subsequent application submission. 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 301-682-5507.

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 – Tab 3**

FY13 PRORP Steering Committee (SC) members should not be involved in any pre-application or application. For questions related to SC members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP [Help Desk](#) (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 FY13 PRORP Idea Development Award Focus Areas.
- **Research Idea:** Describe the ideas and reasoning on which the proposed research is based; include relevant literature citations.
- **Research Strategy:** Concisely state the project's objective and specific aims. Briefly describe the experimental approach. If applicable, describe the roles of the Career Development Investigator and designated mentor(s) 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.
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (four-page limit per individual)
- **Submit Pre-Application – Tab 5**

This tab must be completed for the pre-application to be accepted and processed by 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 based on the following criteria:

  - **Research Idea:** The degree to which the proposed research addresses the intent of the award mechanism and aligns with FY13 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-related orthopaedic research and/or 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. The estimated timeframe for notification of invitation to submit an application is 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 page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Presentation of preliminary data, although not prohibited, is not consistent with the intent of the Idea Development 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 anatomical substances 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 of these components unless otherwise noted. Include only***

***those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal 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 whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government 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, confirming the laboratory space, equipment, and other resources available for the project. ***If a Career Development Investigator is included in the application, letters from the Career Development Investigator's immediate supervisor and Commander must be provided that demonstrate a commitment to allow the Career Development Investigator to participate in the project.***
- Mentor Letter of Support for Optional Nested Career Development Investigator (if applicable): Provide a letter signed by the primary mentor in support of the nested Career Development Investigator. Describe the following:
  - How the Career Development Investigator's achievements indicate a potential for a successful career in orthopaedic research.
  - How the training environment will promote the development of the Career Development Investigator 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 Investigator, and the degree to which the Career Development Investigator 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 Property
  - 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.”  
 Technical abstracts should be written using the following outline:
  - Background: State the FY13 PRORP Idea Development Award 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 for the study.
  - 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-related 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 research and clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a clinically relevant 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-related 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, including guidance on appropriate SOW formats.

- **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-related 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 military services 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(s). If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military services 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 Investigator should:

- Identify the designated 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 Investigator 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 for the Career Development Investigator and designated mentor(s).
  - 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 Investigator and designated mentor(s).
- 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to

submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status 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 makes recommendations for funding to the Office of the Assistant Secretary of Defense, Health Affairs, based on technical merit, the relevance to the mission of the DHP and the 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>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment 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 Innovation and Military Benefit are equally most important with the remaining criteria listed in decreasing order of importance:

- **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, or 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.

- **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-related orthopaedic injuries.
  - How well the project addresses a critical problem in combat-related orthopaedic research or medicine.
  - The degree to which the proposed project, if successful, will advance the research methods, understanding, and/or treatment of combat-related orthopaedic injuries.
- **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 and specific aims are developed, and how the experimental design, methods, and analyses 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.
  - Whether there is sufficient evidence of a plan to resolve intellectual and material property issues, if applicable.
- **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 Investigator will augment the project and study team.
    - How the Career Development Investigator will benefit from participation in this project.
    - How well the mentor, training environment, and career development plan are suited to providing the Career Development Investigator 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 the 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
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative innovation
- Relative military benefit

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **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 peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from the CDMRP eReceipt System 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 FY13 PRORP Steering Committee (SC) 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 FY13 PRORP SC members can be found at <http://cdmrp.army.mil/prorp/panels/panel13>.
- 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.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The proposed project is not relevant to at least one of the FY13 PRORP Idea Development Award Focus Areas.
- The PI does not meet eligibility criteria.

#### **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 USAMRAA 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, 2014. 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: 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: 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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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

Grants.gov Application Components	Action	Completed
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.	