

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

Translational Research Award

Funding Opportunity Number: W81XWH-13-PRORP-TRA

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 Translational Research Award (TRA) was previously offered in FY09, FY11, and FY12 under the name Translational Research Partnership Award. This award supports translational research that will accelerate the movement of promising ideas in orthopaedic research into clinical applications to benefit Warfighters with combat-related traumatic orthopaedic injuries. The TRA is intended for multidisciplinary research collaborations that will accelerate the movement of promising laboratory research into clinical application through combined expertise and efforts. ***NEW for FY13: While a multidisciplinary collaboration is required, the award mechanism is now structured to provide one award to the organization of the identified Principal Investigator (PI).*** Collaborators will not receive individual awards and instead should be included in the PI's submission. ***All applications are required to justify the relevance of the proposed project to military and/or Veteran populations affected by combat-related orthopaedic injury.***

To encourage meaningful and productive multidisciplinary collaborations, ***there must be at least one laboratory scientist and at least one clinician participating in the research.*** A clinician is defined as an individual who is credentialed (possesses the necessary degrees, licenses, and other certifications) and practicing as a care provider in a relevant capacity. In addition, ***at least one member of the research team must have significant experience in either orthopaedic or musculoskeletal research or medicine.*** Biographical sketches should include appropriate

documentation of credentials. It is the responsibility of the PI and the collaborating investigators to describe how their combined expertise will better address the research question, why the work should be performed through collaboration rather than through separate efforts, and how the research design will create a reciprocal flow of ideas and information between the multiple disciplines represented. The proposed collaboration should involve substantial contributions from each of the key collaborators identified, with evidence of significant intellectual input from each key collaborator into the design of the project.

Observations that drive a research hypothesis may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge from providing care to patients. While the ultimate goal of translational research is to move an observation forward into clinical application, the PI should view translational research as a two-way continuum between bench and bedside. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism are described on the National Cancer Institute website <http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals>. These pathways, while created for cancer research initiatives, have broad applicability to other areas of research, are comprehensive, and span the entire translational research continuum from discovery of a target to clinical trials.

The Translational Research Award is not intended to support definitive clinical trials, but may support correlative studies that are associated with an existing clinical trial and projects that optimize the design of future definitive clinical trials. Some limited clinical testing of a novel intervention or device is permissible if the clinical testing is necessary to inform the next step in the continuum of translational research. Such clinical pilot studies should be small, represent only a portion of the proposed Statement of Work, and be utilized to establish feasibility of a potential approach or to aid in device or intervention refinement. Research projects may also include preclinical studies in animal models, human subjects, and human anatomical substances.

Investigators seeking support for a definitive clinical trial should utilize the FY13 PRORP Clinical Trial Award mechanism. A clinical trial is defined as a prospective accrual of patients for a study 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 distinguishing clinical trials from clinical research, the CDMRP provides a Human Subject Resource Document at https://cdmrp.org/Program_Announcements_and_Forms/.

All applications must propose a translational study addressing at least one of the following FY13 PRORP TRA Focus Areas:

- Characteristics of and strategies for optimizing long-term (e.g., 5 to 10 years) functional outcomes for traumatic military amputee and/or limb salvage patients.
- 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.
- Establishment of bone, joint, and soft tissue health guidelines based upon validated measures to aid clinicians in returning patients safely to high-impact activities including,

but not limited to, validation of markers of bone quality that can predict susceptibility to injury, and comparative effectiveness studies of training and therapeutic interventions to improve bone quality and muscle function that maximize performance while minimizing injury.

- Maintenance or enhancement of long-term socket performance and 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.

Applications must include preliminary or published data relevant to the Focus Area(s) and the proposed project; however, these data may come from fields other than orthopaedic research.

NESTED CAREER DEVELOPMENT OPTION

A nested career development opportunity is offered as a Translational Research 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 Translational Research Award application. The Career Development Investigator must be a named individual (“To be named” Career Development Investigators 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 if it is not already included in the Translational Research 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 Translational Research 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 Institutional Review Board (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. Funded applications that include clinical pilot studies may be required to obtain an independent, external scientific review of the clinical protocol prior to HRPO review. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

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. While 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.
 - A collaborative research team is required. There must be at least one laboratory scientist and at least one clinician participating in the collaboration.
 - At least one investigator must have significant experience either in orthopaedic or musculoskeletal research or medicine.
- Nested Career Development Option: Career Development Investigators 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 award.
- 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 **\$750,000** plus indirect costs. If requesting the Nested Career Development Option, the maximum allowable direct costs for the entire period of performance are **\$975,000** 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 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
- Clinical research costs
- Training-related costs for the Nested Career Development Investigator

- Independent scientific review of clinical protocol
- 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 \$7.88M of the FY13 PRORP appropriation to fund approximately 7 Translational Research 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-TRA.

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 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 Translational Research Award Focus Areas.
- **Research Idea:** Describe the ideas and reasoning on which the proposed research is based; include relevant literature citations. Show how the perspectives of the PI and each collaborator contributed to the development of the hypothesis.
- **Research Strategy:** Concisely state the project’s hypothesis/objectives and specific aims. Briefly describe the experimental approach.
- **Collaboration:** Describe how the project depends on the unique skills of each team member. Describe how the proposed multidisciplinary collaboration involves a substantial contribution by each investigator and the reciprocal flow of ideas and information. If applicable, describe the roles of the Career Development Investigator and designated mentor(s) in the project.
- **Translational Potential:** Describe how the proposed research will allow for a reciprocal flow of ideas between basic and clinical science. Explain how the project will accelerate promising laboratory research findings into clinical applications.
- **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.

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.
- 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 Translational Research 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.
- **Collaboration:** How the background and expertise of the proposed research team is appropriate to accomplish the research in a way that could not be accomplished through separate efforts. How the disciplines represented on the research team are appropriate for the proposed work.
- **Translational Potential:** How the project will translate promising, well-founded research findings into clinical applications.
- **Military Benefit:** The degree to which the proposed research, if successful, will accelerate the movement of new diagnostic and therapeutic approaches in orthopaedic research into clinical application and ultimately benefit the health and lives of Warfighters who have experienced or may experience combat-related orthopaedic injury.
- **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 Translational Research 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.

Describe the proposed project in detail using the outline below. *The Project Narrative must include preliminary or published data to support the feasibility of the proposed project; however, these data may come from fields other than orthopaedic research.*

- **Background:** Present the ideas and reasoning behind the proposed research. Cite relevant literature. Describe previous experience most pertinent to this application.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If the proposed research is part of a larger study, present only tasks that the PRORP award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan 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. *This award must not be used to conduct definitive clinical trials*, though limited feasibility testing in human subjects as a portion of the Statement of Work is permissible.

- **Collaboration:** Describe how the research project depends on the unique skills of each member of the research team. Provide the time commitment of each key collaborator toward the proposed research project. Describe how the proposed collaboration involves a substantial contribution by each member, with a reciprocal flow of ideas and information, including the Career Development Investigator (if applicable). Demonstrate how the collaboration will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide evidence of institutional support for resolving potential intellectual and material property issues and removing institutional barriers to achieve high levels of cooperation.
- **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 designated 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 research if funded.
- o Letters of Collaboration: 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.
- o Intellectual Property
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- o 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:

 - o Background: State the FY13 PRORP TRA Focus Area(s) addressed by the proposed research. Present the ideas and reasoning behind the proposed work.
 - o Objective/Hypothesis: State the objective/hypothesis to be tested. Describe the overall research goals for the study.
 - o Specific Aims: State the specific aims of the study.
 - o Study Design: Briefly describe the study design including appropriate controls.
 - o Translation: Describe how the proposed collaboration and research will accelerate promising, well-founded research findings into clinical application.
 - o 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.

 - o 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.
 - o 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?
- o 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: 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 7: Translation Statement (one-page limit):** Upload as “Translation.pdf.”

State explicitly how the proposed research is translational in nature, allowing for the reciprocal transfer of information and ideas between basic and clinical science. Explain how the experience and expertise of the research team is complementary, multidisciplinary, and will accelerate the movement of the results to clinical application. Provide information on the methods and strategies proposed to move the product to the next phase of development, clinical trials, and/or delivery to the military or civilian market after successful completion of the award.

- **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 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 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.shtml>.

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, which are of equal importance:

- **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, logical reasoning, and/or the presentation of preliminary or published data.
 - How well the hypotheses or objectives and 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.
- **Military Benefit**
 - To what degree the proposed project could, if successful, 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 of, and/or treatment of combat-related orthopaedic injuries.
- **Translational Potential**
 - The degree to which the project, if successful, will lead to the translation of promising, well-founded laboratory or clinical research findings into clinical applications for combat-related orthopaedic injuries.
 - How well the proposed research plan will utilize the multiple disciplines represented in the collaboration to create a reciprocal flow of ideas and information between basic and clinical science.
- **Personnel**
 - How the research team's background and expertise are appropriate to accomplish the proposed work.
 - How well the project represents a meaningful collaboration with significant contributions from the proposed collaborators.
 - How the levels of effort by the PI, the collaborators, and other key personnel are appropriate to ensuring 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 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.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.
- 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 a definitive clinical trial.
- The PI does not meet the eligibility criteria.
- The proposed collaboration does not meet the eligibility criteria.
- The proposed project is not relevant to at least one of the FY13 PRORP Translational Research 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 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

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

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 Military Benefit Statement (MilBen.pdf) as Attachment 6.	
	Upload Translation Statement (Translation.pdf) as Attachment 7.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) (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.	