Program Announcement

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Orthopaedic Research Program

Translational Research Partnership Award

Funding Opportunity Number: W81XWH-11-PRORP-TRPA

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)**,** September 7, 2011
- **Invitation to Submit an Application:** By October 4, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, December 5, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** April 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Peer Reviewed Orthopaedic Research Program (PRORP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PRORP was established in fiscal year 2009 (FY09) to support research focused on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or combat-related duties. Appropriations for the PRORP in FY09 and FY10 totaled $134.5 million (M). The FY11 appropriation is $24M.

The FY11 PRORP challenges the scientific community to address the most significant gaps in care for the leading burden of injury and loss of fitness for military duty by funding innovative, high-impact, clinically relevant research to advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities. Applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies are highly encouraged.

B. Award Information

The PRORP Translational Research Partnership Award mechanism was first offered in FY09. Since then, 22 research projects have been proposed, and 7 (representing 19 individual awards) have been awarded funding.

The Translational Research Partnership Award (TRPA) supports translational research that will accelerate the movement of promising ideas in orthopaedic research into clinical applications to benefit Warfighters with combat-relevant traumatic orthopaedic injuries. The award is designed to encourage multi-institutional, multidisciplinary research partnerships among ***two or three*** investigators (designated as partners) to accelerate the movement of promising research hypotheses into clinical application in a manner that would be less readily achievable through separate efforts. ***There must be at least one laboratory scientist and at least one clinician participating in the partnership.*** A clinician is defined as an individual who is credentialed (possesses the necessary degrees, licenses, and other certifications) as a care provider in any relevant capacity at the institution of record. In addition, ***at least one partner must have significant experience either in orthopaedic research or orthopaedic medicine.*** Biosketches should include appropriate documentation of credentials. Partnerships between academic institutions and government agencies and/or military investigators/clinicians are highly encouraged. ***All applications are required to justify the relevance of the proposed project to military and/or veteran populations affected by combat or combat-related orthopaedic injury.***

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, members of the partnership should view translational research as a two-way continuum between bench and bedside. The research plan must involve a reciprocal flow of ideas and information within the partnership. ***It should be clear that all partners have had equal intellectual input into the design of the research project.*** A proposed project in which a clinical partner merely supplies tissue samples or access to patients will not meet the intent of this mechanism. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at

(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 TRPA 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 and human subjects and human anatomical substances**.**

Investigators seeking support for a clinical trial should utilize the FY11 PRORP Clinical Trial Award mechanism (Funding Opportunity Number W81XWH-11-PRORP-CTA). 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, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/.

All TRPA applications ***must*** address at least one of the following Focus Areas:

- **Prevention and treatment of post-traumatic osteoarthritis:** Post-traumatic osteoarthritis is the most common chronic, debilitating condition of combat-injured Warfighters. Most incidences of post-traumatic osteoarthritis are caused by fractures involving the joints. Preventive measures must consider the battlefield environment constraints (to include but not be limited to multiple serious injuries, anti-coagulation effects of medication, and limited imaging capabilities for the first 72 hours). Regenerative approaches must be able to repair large cartilage defects that current therapies (such as microfracture and osteochondral transplantation) do not address.
- **Improved outcomes of severe limb injuries:** The majority of combat-injured Warfighters have at least one extremity injury, most of which are open wounds caused by explosion or gunshot. These injuries are generally more severe than civilian injuries, and nonfunctional nerves and loss of muscle function are frequent outcomes. Within this focus area, mature translational studies on novel therapies to heal large extremity nerve injuries and rehabilitation interventions or orthoses that improve the functional outcomes of individuals with severely injured limbs are needed. Studies that propose treatment strategies to improve outcomes in patients with multiple severe limb-threatening injuries or multiple major limb amputations are of particular interest. Translational studies addressing the treatment and/or prevention of wound infection will be funded through other Department of Defense (DOD) award mechanisms and thus are not being solicited by this Program Announcement/Funding Opportunity. However, investigators with novel treatments for wound infection that are in the clinical trial phases of development are encouraged to apply to the FY11 PRORP Clinical Trial Award (W81XWH-11-PRORP-CTA).

Applications must include preliminary and/or published data relevant to the topic area and the proposed project; however, these data may come from fields other than orthopaedic research.

Use of Human Subjects and Human Biological Substances: All DOD-funded research involving new and ongoing research with human subjects and human biological substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local IRB of record. Local 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 are rigorous and detailed, and will require information in addition to that supplied to the local IRB. 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. 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 Technical Information Center
http://www.dtic.mil

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

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

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

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

U.S. Army Medical Research Acquisition Activity
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. Naval Research Laboratory
http://www.nrl.navy.mil

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

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
    - There must be at least one laboratory scientist and at least one clinician participating in the partnership.
    - At least one partner must have significant experience either in orthopaedic research or orthopaedic medicine.
- Please note that graduate students, postdoctoral fellows, and other "mentored" researchers are not eligible for this award.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance is **$750,000** 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.
- Each partner will be a Principal Investigator (PI), and a separate award will be made to each PI's organization.
- The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

Must be requested for:

- Travel costs, up to $1,800, for the PI to attend one DOD research-related meeting to be determined at the discretion of the Government during the award performance period.

May be requested for (not all-inclusive):

- Salary
- Research supplies

- Equipment
- Clinical research costs
- Independent scientific review of clinical protocol
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $4.5M of the $24M FY11 PRORP appropriation to fund approximately 4 Translational Research Partnership 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. The Government reserves the right to grant more than approximately 4 Translational Research Partnership Awards if additional funding becomes available.

II. SUBMISSION INFORMATION

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

The Translational Research Partnership Award is structured to accommodate at least two, and up to a maximum of three, PIs. ***One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission.*** The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work, and other required components.. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified separately by e-mail. ***Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.*** If an application is invited, only the Initiating PI will receive a letter of invitation via email from CDMRP. The letter will provide the information necessary to begin the application submission through Grants.gov.

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

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-11-PRORP-TRPA.

B. Pre-Application Submission Content and Form

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

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

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

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

  The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section**.**
- **Required Files – Tab 4**

  Preproposal Narrative (2-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:

  - **Research Idea:** Describe the ideas and reasoning on which proposed research is based. Show how the perspective of each partner contributes to the development of the hypothesis.
  - **Research Strategy:** Concisely state the project's objective and specific aims.
  - **Partnership:** Describe how the project depends on the unique skills of each partner. Provide the time commitment for each partner. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
  - **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 scientific observations into clinical applications for treatment of orthopaedic injury.
  - **Military Benefit:** Describe how the proposed research will have an impact on the lives of military Service members and veterans with combat or combat-related orthopaedic injuries.

- **Focus Area:** Explain how the proposed work addresses at least one of the FY11 PRORP TRPA Focus Areas.

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.
- Biographical Sketches (four-page limit each)**:** Include biographical sketches for the Initiating and Partnering PIs.

- **Submit Pre-application – Tab 5**
- **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 its relevance to the mission of the DOD and CDMRP, pre-applications will be screened by the PRORP Integration Panel (IP) based on the following criteria:

  - **Research Idea:** How well the research demonstrates sound scientific rationale.
  - **Research Strategy:** How well the specific aims support the research hypothesis and objectives.
  - **Translational Potential:** How the project will translate promising, well-founded research findings into clinical applications for traumatic orthopaedic injury.
  - **Partnership:** Whether the partnership is multidisciplinary, and includes at least one clinician and one laboratory scientist. Whether the partnership includes at least one partner with significant experience in orthopaedic research or orthopaedic medicine. How the partners' backgrounds and expertise are appropriate to accomplish the proposed research in a way that could not be accomplished by either a single investigator or through separate efforts. How the disciplines and the levels of effort are appropriate for the proposed research.
  - **Military Benefit:** The degree to which the proposed partnership and 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-relevant orthopaedic injury.
  - **Alignment with Focus Areas:** The degree to which the proposed research aligns with at least one of the FY11 PRORP TRPA Focus Areas.

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

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

C. Application Submission Content and Form

Applications will not be accepted unless the Initiating PI has received a letter 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 (AOR) through the Grants.gov portal (http://www.grants.gov/). For the Translational Research Partnership Award, additional application components are also required and should be submitted as directed below.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for the Initiating PI:

Grants.gov application package components: For the Translational Research Partnership 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."

     Describe the proposed project in detail using the outline below. ***The Project Narrative must include preliminary 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 biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials,*** though limited feasibility testing in human subjects as a portion of the Statement of Work is permissible.
- **Partnership:** Describe how the research project depends on the unique skills of each member of the partnership. Provide the time commitment of each partner toward the proposed research project. Describe how the proposed partnership involves a substantial contribution by each partner, with a reciprocal flow of ideas and information. Demonstrate how the partnership 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. ***Each component has no page limit unless otherwise noted.***
  - 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 USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (5-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.

- Letters of Institutional Support**:** Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. For PI(s) who are practicing clinicians, the institution must clearly demonstrate a commitment to the clinician's research.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan (if applicable): 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 (1-page limit):** Upload as "TechAbs.pdf."

  Technical abstracts should be written using the following outline.

  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis. 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.
  - Translational Partnership: Describe how the proposed partnership will accelerate promising, well-founded research findings into clinical application.
  - Military Benefit: State briefly how the proposed project, if successful, will have an impact on combat-relevant orthopaedic injury research and/or patient care.

- **Attachment 4: Public Abstract (1-page limit):** Upload as "PublicAbs.pdf."

  Public abstracts should be written using the following outline.

  - Describe the research objectives and rationale for the proposal in a manner readily understandable by non-scientists.
  - Do not duplicate the technical abstract.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?

- What are the potential applications, benefits, and risks?
- What is the projected time it may take to achieve a clinically relevant outcome?

  - What are the likely contributions of this study to advancing the field of research?

- **Attachment 5: Statement of Work (SOW) (3-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.

  Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.

- **Attachment 6: Military Benefit Statement (1-page limit):** Upload as "MilBen.pdf."

  Describe the impact of this study on the lives of individuals recovering from combat-relevant orthopaedic injuries, including but not limited to how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of these injuries.

  Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces and/or the US veteran population. If active duty military or veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces and/or the US veteran population). Show how the proposed study complements ongoing DOD areas of orthopaedic research interest. Describe how the study design will replicate field conditions, if applicable.

- **Attachment 7: Translation Statement (1-page limit):** Upload as "Translation.pdf."

  Describe the translational research that will be performed through this award and articulate why it could not be achieved through separate efforts. State explicitly how the proposed research is translational in nature, allowing for the reciprocal transfer of ideas between basic and clinical science.

- **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.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
    - PI Biographical Sketch (4-page limit): Upload as "Biosketch_LastName.pdf."
    - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - Key Personnel Biographical Sketches (4-page limit each): Upload as "Biosketch_LastName.pdf."
        - Include Biographical Sketches for the Partnering PI(s).
    - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
        - Include Current/Pending Support for the Partnering PI(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."

    Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PIs, even if they are at the same organization.

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.

Application Components for the Partnering PI(s):

Each Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. **SF 424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**
    - **Attachment 5: Statement of Work (SOW) (3-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI (s) should be noted for each task.***

3. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

   Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget form for the Partnering PI(s) should not include budget information for the Initiating PI or another Partnering PI, if applicable, even if they are at the same organization.

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

5. **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 shall result in application rejection.

E. Other Submission Requirements

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

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Office of the Assistant Secretary of Defense, Health Affairs), based on technical merit, the relevance to the mission of the DOD and CDMRP, 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the

panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (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 criteria, which are listed in decreasing order of importance:

   - **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-relevant orthopaedic injuries.
   - **Research Strategy and Feasibility**
     - The degree to which the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data, and logical reasoning.
     - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
     - How well the PIs acknowledge potential problem areas and consider alternative approaches.
     - The degree to which the plan to study military populations, if applicable, is appropriate and feasible.
   - **Military Benefit**
     - The degree to which the proposed research, if successful, will have a significant impact on the diagnosis and treatment of combat-relevant orthopaedic injuries.
     - How well the project addresses a critical problem in combat-relevant orthopaedic injury research or medicine, specifically with respect to FY11 PRORP TRPA Focus Areas.
   - **Partnership**
     - The degree to which the proposed partnership will advance orthopaedic research in a way that could not be accomplished by investigators working independently.
     - How well the application supports the requirement that all partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.

- How well the multiple institutions (if applicable) and multiple disciplines within the partnership will support the proposed project.
- How well the partners' background, expertise, and levels of effort will support the proposed project.
- Whether there is sufficient evidence of a plan to resolve intellectual and material property issues.

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

- **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 CDMRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:
   - Adherence to the intent of the award mechanism
   - Program portfolio composition in relation to Focus Areas
   - Programmatic relevance
   - Ratings and evaluations of the peer reviewers
   - Relative military benefit

C. Recipient Qualification

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

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

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, you 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:

- FY11 PRORP Integration Panel (IP) member is found to be involved in the preapplication 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 FY11 PRORP IP members may be found at http://cdmrp.army.mil/prorp/panels/panel11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The proposed research is a definitive clinical trial.
- The partnership does not include at least one clinician and one laboratory scientist.
- The partnership does not include an investigator with significant experience in orthopaedic research or orthopaedic medicine.
- The PI(s) does not meet the eligibility criteria.
- The proposed project is not relevant to at least one of the FY11 PRORP TRPA 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 US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

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

Quarterly technical progress reports may be required.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes. Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 1-800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI 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 Public Abstract (PublicAbs.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 Approval for Access to Target Military and VA Patient Populations (Access.pdf) as Attachment 8.		
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 form 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.		