# Program Announcement

**Defense Health Program**

**Defense Medical Research and Development Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

# Peer Reviewed Orthopaedic Research Program

## Technology Development Award

**Funding Opportunity Number: W81XWH-11-PRORP-TDA**

**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.***

## TABLE OF CONTENTS

# 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

Combat-injured Warfighters who have lost one or both arms have limited options in reliable prostheses that are lightweight, easy to control, durable, and flexible. A majority of the upper extremity prostheses in use today are simple body-powered hooks that are based upon technology that has not changed greatly since World War I. More recent advances in technology have led to the development of myoelectric and other robotic prostheses, which provide a greater range of motion and other enhancements over their body-powered counterparts, but are also heavier, more expensive, and more prone to malfunction. The FY11 PRORP Technology Development Award (TDA) is being offered to support the development and testing of an upper extremity prosthetic system that capitalizes on and augments existing body-powered prostheses to create an evolutionary externally powered prosthesis. More specifically, the PRORP seeks applications for research projects to develop a ***modular, interoperable, three-degrees-of-freedom, externally powered prosthetic wrist with a one-degree-of-freedom terminal device and accompanying control strategies.*** Interest is in candidate solutions and prototype systems that are developed enough to support refinement and initial feasibility testing during the performance period of the award. Redesigning existing devices to improve features such as weight and size may be considered as within the scope of this Program Announcement/Funding Opportunity provided the alterations equate to significant improvements in clinical utility. Systems that are extensible across multiple manufacturers through open systems architecture are preferred, as are solutions that demonstrate compatibility with other prosthetic systems in development, thereby increasing options available to consumers.

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, and methods to solicit and integrate the needs of those populations from a user perspective should be incorporated in the project design.

The TDA is intended to support advanced translational studies targeted toward the design, development, and demonstration of novel upper extremity prostheses that meet the above

specifications. Projects may propose design verification and validation studies, development of clinical prototype devices, preclinical safety and efficacy testing, and activities toward pursuit of regulatory approval for clinical testing. The TDA is not intended to support definitive clinical trials, but limited clinical testing is permissible if the clinical testing is necessary to inform the next step in devices/system development. 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 refinement.

***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/.

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

**Use of Human Subjects and Human Biological Substances:** All Department of Defense (DOD)-funded research involving new and ongoing research with human subjects and human biological substances must be reviewed and approved by the 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, although not required, PIs are strongly encouraged to establish multi-institutional and multidisciplinary research collaborations, especially those with military laboratory scientists and/or clinicians. 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

1

## C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- 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 **4** years.
- The maximum allowable direct costs for the entire period of performance is **$2 Million (M)** 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 **4** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget 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
- Support for multidisciplinary collaborations
- 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 $3M of the $24M FY11 Peer Reviewed Orthopaedic Research Program appropriation to fund approximately 1 Technology Development Award application, 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 1 Technology Development Award 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/).

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-TDA.

## B. Pre-Application Submission Content and Form

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

PIs and organizations identified in the application should be the same as those identified in the pre-application. If 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**
- **Required Files – Tab 4**

  **Preproposal Narrative (3-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:

  - **Military Benefit:** Briefly state how the proposed technology will, in the near and/or far term, provide a significant benefit to the lives of individuals who have sustained combat-relevant upper extremity orthopaedic injuries, including concepts and methods that will advance the field of prosthetic device research and/or clinical care.
  - **Technology Development Product:** Briefly describe the proposed device and how it improves upon existing upper extremity prostheses. Indicate any existing technologies or components that are incorporated in the product's design or that serve as predicates for development. Where applicable, describe how the proposed device/system will interact or integrate with existing systems.
  - **Research Strategy:** Concisely state the scientific strategy that will be used to develop the technology, including the broad objective and specific aims.
  - **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.

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

- References Cited (1-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 (4-page limit each)**:** Include biographical sketches for the PI and other key collaborators.

- **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:

  - **Military Benefit:** The degree to which the proposed technology will accelerate the movement of upper extremity prosthetic research and development toward a significant benefit to the health and lives of Warfighters who have experienced combat-related orthopaedic injury.
  - **Technology Development Product:** How well the pre-application describes a plan to create a modular, interoperable, three-degrees-of-freedom, externally powered prosthetic wrist with a one-degree-of-freedom terminal device and accompanying control strategies.
  - **Research Strategy:** How well the specific aims and research plan support the technology development.
  - **Personnel:** How the personnel's background and expertise are appropriate to accomplish the proposed research.

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

  Following the pre-application screening, 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 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/).

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

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below. The inclusion of preliminary and/or published data relevant to the proposed project is required.

     - **Background**: Present the ideas and reasoning supporting the proposed research, to include relevant literature citations. Describe scientific findings and previous experience most pertinent to this proposal. Include information on the extent to which technological components of the proposed system have been proven, as applicable.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If this proposal is part of a larger study, present only aims that this DOD award would fund.
     - **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Include, at a minimum, the project's approach to the following areas: wrist design and proposed functionality; powering technology; terminal device design; system modularity; physical assembly of the system; control strategies. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may 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.

   - **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 (five-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 Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (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 of the study or the hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Research Plan/Study Design: Briefly describe the study design including appropriate controls.
  - 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 clinical 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 clinical research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a clinically relevant outcome?
  - What are the advantages of the proposed technology over existing upper extremity prosthetic devices?
- 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.

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

  Describe the impact of this study on the lives of individuals with upper extremity amputations, including but not limited to how the expected results of the proposed work will contribute to the goals of decreasing the clinical impact of these injuries.

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

- **Attachment 7: Transition Plan (1-page limit):** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product to the next phase of clinical trials and/or delivery to the military or civilian market after successful completion of the award, including, if applicable, information regarding transfer to a commercial partner(s) for further clinical development, manufacturing development, and regulatory management. The transition plan should include the components listed below.
  - Details of the funding strategy that will be used to bring the outcomes to the next level of clinical trials and/or delivery to the military or civilian market (e.g., specific potential industry partners, specific funding opportunities to be applied for).

- A description of collaborations and other resources that will be used to provide continuity of development. For any industry partner(s), include a description of prior product development and/or marketing experience.
- A brief schedule and milestones for bringing the outcome(s) to the next phase of clinical trials and/or delivery to the military or civilian market.
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- Include a description of relevant product patents and intellectual property ownership, and their potential impact on product development and the Government's ability to access any technology or products supported with this 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) signed by the lowest ranking person with approval authority for studies involving active duty military, veterans, 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."
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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 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 order of decreasing importance:
    - **Military Benefit**
        - The degree to which the proposed project, if successful, will impact the lives of those affected by combat-relevant orthopaedic injuries.
        - How well the project addresses a critical problem or barrier to improved functionality of prosthetic devices for combat and combat-related injuries resulting in upper extremity amputation.

- **Technology Development Product**
    - How well a clear product(s) has been identified.
    - How well the application describes a plan to create a modular, interoperable, three-degrees-of-freedom, externally powered prosthetic wrist with a one-degree-of-freedom terminal device and accompanying control strategies.
    - The potential for the product and its associated technologies, if successfully developed, to change the concepts, technologies, methods, or services in upper extremity prosthetic device development and clinical usage.
    - The degree to which the product will provide significant advantages over other existing and developing prosthetic devices.
- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and/or logical reasoning.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and support completion of the aims.
    - How well the PI acknowledges potential problems and addresses alternative approaches.
    - The degree to which the plan to study military populations, if applicable, is appropriate and feasible.
- **Transition Plan**
    - Whether the plan for bringing the product to delivery is feasible and appropriate.
    - Whether there is evidence that the PI has or can secure the additional funding needed to bring the product to delivery (if applicable).
    - How well intellectual property, licensing, and/or business professionals have been included or engaged.
    - How well the resources proposed to bring the product to delivery support the likelihood of success.

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

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

- **Environment**
  - The degree to which the scientific environment is appropriate for the proposed research.
  - The degree to which the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - Whether the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of 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
   - 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.

### 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 PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

### 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.

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

### 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 | 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 Transition Plan (Transition.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. | |