Program Announcement

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Orthopaedic Research Program

Clinical Trial Award

Funding Opportunity Number: W81XWH-11-PRORP-CTA

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 formal protocol for the proposed clinical trial should not be submitted as the Clinical Trial Award application. A formal protocol will be requested if the application is recommended for funding.

New for 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 Clinical Trial Award (CTA) is intended to support the rapid implementation of clinical trials with the potential to have a significant impact on military combat-relevant orthopaedic injuries. The clinical trials may be designed to evaluate promising new products, pharmacologic agents (drugs or biologics), devices, clinical guidance, and/or emerging approaches and technologies. All applications are required to justify the relevance of the proposed project to military and/or veteran populations affected by combat-relevant orthopaedic injury. ***Collaboration with military researchers and clinicians is encouraged, and studies that include active duty military or Veteran participants as all or a portion of the study population will be given higher priority for funding.***

Proposed projects may range from small proof-of-concept (i.e., pilot, first in human, or Phase 0) trials to demonstrate feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations. Proof-of-concept trials should not request the maximum funding amount allowed under this program announcement/funding opportunity. All funding amounts requested should be well justified and appropriate to the scope of work proposed.

Funding from this award mechanism must support a clinical trial and cannot be used for preclinical research studies. 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. Refer to the General Application Instructions, Appendix 5, for additional information and resources for studies involving human subjects.

All 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, with infection and non-union as common complications. Nonfunctional nerves and loss of muscle function are frequent outcomes. Within this focus area, clinical studies on approaches to reduce or treat infection, therapies to heal large extremity nerve injuries, and novel rehabilitation interventions or orthoses that improve the functional outcomes of individuals with severely injured limbs are sought. 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.

If the study proposed involves the use of a drug that has not been approved by the Food and Drug Administration (FDA) for its investigational use, then an Investigational New Drug (IND) application to the FDA may be required and must be submitted to the FDA prior to full application submission. If the proposed study involves an investigational device that has not been approved or cleared by FDA for its investigational clinical use, the study may be required to comply with the FDA Investigational Device Exemption (IDE) regulations. If applicable, the IDE application must be submitted prior to full application submission. ***The Government reserves the right to withdraw funding if documentation of the IND or IDE has not been obtained within 6 months of the award date.***

The following are important aspects of submission to the FY11 PRORP CTA:

- The proposed clinical trial is expected to begin no later than 12 months after the award date.
- The proposed intervention to be tested should offer significant potential impact for military personnel with combat-relevant orthopaedic injuries.
- Inclusion of preliminary data relevant to the proposed research is required.
- The proposed research project should be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.
- The application should demonstrate documented availability of and access to the drug/compound, device, and/or materials needed, as appropriate.
- The application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study. The PI should discuss how accrual goals will be achieved, and how standards of care may impact the study population.

- The proposed clinical trial should include clearly defined and appropriate endpoints.
- The application should include a clearly articulated statistical analysis plan, as well as appropriate statistical expertise and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- The application should include a study coordinator(s) who will guide the clinical protocol through the local Institutional Review Board (IRB) of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.
- The application must provide evidence of an existing IND/IDE or submission of an IND/IDE application, if applicable. ***If the IND/IDE is not received within 6 months of the award date, the Government reserves the right to revoke funding.***
- The application should include a Transition Plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the PRORP award.

NESTED CAREER DEVELOPMENT OPTION

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

- Career Development Principal Investigator: Career Development PIs must be active-duty research- or physician-scientists at either the postdoctoral or early-career level. The Career Development PI may be the PI or a co-PI of the application. Only one Career Development PI may be included within a given Clinical Trial Award application. "To be named" Career Development PIs are not allowed.
- Orthopaedic Research Mentorship: A designated mentor is required. The mentor may be the PI of the application, a member of the research team, or outside of the research team. This mentor must be an established orthopaedic researcher; have a history of orthopaedic research funding; and have a record of orthopaedic research publications in peer-reviewed journals. In addition, the mentor must demonstrate a commitment to developing and sustaining the Career Development PI's research career in orthopaedic research. The mentor may request salary support, as appropriate to his/her level of effort. ***To promote collaboration between military and non-military organizations, it is encouraged, but not required, that the mentor be from an academic, VA, or other non-military organization.***
- Applications that contain a nested Career Development PI will qualify for a higher level of funding as described under the Funding Section (Section I.D).
- Supporting documentation should include a biographical sketch for the Career Development PI and a letter of support from the Career Development PI's primary mentor. A biosketch must also be provided for the mentor if not already included as a key personnel biosketch in the Clinical Trial Award application.

- ***To qualify for the nested Career Development option, all requirements described above must be included in the application. If these requirements are not met, the Government reserves the right to review the application for a traditional Clinical Trial Award.***

Use of Human Subjects and Human Biological Substances: All Department of Defense (DOD)-funded research involving new and ongoing research with human subjects and human biological substances must be reviewed and approved by the 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. ***Allow a minimum of 4 months for regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, for more information and resources.

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

Encouraged DOD Collaboration and Alignment: Military relevance is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their projects with military and/or VA research laboratories and programs. 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
http://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

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

D. Funding

- The maximum period of performance is 4 years.
- The maximum allowable direct costs for the entire period of performance is **$2.5M**, plus indirect costs.
    - If requesting the Nested Career Development Option, the maximum allowable direct costs for the entire period of performance is **$2.725M**, plus indirect costs.
- The applicant is encouraged to request less than the maximum allowable direct cost limit, as appropriate to the scope of work proposed.
- 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 of non-government personnel
- Salary of contract research personnel at government facilities

- Salary of mentor for Nested Career Development PI
- Research supplies
- Equipment
- Clinical research costs
- Training-related costs for Nested Career Development PI
- Travel between collaborating organizations
- Support for multidisciplinary collaboration
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

Must not be requested for:

- Preclinical research studies
- Salary of government personnel

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $13M of the $24M FY11 Peer Reviewed Orthopaedic Research Program appropriation to fund approximately 3-6 Clinical Trial 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 3-6 Clinical Trial 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/).

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-CTA.

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.

Changes in the PI or organization after the pre-application deadline are strongly discouraged. 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 address the following:

  - **Focus Area**: Identify which of the PRORP Clinical Trial Award focus areas this application addresses.
  - **Research Idea:** Describe the ideas and reasoning on which proposed work is based. Clearly specify which type (e.g., drug, device, behavioral) of clinical trial is being proposed, and indicate the phase of trial and/or class of device and regulatory status, as appropriate.
  - **Research Strategy:** Concisely state the project's objectives and specific aims. Briefly describe the patient population(s) to be recruited for the clinical trial.
  - **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project. If applicable, describe the roles of the Career Development PI and mentor in the project.
  - **Military Benefit:** Describe how the proposed work will have an impact on accelerating the movement of a promising treatment for orthopaedic injury into a military combat-relevant clinical application.

  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.
  - Key Personnel Biographical Sketches (4-page limit per individual): 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:

  - **Research Idea:** The degree to which the proposed research addresses the intent of the award mechanism and aligns with PRORP Clinical Trial Award focus areas.
  - **Research Strategy:** How well the specific aims support the research idea and objectives.
  - **Personnel:** How the personnel's background and expertise are appropriate to accomplish the proposed research.
  - **Military Benefit:** The degree to which the proposed research, if successful, will have a significant clinical impact to innovate and/or improve clinical care for Warfighters who have sustained combat-relevant orthopaedic injury. Whether the proposed study includes active duty military personnel and/or veterans in the targeted study population.

- **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 Clinical Trial 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

New for FY11: The Project Narrative is NOT the formal clinical trial protocol (as in previous years). Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6, 7, and 8, described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

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

  Describe the proposed project in detail using the outline below.

  - **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

    If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award. ***For ongoing protocols, HRPO approval is required prior to initiation of any human subjects research activities supported by the USAMRMC.***
  - **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
  - **Study Design:** Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.
    - Identify the intervention to be tested and describe the projected outcomes.
    - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
    - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
    - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
    - Describe the reliability and validity of psychometric measures, if applicable.

- **Statistical Plan and Data Analysis:** Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Describe the data analysis plan in a manner that is consistent with the study objectives.

- **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. ***If a Career Development PI is included in the application, letters from the Career Development PI's immediate supervisor and Commander must be provided that demonstrate a commitment to allow the Career Development PI to participate in the project.***
  - Mentor Letter of Support for Optional Nested Career Development PI (if applicable): Provide a letter signed by the primary mentor in support of the nested Career Development PI. Describe the following:
    - How the Career Development PI's achievements indicate a potential for a successful career in orthopaedic research.
    - How the training environment will promote the development of the Career Development PI as an orthopaedic researcher.

- The mentor's qualifications, including how the research being performed under the mentor's direction is relevant to combat-related orthopaedic injury.
- The mentor's proposed interactions with the Career Development PI, and the degree to which the Career Development PI will participate in the execution of the application if funded.

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

- **Attachment 3: Technical Abstract (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.
  - Specific Aims: State the specific aims of the study.
  - Research Plan/Study Design: Briefly describe the clinical study design including appropriate controls. State how the proposed projects address the PRORP Clinical Trial Award focus areas.
  - 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 application 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?

- Briefly describe how the proposed project will benefit military populations and impact combat-relevant orthopaedic research and/or patient care.

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

- **Attachment 6: Human Subject Recruitment and Safety Procedures (no page limit):** Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from which the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual, including those specific to recruitment from military and/or veteran populations (if applicable). Provide plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

  b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

  c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and health care provider identification). Include a description of any considerations unique to recruitment from military medical treatment facilities, if applicable.

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.

- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements, and should accurately reflect the study.

d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent.
- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+10USC980. If applicable, please refer to the General Application Instructions, Appendix 5, for more information.
- Provide a draft in English of the proposed Informed Consent Form. A plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial should be included.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for

entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify the study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response:**
  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel, or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
  - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 7: Intervention (no page limit):** Upload as "Intervention.pdf." The Intervention attachment should include the components listed below.

a. Description of the Intervention: As applicable, the description of the intervention should include the following components: Source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include detailed operational instructions, and any potential risks to users, and intended benefits. Other types of interventions should be fully described.

b. Study Procedures: Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures.

- **Attachment 8: Data Management (no page limit):** Upload as "Data_Manage.pdf." The Data Management attachment should include the components listed below.

  a. Data Management: Describe all methods used for data collection to include the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - **Confidentiality:**
    - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
    - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
    - Address requirements for reporting sensitive information to state or local authorities.
  - **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
  - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

  b. Laboratory Evaluations:

  - **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
  - **Evaluations to be made.** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - **Storage.** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Labs performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that

should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 9: Study Personnel and Organization (no page limit):** Upload as "Personnel.pdf." The Study Personnel and Organization attachment should include the components listed below.

  a. Principal Investigator/Study Staff: Provide an organizational chart identifying key members of the study team including institution/center/ department. Briefly describe their roles on the project. A medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.

  b. Study Management Plan: Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).

- **Attachment 10: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit):** Upload as "Surveys.pdf." The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study.

- **Attachment 11: Military Benefit Statement (1-page limit):** Upload as "MilBen.pdf."

  State explicitly how the proposed clinical trial, if successful, will accelerate the movement of the product, pharmacologic agent, device, clinical guidance, and/or emerging technology into clinical practice for combat-relevant orthopaedic injuries. Further, 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. The following are examples of ways in which proposed studies, if successful, may have an impact. ***Although not all-inclusive***, these examples are intended to help PIs frame the impact of the proposed research:

  - Has the potential to change the standard of care for military orthopaedic injuries
  - Proposes new paradigms or challenges existing paradigms in patient care of military orthopaedic injuries
  - Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care

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

- **Attachment 12: 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 13: 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.

- **Attachment 14: Career Development Statement (3-page limit): Upload as** "CareerDev.pdf."

  The required Career Development Statement from the proposed PI should:

    - Identify the primary mentor. Multiple mentors may be proposed, if appropriate, but one must be identified as primary.

- Describe a Career Development Plan, which may include coursework, hands-on laboratory and clinical techniques, conferences, seminars, teaching responsibilities, and/or clinical responsibilities.
- Describe the research that will be performed by the Career Development PI in the context of the proposed clinical trial.
- Articulate career goals and how the proposed research training will promote a career in orthopaedic trauma research.

- **Attachment 15: IND/IDE Documentation Form (if applicable): Upload as** "IND.IDE.pdf."

  Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.

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."
     - If applying for the higher level of funding for the Nested Career Development Option, include a biographical sketch of the Career Development PI and mentor.
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
     - If applying for the higher level of funding for the Nested Career Development Option, include the current/pending support of the Career Development PI and mentor.

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

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

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines 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 scored criteria, which are of equal importance:

   - **Ethical Considerations**
     - How the level of risk to human subjects is minimized, and whether there is sufficient evidence of a monitoring plan that is appropriate for the level of risk.
     - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
     - To what degree privacy issues are appropriately considered.

- To what degree the process for seeking informed consent is appropriate, and whether safeguards are in place for vulnerable populations.

- **Intervention**
  - Whether there is evidence to support availability of the intervention, if applicable, for the proposed clinical trial.
  - To what degree the intervention addresses the clinical need(s) described.
  - How the intervention advances patient care beyond the currently available interventions.
  - Whether a member of the study team holds the IND/IDE, and whether the timeline proposed for IND/IDE application is appropriate (if applicable).
  - For investigator-sponsored INDs, whether there is institutional support to serve as a sponsor, and whether they are equipped to assume the monitoring required by the FDA.
  - To what degree the data collection instruments (e.g. surveys, questionnaires), if applicable, are appropriate to the proposed study.
- **Military Benefit and Clinical Impact**
  - How relevant the anticipated outcomes of the proposed clinical trial are to individuals with combat and combat-related orthopaedic injuries.
  - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
  - The degree to which the potential outcomes of the proposed clinical trial will provide/improve the short-term benefits for individuals.
  - How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.
  - The degree to which the results of the proposed clinical trial will affect the patterns of clinical practice for military combat-relevant orthopaedic injuries.
- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in spinal cord injury, and clinical studies).
  - How the levels of effort of the study team members are appropriate for the successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, and standardization of procedures) meet the needs of the proposed clinical trial.

- **Nested Career Development applicants (if applicable):**
  - How the qualifications of the Career Development PI will add to the project.
  - How the Career Development PI will benefit from participation in this project.
  - How well the mentor, training environment, and career development plan are suited to providing the Career Development PI with a training experience that will further his/her career at the forefront of orthopaedic research.

- **Recruitment, Accrual, and Feasibility**
  - How well the PI addresses the availability of human subjects for the clinical trial, and the prospect of their participation.
  - Whether the PI has demonstrated access to the proposed human subjects population.
  - How the recruitment, informed consent, screening, and retention processes for human subjects will be conducted to meet the needs of the proposed clinical trial.
  - Identification of possible delays and evidence of an adequate contingency plan to resolve potential delays (e.g., slow accrual, attrition).
  - To what extent the proposed clinical trial affects the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).
- **Research Strategy**
  - How well the scientific rationale for testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
  - How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to clearly answer an important clinical objective.
  - How the inclusion, exclusion, and randomization criteria meet the needs of the proposed clinical trial.
- **Statistical Plan**
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Transition Plan**
  - Whether the funding strategy described to bring the outcome(s) to the next level of clinical trials and/or delivery to the military or civilian market is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.

- How the schedule of milestones for bringing the outcome(s) to clinical trial and/or delivery to the military or civilian market is appropriate.
- How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
- How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.

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

- **Environment**
  - Whether there is sufficient evidence to indicate an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
- **Budget**
  - Whether the budget is appropriate for the proposed clinical trial and within the limitations of the award mechanism.
- **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
- Programmatic relevance in relation to PRORP Focus Areas
- Program portfolio composition
- Ratings and evaluations of the peer reviewers
- Relative military benefit and clinical impact

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.
- Human Subject Recruitment and Safety Procedures (Attachment 6) is missing.
- Intervention (Attachment 7) is missing.
- Data Management (Attachment 8) 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 not a clinical trial.
- IND/IDE has not been applied for or obtained, if applicable.
- The PI does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the 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 will be required.

D. Award Transfers

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

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

A change in PI will not be allowed for the CTA except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

E. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator may be requested to participate in a pre-award meeting.

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 Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 6.	
	Upload Intervention (Intervention.pdf) as Attachment 7.	
	Upload Data Management (Data_Manage.pdf) as Attachment 8.	
	Upload Study Personnel and Organization (Personnel.pdf) as Attachment 9.	
	Upload Surveys, Questionnaires, and Other Data Collection Instruments, if applicable Upload (Surveys.pdf) as Attachment 10.	
	Upload Military Benefit (MilBen.pdf) as Attachment 11.	
	Upload Transition Plan (Transition.pdf) as Attachment 12.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) (Access.pdf), if applicable, as Attachment 13.	
	Upload Career Development Plan (CareerDev.pdf) as Attachment 14.	
	Upload IND/IDE Documentation Form (IND.IDE.pdf) as Attachment 15.	
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.	