DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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Request for Information: Translational and Clinical Research for Traumatic Orthopaedic Injury

Key Dates
Release Date: May 18, 2011
Response Date: June 8, 2011

Issued by
The Peer Reviewed Orthopaedic Research Program, Congressionally Directed Medical Research Programs, United States Army Medical Research and Materiel Command

Background
The Peer Reviewed Orthopaedic Research Program was established within the Defense Health Program of the Department of Defense to support research focused on optimizing recovery and restoration of function for military personnel with orthopaedic injuries sustained in combat or combat-related duties. The PRORP is considering offering program announcements to solicit for mature translational and clinical trial research projects, and is issuing this RFI to survey available and/or emerging biomedical technologies that have the potential to address the following focus areas of interest:

A. Prevention and treatment of post traumatic osteoarthritis

- Post traumatic osteoarthritis is the most common chronic, debilitating condition of combat-injured Warriors. Most incidences of post traumatic osteoarthritis are caused by fractures involving the joints. The PRORP is interested in mature translational and clinical research aimed at preventing or treating this condition. Preventive measures must consider the battlefield environment constraints (to include but not limited to multiple serious injuries, anticoagulation 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.

B. Improved outcomes of severe limb injuries

- The majority of combat-injured Warriors 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 nonunion as common complications. Nonfunctional nerves and loss of muscle function are frequent outcomes. Clinical studies on approaches to reduce or treat infection, therapies that heal large motor nerve injury, and novel rehabilitation interventions or orthoses that improve the functional outcomes of individuals with severely injured limbs are needed.

C. Improved outcomes of multi-limb trauma patients

- Combat casualties facing multiple major limb amputations or severe limb-threatening injuries requiring salvage techniques represent a small but very important subset of patients. Clinical studies to examine surgical, rehabilitative and psychosocial aspects of coping with and returning to life afterwards; as well as treatment strategies to improve outcomes in these specific patients will be considered.

D. Upper Extremity Prosthetic

- Combat-injured Warriors that have lost one or both arms have limited options in reliable prosthetics that are lightweight, easy to control, and flexible. The PRORP is interested in advanced technology that could be used to develop and test a modular, interoperable, three-degrees-of-freedom (DOF), powered prosthetic wrist and one DOF terminal device with accompanying control strategies. Of highest interest is technology that solves unmet clinical needs, with priority given to function, weight, reliability, and durability, rather than cosmetic appearance. Interest is in candidate solutions and prototype systems at the stage of refinement and initial feasibility testing or beyond.

Information Requested

To respond to this RFI, please address the following questions. It is requested that each response address a single focus area. If you would like to comment on multiple focus areas, you are encouraged to submit multiple responses.

1) What novel approaches that meet the above focus areas are sufficiently developed for clinical trial research? Please describe any relevant research of which you are aware, with brief details about each therapeutic or preventive intervention, and the stage of clinical development in progress. If relevant, include information on Investigational New Drug or Investigational Device Exemption status.

2) What novel approaches that meet the above focus areas are not yet ready for clinical trial, but are considered to be at a mature translational research stage? Briefly describe each relevant approach, including status of any animal or observational/clinical validation, technology development, and manufacturing progress. Estimate time needed for additional research and development before clinical trial readiness.

3) With regard to upper limb powered prosthetic solutions, please describe current capabilities to assemble a modular three DOF wrist, specifying the size and weight footprints of each possible configuration in order to evaluate the limitations for fitting based on residual limb length. Briefly describe design of the terminal device and accompanying powering technology. Describe any approaches that capitalize on and augment the features of existing body-powered devices to create an evolutionary externally powered product. Discuss the modularity of the system both in terms of physical assembly and control capability. Responses should include information on the extent to which each technological component of the system has been proven, as well as compatibility across other prosthetic systems and manufacturers.

Response and Process

To facilitate review of responses, please clearly mark which of the above focus areas is relevant to the response. Please respond no later than June 8, 2011. Responses should be limited to 500 words or less, and can be submitted to cdmrp.prorp@amedd.army.mil. No telephone calls please.

This RFI is issued solely for information and planning purposes and does not constitute a solicitation or issuance thereof. All information received in response to this RFI that is marked proprietary will be handled accordingly. Responses to this RFI will not be returned. Responses to this RFI are not offers and cannot be accepted by the Government to form a binding contract or award. Responders are solely responsible for all expenses associated with responding to this RFI.