

Draft



DEPARTMENT OF VETERANS AFFAIRS  
Veterans Health Administration  
Washington DC 20420

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In Reply Refer To: 121

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OFFICE OF RESEARCH AND DEVELOPMENT INFORMATION LETTER

SOLICITATION OF APPLICATIONS FOR  
TECHNOLOGY ASSESSMENT OF MAJOR LIMB PROSTHETICS

1. **Purpose.** This Veterans Health Administration (VHA) Office of Research and Development (ORD) Information Letter announces the opportunity for investigators from Department of Veterans Affairs (VA) medical centers to compete for research funding for studies focusing on technology assessment of major limb prosthetics.
2. An important goal of the prosthetics portfolio of the Rehabilitation Research and Development Service (RR&D) is to document and define the impact of traditional rehabilitation treatment for amputees, in order to improve outcomes. Objective assessments of prostheses quality are necessary in order to achieve clinical efficacy. Clinical evaluations, as well as other techniques, are also important in determining the potential for this technology to improve functional independence and quality of life of veterans with severe physical disabilities. **NOTE:** *This solicitation is in accordance with Title 38 United States Code (U.S.C.) 7303.*
3. Major limb loss is a devastating condition afflicting a growing number of military personnel serving in Operation Enduring Freedom and Operation Iraqi Freedom. The urgency to address the needs of amputees cannot be overstated. Proper prescriptions, rehabilitation and functioning are vital to the successful use of prosthetics by amputees. The need for comprehensive objective information about the quality and functional reliability of prostheses is paramount.
4. Current International Standards Organization (ISO) standards are the preferred Structural Standards for Prosthetic components and do not refer to the quality of the device under real-life testing parameters. Therefore, manufacturer testing does not consistently stand up to rigorous scientific design parameters under conditions the user would be exposed to on a daily basis. Execution of studies aimed at determining the reliability and effectiveness of prostheses over time and under real-life conditions, is critical.
5. RR&D will accept research proposals that focus on technological assessment of major limb prostheses in order to provide an objective assessment of prosthetic durability, stability, cost-effectiveness, long-term use and a compendium of other important factors relevant to clinical efficacy for veteran amputees.

6. Studies that pay special attention to activities of daily living (ADLs) of the user are expected. Studies that do not provide data important for improving current prosthetic design, developing prosthetic prescriptions or exceed manufacturer-testing parameters in a clinically meaningful way will not be considered.
7. Investigators such as certified prosthetists, biomedical engineers, physiatrists, orthopedic surgeons, and physical and occupational therapists who challenge existing paradigms and incorporate innovative ideas in prosthetics research are encouraged to apply. Examples of priority research areas include, but are not restricted to:
  - a. Compressive mechanical properties of prostheses and their componentry as they relate to ADLs;
  - b. Static and dynamic loading stability that translates into durability for long-term use;
  - c. 3-D forces and torque related to ADL,
  - d. Normal ambulation behavior and behavior that maximizes use;
  - e. Head-to-head trials between different prosthetic designs;
  - f. Energy consumption of amputee during use and other parameters related to the overall health of the veteran amputee;
  - g. Climatic compatibility of new technology; and
  - h. Prosthetic designs—exoskeleton, endoskeleton, and myoelectric.
8. Successful proposals most responsive to this solicitation will incorporate multi-site interdisciplinary approaches that improve upon prosthetic design, and result in devices with higher performance and longer life. Development of guidelines for prosthetics use to ensure that the prescription grading system will be of value in the clinical decision-making process is also desirable. Research should be designed to establish evidence-based practices for the reliable use and limits of prostheses and to develop or establish research methodologies, which may be reproduced for further evaluation activities in this area. Investigations that combine bioengineering and clinical assessments will receive high priority.
9. Research proposals will be reviewed for scientific merit, relevance to the veteran population, capability of applicant to meet intended outcome of proposed research program, and potential contribution of proposed research to the field of rehabilitation and ultimately, quality of life to veterans. Criteria for review and evaluation are:
  - a. Relevance to veteran population,

- b. Relevance of stated hypothesis to the mission of RR&D,
  - c. Relationship of stated hypothesis to proposed research activities and/or methodologies,
  - d. Potential of proposed research plan to produce new and beneficial information with the expectation for therapeutic intervention and exponential increase in research findings,
  - e. Incorporation of expertise required to carry out all facets of the proposed research plan,
  - f. Contribution to overall VA RR&D portfolio,
  - g. Appropriateness and statistical significance of VA patient pool,
  - h. Adequacy of VA facilities and equipment,
  - i. Ability of budget to cover all reasonable costs related to the proposal, and
  - j. Appropriateness and detail of subcontract (if required).
10. Funding of proposals is contingent upon the availability of funds.
11. Important Due Dates:
- a. Letters of Intent: March 31, 2004
  - b. Proposals due at RR&D Service: June 1, 2004
  - c. Review: June 15, 2004
  - d. Projected funding date: July 1, 2004
12. See Attachment A for requirements.
13. Applications and instructions for the RR&D standard review process are available on the RR&D website at <http://www.var.d.org>. Direct questions about scientific and/or research issues to:

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#### Attachments

DISTRIBUTION: CO: E-mailed  
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## **ATTACHMENT A**

### **REQUIREMENTS**

1. Proposals must incorporate proven techniques for adequate analysis and dissemination of results in leading peer-reviewed journals. Therefore proposals must:
  - a. Use adequate subject pools,
  - b. Incorporate rigorous statistical analyses, and
  - c. Clearly define outcomes.
2. Although preliminary data in support of the studies is not required, a demonstration of previous research, sound rationale, and appropriate expertise is expected.
3. Principal investigator (PI) and co-principal investigators (Co-PIs) must have Ph.D. and/or M.D. degrees and at least a 5/8th Department of Veterans Affairs (VA) appointment.
4. All applicants must submit a Letter of Intent (LOI) by March 31, 2004. LOIs must be directed through the Associate Chief of Staff for Research and Development (ACOS/R&D) and include:
  - a. Names of key investigators (PI, Co-PI, co-investigators),
  - b. Brief background,
  - c. Clearly stated hypothesis,
  - d. Outline of Methods,
  - e. Estimated Budget, and
  - f. Appropriate references.
5. This Request for Proposals will use Program Funding (822). The applicant must be solely responsible for planning, directing, and executing the proposed project. The applicant may request up to \$250, 000 direct costs per year for 3 years.