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**DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420**

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In Reply Refer To: 122P

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OFFICE OF RESEARCH AND DEVELOPMENT INFORMATION LETTER

**SOLICITATION OF APPLICATIONS FOR AMPUTATION AND PROSTHETICS
OUTCOMES RESEARCH**

1. 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 submit proposals for research on amputation and prosthetic health outcomes. Designated research funds are available to support rehabilitative health services research that will produce new knowledge for improving the effectiveness and cost effectiveness of care delivery for patients with amputations and prosthetics by drawing on the perspectives and experiences of diverse disciplines and professions. The Rehabilitation Research and Development Service (RR&D) and Health Services Research and Development Service (HSR&D) have collaborated in the development of this solicitation and will jointly review the proposals.
2. An important goal of this solicitation is to optimize amputee functioning, independence, and quality of life. Approaches are expected to incorporate outcome evaluations, including defining best practices involving traditional and non-traditional rehabilitation treatment for amputees, including use of prosthetics and documenting their impact toward improving patient- and system- level outcomes. *NOTE: This solicitation is in accordance with Title 38 United States Code (U.S.C.) 7303.*
3. Injuries inflicted on military personnel serving in Operation Enduring Freedom and Operation Iraqi Freedom underscore the need for research efforts to address the outcomes of rehabilitative services, specifically, prosthetic services for traumatic injury amputees. With recent advances in modern medicine and medical technology, such as Kevlar helmets, body armor with ceramic plates and innovative medical facilities, most soldiers who are injured survive. However, a significant number of injuries that soldiers sustain (i.e., limb loss), often leave them disabled and in need of prosthetic devices such as lower limb, upper limb, and cosmetic prostheses.
4. Extraordinary efforts of clinicians and researchers are addressing preventing amputation procedures due to traumatic limb loss associated with active combat duty. There also is a rapidly growing veteran amputee population related to non-combat conditions. Mainly, as the veteran population ages, the high incidence of amputations is a direct complication of diabetes and peripheral atherosclerotic disease. However, regardless of the cause for

amputation, whether from combat, civilian accidents, or the result of progressive diseases, the ultimate goal for VHA clinicians and researchers is to provide veterans with maximum quality of life and functioning.

5. Proposed studies should address the outcomes of amputation and prostheses services that aim to optimize patients' physical functioning, independence, and quality of life. The underlying clinical condition may be selected from a broad range of events common among veterans, including traumatic accidents, environmental exposures, military exposure, injury, and disease resulting in amputation (i.e., diabetes, vascular disease, etc.). Studies may address the outcomes of services designed to restore or compensate loss of limb function. These include the services provided by all pertinent VA health care professionals, especially rehabilitation specialists such as PM&R physicians, orthopedic surgeons, physical therapists, occupational therapists, nurses, psychologists, social workers, and other allied health personnel (and non-VA providers, as comparisons).
6. Proposed studies should focus on the outcomes of VA amputee and prostheses services. Pertinent outcomes fall into two major categories (Patient- and System-level):
 - a. Patient-Level Topics. Studies intended to explain the outcomes that most directly concern patients and their families. In general terms, these include functional status, independence, health status, symptoms and symptom management strategies, prognosis, quality of life, and satisfaction with care. More specifically, patient level outcomes may include amputation and use of prostheses, and other functions that affect independence, productivity, and quality of life. Studies might also include aspects of caregiver burden and family assistance involved with maintaining amputee patients in independent living situations. Studies focused on evaluating devices and technologies (e.g., durability of prostheses) are **NOT** responsive to this solicitation; however, studies focused on increasing the use of aids provided to patients will be considered.
 - b. System-Level Topics. Studies intended to explain and guide improvements in the design, administration, and/or management of prostheses services. This includes system-level outcomes, especially quality of care, cost, access to needed services, and efficient provision of prostheses.
 - c. Examples of priority patient and system-level rehabilitative amputee and prosthetic questions include, but are not limited to:
 - (1) Validation study of the National Prosthetic Patient Database (NPPD). The NPPD is a potentially important database of patient eligibility, prosthetic treatment, date of provision, cost, and vendor. To date, there have been no comprehensive studies on the accuracy of the database, although some preliminary studies suggest that validating the database would enhance its utility.
 - (2) Comparisons of cost-effectiveness and effectiveness of competing models for prostheses in patient treatment. Analysis of the extent to which prosthetic prescriptions are based upon real-life activities is also valuable.

- (3) Analysis of the relationship between delivery of rehabilitation services and resulting outcomes. What is the likelihood of improvement, sustainability of benefit, risk of secondary disability or deterioration due to re-injury, infection, noncompliance, and aging? For example, examine medical reasons why veterans, with transfemoral or bilateral amputation sustain recurrent superficial infections in the residual limb. How do the outcomes of VA services compare across VA (and if feasible) non-VA systems?
- (4) Analysis of the degree to which veterans are able to utilize their prosthetic devices for daily living and work activities. If veterans are limited in their use of prosthetic devices, what problems are experienced (e.g., pain, fit and attachment problems, embarrassment of having a prosthetic)? Are some quality of life problems a consequence of prosthetic inadequacies during activities that are high-energy, such as climbing stairs? What are the most effective and cost-effective means of addressing these problems?
- (5) Examination of disorders and subsequent risk factors that commonly result in amputations (e.g., diabetes, cardiovascular disease) and effective means of delivering cost-effective care to veterans with these complex needs.
- (6) Evaluation of the healing process of the ischemic and diabetic limb and what early functional rehabilitation interventions may result in successful outcomes.
- (7) Examination of the relationship between psychosocial factors and amputation. Are there unique psychosocial needs depending on how the injury was sustained (e.g., combat, chronic illness, car accident)? Examination of self-perception, self-esteem, anxiety, and depression as it correlates with amputation (e.g., pre-amputation intact body, body with limb loss, and body with wearing a prosthesis).
- (8) Identifying barriers (e.g., emotional, social, and physical) to reintegrating into military service or civilian life. For example, when and how does manifested post-traumatic stress disorder prevent and affect successful reintegration into the workforce?
- (9) Identification of qualitative aspects of managing amputation as a chronic condition by defining qualitative aspects of well-being, caregiver burden, and barriers to obtaining needed services and assistive prosthetic devices. Are there gaps in patient and caregiver knowledge and understanding about amputation, prostheses, and management strategies that can be addressed by the VA?
- (10) What is the relationship between general healthcare and healthcare for amputees? What factors facilitate or impede optimal health promotion among groups of veterans with amputations?
- (11) Develop and evaluate or determine efficacious and effective rehabilitation methods for veteran utilization of prostheses (e.g., treadmill or lokomat).

7. Research on amputation and prosthetics impairment outcomes requires valid and reliable measures for a variety of complex variables. In cases where good instruments do not already exist, ORD is interested in supporting projects to develop them. *NOTE: Investigators need to provide a detailed explanation of how the proposed measure differs from any existing measures.* Possibilities include:
 - a. Measures of patient outcomes for amputees and their use of specific prostheses or for common constellations of problems that require the use of healthcare services. Outcomes for new measures may be needed in the areas of health status, functional status, and independence for persons with amputation who are receiving VA prosthetics services. Both subjective and objective measures of outcomes are appropriate.
 - b. Measures and instruments for assessing patient factors that influence the outcomes of healthcare services, especially patient perceptions and values related to their condition and its treatment or management, patient decision making, and behavior. For example, measures or instruments to assess patients' treatment goals and preferences, patient satisfaction, or compliance with prescribed regimens related to treatment and rehabilitation, or to screen/identify patients who are likely to benefit from prostheses services.
 - c. Case mix measures to address the severity of problems and/or the combination of disabilities and impairments in the study population (e.g., amputation plus chronic disease).
8. Proposed projects are expected to employ state-of-the art research methods appropriate to the research question(s) and population to be studied. In general, priority will be given to explanatory studies (over descriptive studies) and studies designed to maximize the generalizability of findings. It is expected that most studies will require collection of primary data, perhaps in combination with secondary data.
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 ORD mission,
 - 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 research 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: April 30, 2004
- b. Proposals due: June 8, 2004
- c. Review: week of June 22-June 29, 2004
- d. Projected funding date: August 2, 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.vard.org>. All applications should follow the RR&D process. Direct questions about scientific and/or research issues concerning this solicitation for proposals to: Denise Burton, Ph.D., Portfolio Manager, Chronic Medical Diseases for RR&D, at 202-254-0268; email: denise.burton@hq.med.va.gov; fax: 202-254-0473; or at:

Denise Burton, Ph.D.
Portfolio Manager, Chronic Medical Diseases
Rehabilitation Research and Development Service 122P
810 Vermont Avenue, N.W.
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Questions specifically related to HSR&D should be directed to:

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Attachments

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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 and assess 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) that is received in VA Central Office (122P) by April 30, 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 be funded by 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.
6. Proposals received in response to this announcement will undergo merit review, by a subcommittee of the HSR&D and RR&D Scientific Merit Review Boards (SMRBs). The review is rigorous and standards are very high; both scientific merit and expected contribution to improving VA health services are considered.