

June 24, 2010

**REQUEST FOR PROPOSALS FOR REHABILITATION RESEARCH AND
DEVELOPMENT CENTERS OF EXCELLENCE (CoE)**

1. PURPOSE: This Veterans Health Administration (VHA) Notice announces the opportunity for Department of Veterans Affairs (VA) medical facilities to submit proposals for establishing Rehabilitation Research and Development Service (RR&D) Centers with focus on research in high-priority areas relevant to the rehabilitation needs of Veterans. It also serves as the announcement for currently funded RR&D CoEs to submit their application for competitive renewal. *NOTE: Required formats and instructions for submitting applications are provided in Attachments A and B.*

2. BACKGROUND

a. VA RR&D Centers are intended to be a resource, first, for the Veterans served by VA, especially by the host VA medical facility and, second, for the rehabilitation community at large. They are expected to provide cutting edge solutions to the issues of chronic impairment. It is anticipated that Centers will establish and cultivate a community of VA clinical scientists and scholars within the VA health care system for the purpose of pursuing specific research objectives in accordance with a well-reasoned 5-year plan. This Notice does not support Centers based predominantly at non-VA sites. Funding for three VA RR&D Centers is due to expire. Each of these Centers must submit an application for competitive renewal (see subpar. 2a (3)). Applications from new centers are reviewed concurrently.

(1) Centers are to develop an integrated thematic research core as a unifying focus of research activities. They are expected to:

(a) Become nationally recognized "Centers of Excellence" in a selected area of research relevant to Veterans with disabilities (see par. 4 for criteria).

(b) Successfully leverage core support funding through nationally-competed and scientifically reviewed funding vehicles, such as: VA investigator-initiated programs, Federal granting agency programs, private foundation awards, and collaborations with commercial partners.

(c) Mentor and support junior investigators, both clinician and non-clinician scientists, through pre- and post-doctoral programs and recruit them into VA.

(d) Nurture strong interactive relationships with the appropriate VA medical facility clinical service providers engaged in rehabilitation, long-term management of impairment, and overall quality of life issues.

(e) Maintain collaborative partnerships of mutual benefit to VA, VA medical facility, and the supporting community institutions (e.g., schools of medicine, allied health sciences, and engineering, as applicable to research focus).

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(f) Facilitate effective information dissemination for a broad spectrum of audiences.

(g) Foster the integration of research findings into clinical practice throughout the health care delivery system.

(h) Actively participate in the national consortium of VA RR&D Centers to strengthen natural collaborative bonds and advance VA RR&D in the scientific community and national consciousness.

(2) Current foci of RR&D Centers are: Vision Impairment and Aging (Atlanta); Translational Research for Traumatic Brain Injury (TBI) and Stress Disorders (Boston); Functional Electrical Stimulation (Cleveland); Advanced Platform Technology (Cleveland); Brain Injury Rehabilitation (Gainesville); Neurons to Networks (Houston); Prevention and Treatment of Visual Loss (Iowa City); Bone and Joint Rehabilitation (Palo Alto); Wheelchairs and Associated Rehabilitation Engineering (Pittsburgh); Rehabilitative Auditory Research (Portland); Restorative and Regenerative Medicine (Providence); Limb Loss and Prosthetic Engineering (Seattle); Maximizing Rehabilitation Outcomes (Tampa); and Restoration of Neurological Function (West Haven).

(3) Centers up for competitive renewal are focused on Task-Oriented Exercise and Robotics in Neurological Disease (Baltimore); Innovative Visual Rehabilitation (Boston); and Medical Complications of Spinal Cord Injury (SCI) (Bronx).

(4) RR&D funds five Research Enhancement Award Programs (REAPs) in Biological Therapeutics to Restore Nervous System Function (Baltimore); Rehabilitation Outcomes (Gainesville); Promotion of Functional Recovery Post SCI (Hines); Auditory and Vestibular Dysfunction (Mountain Home); and Multimodal Strategies for Improving Recovery from Brain Injury (San Francisco).

b. VA RR&D emphasizes and funds basic research to repair and optimize function of injured organs and tissues; prosthetics and neuroprosthetics research to replace what cannot be repaired; translational research to bring basic discoveries to clinical use; and clinical research to maximize function. Proposed research foci must be in a rehabilitation area of importance to the Veteran population with evidence for potential clinical applicability. In addition to areas already funded, encouraged areas of new emphasis include, but are not limited to:

(1) **Regenerative Medicine.** Areas of programmatic need include:

(a) Neural repair (i.e., identification of the appropriate combination(s) of therapies for Spinal Cord Injuries (SCI), TBI, stroke, Multiple Sclerosis (MS), Parkinson's Disease (PD), Alzheimer Disease (AD), and other chronic neurological disorders).

(b) Cell therapy (i.e., stem cells, Schwann cells, oligodendroglia, etc.).

(c) Neurotrophic factors (i.e., glial cell-line derived neurotrophic factor, brain derived neurotrophic factor, nerve growth factor, etc.).

(d) Delivery systems for Neurotrophic factors or drugs (i.e., genetically-engineered cells, viral vectors, dissolvable-biomaterial polymers, etc.).

(e) Factors that overcome inhibition (i.e., chondroitinase ABC, Rho-kinase inhibitors).

(f) Bioengineered scaffolds (i.e., Agarose, extracellular matrix molecules, poly lactide co-glycolide, etc.).

(2) **Musculoskeletal Repair.** Creation of bone and cartilage ex vivo (i.e., outside of the living body) with the:

(a) Appropriate biomechanical properties of endogenous tissue;

(b) Ability to withstand long-term usage; and

(c) Ability to integrate with endogenous tissue (biocompatibility).

(3) **Social Reintegration and Vocational-Work Rehabilitation.** Research in these high priority areas is encouraged in the following domains for Veterans with all types of disabilities:

(a) Development of appropriate outcome measures to determine the efficacy of interventions with disabled Veterans;

(b) Development of empirically-validated interventions that optimize enduring work participation for disabled Veterans; and

(c) Maximization of social, economic, and personal well-being using appropriate validated outcome measures.

(4) **Upper Extremity Orthotics and Prosthetics Engineering.** This new area of emphasis in the VA arises from the unprecedented research investment in upper extremity prosthetics under the Defense Advance Research Projects Agency's (DARPA's) Revolutionizing Prosthetics 2007-2009. VA is presently the primary Federal transition partner to conduct the additional research to bring these arms into use by Veterans. A CoE (or REAP) in Upper Extremity Orthotics and Prosthetics Engineering would conduct additional technical and engineering research that might include, but is not be limited to:

(a) Identification of additional improvements that can be made in these arms, especially with respect to control inputs and strategies;

(b) Development of methodology and technology to make upper extremity prosthetics as modular and interoperable as possible;

(c) Development of additional applications for these arms, beyond Veterans with amputations, such as attaching the arms to wheelchairs to assist Veterans with high-level SCI to perform activities of daily living;

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(d) Development of a research database to track deployment of these arms within VA, and identify protocols and best practices for the technical maintenance of the arms under conditions of daily use;

(e) Conducting long-term post-market surveillance of the arms to identify and correct problems that may arise in long-term use; and

(f) Initiating an engineering-training program for VA prosthetics who will be prescribing the arms within VA.

3. FUNDING: Any VA medical facility with significant rehabilitation research capacity and with well-established academic partnerships is encouraged to apply. Maximum RR&D awards of core funding will be up to \$1,000,000 annually, with required competitive renewal on a 5-year cycle.

a. Each Center must have a Director and Associate Director for Research with doctoral degrees and at least a 5/8th VA appointment. Either the Director or Associate Director must be a clinician with medical care funds committed by the host VA medical center in support of clinician salary. The medical and scientific leadership team is expected to:

(1) Identify research goals and objectives within a given focus area and direct research plans towards achievement of specified goals and objectives with these plans including collaborative activities;

(2) Develop a 5-year research program with specific aims directed toward new discoveries that have the potential to impact on clinical practice;

(3) Achieve maximal administrative efficiencies, control and reporting capabilities, project monitoring, and leveraging of limited core support funds at local and national levels; and

(4) Support the growth and enhancement of a vigorous and creative "learning environment," as well as maintain information dissemination activities that promote findings from VA RR&D CoEs.

b. RR&D Center proposals are scientifically reviewed for merit to objectively determine relevance of the proposed research 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, long-term management of impairment, and overall quality of life issues for Veterans with disabilities.

4. GENERAL REQUIREMENTS: Criteria for review and evaluation are:

a. **Strength of Proposed Research Focus.** This includes the:

(1) Relevance to Veteran population;

- (2) Relationship of proposed research activities to announced research focus;
- (3) Potential of proposed research to produce new and useful information;
- (4) Clarity and ability to execute the research plan; and
- (5) Contribution to overall VA RR&D portfolio.

b. **Effectiveness of Operating Plan.** This includes the:

- (1) Ability to achieve intended research outcomes;
- (2) Ability to coordinate the proposed collaborations and evidence of their benefits to VA and Veteran health care;
- (3) Feasibility of evaluation and quality assurance methods;
- (4) Sufficient coverage of all required disciplines;
- (5) Ability to build research capacity within VA; and
- (6) Effectiveness of the plan to disseminate research findings.

c. **Adequacy of Resources.** This includes the:

- (1) Scientific strength of current VA Research and Development (R&D) Program, especially in rehabilitation research;
- (2) Vitality of rehabilitation clinical base within a VA medical facility;
- (3) Support and demonstrated commitment of VA medical facility(s) and cited affiliations;
- (4) Demonstrated scientific, engineering, or medical leadership of key personnel at VA;
- (5) Evidence of VA-based core of investigators; and
- (6) Adequacy of VA facilities and equipment.

d. **Budget and Cost Effectiveness.** This includes the:

- (1) Ability to support program activities,
- (2) Reasonable costs, and
- (3) Appropriateness and detail of subcontract budget (if required).

5. GENERAL GUIDELINES FOR APPLICANT SITES

- a. All Center funding awards are contingent on availability of funds.
- b. All applicant sites must submit a Letter of Intent (LOI) to Apply by July 31, 2010 (see Att. A). LOIs must be directed through the facility Associated Chief of Staff for Research and include:
 - (1) Names of key investigators,
 - (2) Certification from the facility that the principal investigators have at least 5/8th VA appointments, and
 - (3) Certification that space will be provided at VA facility to support the proposed center.
- c. The facility R&D Committee must review and approve all applications before submission. If a Center is awarded, then an appropriate response from Human Subject, Animal Safety, and Bio Safety Subcommittee reviews and approval are required.
- d. Scientifically approved proposals will require administrative site visits in advance of making definitive funding determinations.
- e. The Center Director and Associate Director must be eligible to receive VA research support in accordance with VHA Handbook 1200.15 (eligibility must be established prior to submission of the proposal).
- f. Annual (non-competing) progress reports for the Center are reviewed administratively by RR&D to monitor performance against stated program plans. *NOTE: Unsatisfactory performance will result in probationary status or termination of funding.*

6. TIMELINE FOR PROPOSAL SUBMISSION, REVIEW, AND AWARD

- a. Letters of Intent: July 31, 2010;
- b. Proposals or applications are due in VHA Central Office (see Att. B): September 30, 2010;
- c. Review: November 2010;
- d. Administrative site visits: December 2010; and
- e. Funding Effective Date: Winter 2011.

7. FOLLOW UP RESPONSIBILITY: The Director, RR&D Service, is responsible for the content of this Notice. Questions may be addressed to Jay Freedman, PhD, Scientific Program Manger, at (202) 461-1699 or jay.freedman@va.gov.

8. **RESCISSION:** This VHA Notice expires December 31, 2010.

Robert A. Petzel, M.D.
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 6/25/2009

ATTACHMENT A

**INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT (LOI)
TO ESTABLISH OR FOR COMPETITIVE RENEWAL OF
REHABILITATION RESEARCH AND DEVELOPMENT (RR&D) CENTERS**

1. SCOPE

a. **The Letter of Intent (LOI) Review.** The LOI review serves to:

(1) Confirm that each proposal forwarded in response to this Notice is within the announced intent and scope of Rehabilitation Research and Development Service (RR&D) Centers; and

(2) Identify and resolve major problems such as Department of Veterans Affairs (VA) investigator eligibility and VA off-site research issues prior to allowing the submission of a full proposal.

b. **Due Date.** LOIs to submit proposals to establish or for competitive renewal of RR&D Centers are due on July 31, 2010. LOIs received after this date will not be reviewed. Proposals will not be accepted without an approved LOI.

c. **Review Process.** LOIs are reviewed for scientific merit, relevance to Veterans' needs, RR&D priority areas, and whether the proposed research advances the knowledge base of rehabilitation research. Written notification regarding results of the review is sent within 6 weeks through the facility Office of the Associate Chief of Staff (ACOS) for Research and Development (R&D). An investigator must have an approved LOI in order to submit a proposal to establish or for competitive renewal of a RR&D Center for review.

d. **Eligibility.** RR&D is an intramural research program. All applicants (i.e., the Principal Investigator (PI) and any Co-PI for VA research funds) must hold a minimum 5/8th VA salaried position. Individuals with less than a 5/8th VA appointment are encouraged to seek at least a 5/8th VA official appointment. Investigators wishing to join VA must indicate so in writing within the context of the LOI. Should an applicant's proposal be approved, funding is not forwarded until VA appointment is secured.

e. **Site.** VA RR&D Centers generally must be housed within VA health care facility. Space needs to be in clear juxtaposition to related clinical care. It needs to be evident to Veterans receiving care that research related to their needs is being carried out and that they have access to state-of-the-art care resulting from such research.

f. **Off-Site Research.** As an intramural program, it is VHA policy to ensure that all VA-funded research is performed within VA medical centers or VA-leased space, except when off-site facilities provide unique research opportunities. A Center investigator who applies for VA research support and who has performed or seeks permission to perform research outside of VA medical centers, VA-owned or VA-leased space, must request a waiver from RR&D to perform all or a portion of a VA-funded research off-site. The request for a waiver is to accompany the LOI and must be received no later than 60 days prior to the proposal submission due date (see VHA Handbook 1200.16).

2. FORMAT

a. **VA Form 10-1313-13, Cover Sheet.** VA Form 10-1313-13, Cover Sheet, must be submitted with a LOI. Check applicable categories in each box and type in all requested information. *NOTE: In Box #2, marked Program Area, state priority area and specify "Center."*

b. **Length.** The information contained in the LOI can be up to three pages of text, plus one page of cited references. An additional page describing the PI's experience in the proposed research area is allowed.

c. **Margins.** Use at least 1-inch margins on all four sides. Consecutively number pages in lower right corner.

d. **Font Style and Size.** Use either 12-Times New Roman or 11 Point-Arial. *NOTE: Any LOI using low quality or small print will be returned without review. Use bold type for all major section headings, and separate major sections with a double space.*

c. **Text Pages (maximum of three).** At the top of each page, type PI's name and Project Title and date. In the following order, state:

(1) **Purpose.** List the goals and specific objectives of the proposed program of research (use approximately 1/4 page).

(2) **Background** (use approximately 1/2 page).

(a) State the scientific rationale for the proposed research and its relationship to other major research findings.

(b) Explain how this research will advance knowledge in rehabilitation research.

(c) Describe the significance of the research and how it relates to RR&D priority areas. Indicate how this research directly benefits Veterans and how it contributes to the quality of services provided by VA.

(3) **Expected Outcomes or Products.** Describe the outcome in terms of expected time and resources needed to develop a Center program in this area (use approximately 1/4 page).

(4) **Proposed Areas of Study.** Outline the proposed areas of study (use approximately one page).

(a) Identify VA patient population, sample size, and rationale for inclusion or exclusion of population served; additional efforts must be exerted to include women and members of diverse ethnic and racial groups.

(b) Identify key issues that may have an impact on the success of the Center.

(c) Specify if proposed research is with animals and, if so, what is the time frame for clinical application.

(d) Indicate implications for technology transfer and potential for replication.

(5) **Participants.** Identify PI(s), co-investigators, and consultants; state their areas of expertise.

(6) **Resource and Budget.** RR&D Centers are funded for 5 years with up to \$1,000,000 a year.

(7) **Project History**

(a) Indicate if this Center is new, a continuation of an existing Center (years funded), or related to a previously disapproved Center submission.

(b) Indicate the Project number, title, and date of the previous related submission.

(8) **Research Site.** State the name of the facility where the majority of research (patients and laboratory work) will take place (Item 6 on VA Form 10-1313-13, Cover sheet).

3. SUBMITTING THE LOI. An electronic copy of the LOI is required.

(a) The LOI must be signed by either the ACOS for R&D, R&D Coordinator, or an appropriate designee. *NOTE: LOIs from R&D regionalized facilities will not be accepted without being processed through the appropriate research office.*

(b) The LOI must be sent as a single PDF file to rrdreviews@va.gov by July 31, 2010. Name the file as follows: principal investigator's last name_station number_CenterLOI (e.g., Jones_122_CenterLOI). Use the following text in the email "Subject:" line: [insert PI last name] Center LOI. *NOTE: LOIs received after July 31, 2010, will not be accepted.*

4. INQUIRIES AND ADDITIONAL INFORMATION. Inquiries should be directed to Jay Freedman, PhD, at (202) 461-1699 or jay.freedman@va.gov.

ATTACHMENT B

**INSTRUCTIONS FOR SUBMISSION OF APPLICATION
REHABILITATION RESEARCH AND DEVELOPMENT (RR&D) CENTERS**

1. GENERAL. Whether preparing a first-time or competing renewal application, the proposal must be well organized, clearly presented, and complete without presumption of reliance on previous proposal submissions or of assumed public common knowledge.

2. FORMS. Department of Veterans Affairs (VA) Forms 10-1313-1 through 8, Merit Review Application, are to be used for Center proposals. Forms are available through each VA facility's Office of Associate Chief of Staff (ACOS) for Research and Development (R&D), or equivalent.

3. CONTENT ORDER

a. **VA Form 10-1313-1, Merit Review Application.** Provide brief identifying information. Items which may require clarification are:

(1) Items 1, 2, and 4. Leave blank.

(2) Item 3. Review group should be identified as "Center."

(3) Items 5 and 6. For applications proposing consortia, identify lead site.

(4) Item 9. List the Center Director as Principal Investigator (PI), Associate Director as Co-Principal Investigator (Co-PI).

(5) Item 10. Center the title; it needs to be short and easily identify the program and its focus.

(6) Item 11. Amount requested should be for fiscal years.

b. **VA Form 10-1313-2, Summary Description of Program.** Provide a brief narrative scientific abstract not to exceed 500 words. List key words that best describe the program's scientific disciplines and research focus.

c. **Table of Contents**

d. **Approved Letter of Intent (LOI)**

e. **Narrative.** Should not exceed 40 pages (including figures and tables), with no more than 5 additional pages for references. This page limit does not include VA forms or appendixes. Components expected to be contained in the narrative and suggested page lengths include discussions of:

(1) Intended research directions and the proposed methods for implementing them (eight to ten pages).

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(a) How each group of related research will contribute sequentially or cumulatively to the resolution of practical rehabilitation problems.

(b) The focus in relation to health care needs of the Veteran population, VA medical center or Veterans Integrated Service Network mission, and the mission of VA's R&D.

(c) How current local programs and affiliations complement focus.

(d) A review of the current status of nation's research in this area.

(e) Expected outcomes of proposed research direction.

(2) Available resources (three to five pages).

(a) An identification of clinical activities at the hospital that would provide a base for research.

(b) Current Rehabilitation R&D Program and highlight successful investigations in this area.

(c) Available VA physical facilities and program equipment.

(d) Academic affiliation contributions in the areas of personnel, equipment and opportunities for learning.

(e) An identification of three to 5 lines of research and detail proposed scientific protocol, including state of research in the field, hypotheses, and proposed study methods (15 to 25 pages).

(3) The present or proposed Center organization and staffing plan showing lines of authority and communication and describing operational responsibility (three to five pages) follows:

(a) Explain how components will interface.

(b) Discuss planned interaction with university and other community affiliations, showing purpose and mutual benefit of interaction.

(c) Outline any planned formal mechanisms for information dissemination.

(d) Detail program evaluation and quality assurance mechanisms.

(e) Identify administrative controls.

(f) Justify and include a copy of all formal agreements with non-VA institutions in appendixes.

f. **VA Form 10-1313-3, Current Funds and First Year Request for Program, and VA Form 10-1313-4, Estimated Expenses of Program.** These forms are to be used to submit proposed 5-year budget.

g. **VA Forms 10-1313-5, Investigator's Biographic Sketch, and VA Form 10-1313-6, Investigator's Bibliography.** These forms are to be used to provide biographical sketches and a list of up to ten recent or significant publications for each of the Center's key VA and non-VA collaborating staff. Include up to five manuscripts reprints, which the PI determines best reflect work in proposed area; these may be included as appendixes.

h. **VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support and VA Form 10-1313-8, Summary Statement Abstract and Budget Summary.** These forms are to be used to list each investigator's current and pending total VA and non-VA research support.

i. **Appendixes.** Appendixes are to be identified and labeled.

(1) A letter of commitment from the VA medical facility Director and a letter of approval from the R&D Committee are required for review.

(2) Include letters of commitment and memoranda of understanding with collaborating institutions.

NOTE: Letters of support from elected officials are not to be solicited or included.

j. **Authorization To Share Materials For Review.** It is expected that VA and non-VA reviewers will review proposals. Append the following statement, signed by the PI and Co-PI: "VA is authorized to share copies of all materials included in this application, for the purpose of scientific merit review."

4. SUBMISSION. Applications must be submitted as a single PDF file on a CD. Label the CD with the date, principal investigator's name and the title of the proposed project. Applications must be mailed to:

Rehabilitation Research and Development Service (122P)
Office of Research and Development
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
(202) 461-1740
Attn: CENTER

NOTE: Proposals received after September 30, 2010, will not be reviewed. Proposals will not be accepted without an approved LOI. LOIs received after July 31, 2010, will not be accepted.