

August 19, 2008

**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. *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 five VA RR&D Centers expires in 2009. Each of these Centers must submit an application for competitive renewal. Applications from new sites 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. For criteria, see paragraph 4 (General Requirements) of this notice.

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

(c) Mentor and support young 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, the VA medical facility, and the supporting community institutions (e.g., schools of medicine, allied health sciences and engineering as applicable to research focus).

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

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(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); Bone & Joint (Palo Alto); Amputation, Prosthetics and Limb Loss Prevention (Seattle); Rehabilitative Auditory Research (Portland); Functional Electrical Stimulation (Cleveland); Innovative Visual Rehabilitation (Boston); Task-Oriented Exercise and Robotics in Neurological Disease (Baltimore); and Medical Complications of Spinal Cord Injury (SCI) (Bronx).

(3) Centers up for competitive renewal are focused on Brain Injury Rehabilitation (Gainesville); Wheelchair and Related Technology (Pittsburgh); Restoration of SCI and Multiple Sclerosis (West Haven); Restorative and Regenerative Medicine (Providence); and Advanced Platform Technology (Cleveland).

(4) RR&D funds five Research Enhancement Award Programs (REAPs) in Auditory and Vestibular Dysfunction (Mountain Home); Tissue Engineering (Boston); Technology for “At-Risk” Patients (Tampa); Promotion of Functional Recovery Post SCI (Hines); and Rehabilitation Outcomes—Stroke (Gainesville).

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) **Traumatic Brain Injury (TBI)**. (Basic and clinical research, including mild TBI). Developing comprehensive test batteries that diagnose mild TBI is a high priority. Also encouraged is research on interventions that enhance cognitive, social and emotional functioning of veterans with TBI. Examples of programmatic areas include:

(a) Diagnosis of mild TBI – imaging, appropriate cognitive evaluation measures.

(b) Development of animal models predictive of human TBI – closed head injuries (i.e., diffuse axonal injury), etc., for all degrees of TBI.

(c) Novel forms of treatment – regenerative medicine approaches, psycho-social therapy, etc., for all degrees of TBI.

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

(a) Neural repair – 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.).

(3) **Musculoskeletal Repair.** Creation of bone and cartilage ex vivo 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).

(4) **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.

3. FUNDING: Any VA medical facility (or consortium of VA medical facilities) 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 \$950,000 annually, with required competitive renewal on a 5-year cycle.

a. Each Center will 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

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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. Research plans need to include 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 Centers.

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 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 APPLICANTS:

a. All Center funding awards are contingent on availability of funds.

b. All applicants must submit a Letter of Intent (LOI) to Apply by September 30, 2008 (see Att. A). LOIs must be directed through the facility ACOS 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 the VA facility to support the proposed center.

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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 BioSafety Subcommittee reviews and approval are required.

d. Applicant sites may be a single VA medical facility or a consortium of collaborating VA medical facilities. Consortium applicants must identify a lead site with a well-established academic partnership. Organizational relationships and responsibilities of consortia are to be clearly delineated.

e. Scientifically approved proposals will require administrative site visits in advance of making definitive funding determinations.

f. 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).

g. 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: September 30, 2008;
- b. Proposals or applications are due in VHA Central Office (see Att. B): November 24, 2008;
- c. Review: February 2009;
- d. Administrative site visits: March 2009; and
- e. Funding Effective Date: Spring 2009.

7. FOLLOW UP RESPONSIBILITY: The Director, Rehabilitation Research and Development Service, is responsible for the content of this Notice. Questions may be addressed to 202-461-1755.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

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ATTACHMENT A

**INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT (LOI)
TO ESTABLISH 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 RR&D Centers are due on September 30, 2008. LOIs received after this date will not be reviewed. Proposals will not be accepted without an approved LOI.

c. **Review Process.** LOI is 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 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 the VA appointment is secured.

e. **Site.** VA RR&D Centers generally must be housed within the 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

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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, 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. 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.

e. Use bold type for all major section headings, and separate major sections with a double space.

f. **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.

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

(5) **Participants.** Identify PI, Co-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 \$950,000 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. Both a hard copy and an electronic copy (on a CD) of the LOI are 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 and electronic copy (on a CD) must be sent to the following address by September 30, 2008. *NOTE: Prior approved e-mail or facsimile copies will be accepted, but the original must still be mailed.*

Rehabilitation Research and Development Service (122P)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
202-461-1755
Attn: CENTER LOI

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4. INQUIRIES AND ADDITIONAL INFORMATION. Inquiries should be directed to: 202-461-1755.

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 forty pages (including figures and tables), with no more than five 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 (VISN) 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 five lines of research and detail proposed scientific protocol, including state of research in the field, hypotheses, and proposed study methods (fifteen to twenty-five 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) Include letters of commitment and memoranda of understanding with collaborating institutions as appendixes. A letter of commitment from VA medical facility Director and a letter of approval from R&D Committee are required for review.

(2) For consortium applications, a letter from each participating facility's Director and R&D Committee is to be included. *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

a. Submit the original application plus fifteen copies of the proposal to:

Rehabilitation Research and Development Service (122P)
Office of Research and Development
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
202-461-1755
Attn: CENTER

b. Copies are to be duplicated back to back. With the exception of special forms, standard 8 1/2" x 11" white paper is to be used.

5. ELECTRONIC SUBMISSION. In addition to the requirements for a hard copy submission, an electronic submission of the proposal is required. The disk need to be a 3 1/2 inch floppy disk

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or a compact disk. The disk must be labeled with the date, principal investigator's name and the title of the proposed project. The disk must be included with the hard copy proposal submission.

***NOTE:** Proposals received after November 24, 2008, will not be reviewed. Proposals will not be accepted without an approved LOI. LOIs received after September 30, 2008, will not be accepted.*