

October 2007

**DEPARTMENT OF VETERANS AFFAIRS**  
**Veterans Health Administration**  
**Washington DC 20420**  
**OFFICE OF RESEARCH AND DEVELOPMENT**  
**Request for Proposals**  
**NURSING RESEARCH INITIATIVE**

**1. Purpose.**

The Department of Veterans Affairs (VA) Office of Research and Development (ORD) is pleased to support the Nursing Research Initiative (NRI).

Although nurses have always been an integral part of VA research teams, nurses remain underrepresented as principal investigators (PIs) in VHA. The NRI solicits proposals from VA nurse investigators who are in the early stages of their research careers for a mentored research project, leading to independence in the PI role. All ORD Services (Biomedical Laboratory Research and Development, Clinical Science Research and Development, Rehabilitation Research and Development, and Health Services Research and Development) will accept investigator-initiated proposals as part of the NRI; investigators are encouraged to consult the participating VA Research and Development programs and their Web sites (see <http://www.research.va.gov/>).

Topical areas of interest described in this solicitation are mission-oriented, of high priority to the care of veterans, and were determined by the Office of Research and Development with input from the Office of Nursing Services.

**2. Research Foci.**

Within an interdisciplinary context, VA nursing research focuses on identifying, testing and/or implementing nursing interventions that enhance health and prevent disease in veterans across the care continuum. Across VHA, these nursing interventions are patient-centered, culturally congruent, cost-effective and outcome-driven.

Proposals submitted under this initiative should be patient-centered and designed to maximize the eventual application of findings and conclusions to the care of veterans. Interdisciplinary research, multi-site research projects, and pilot studies are encouraged. Types of research projects and pilots, high priority issues, and examples of possible topics are provided below.

Special populations of interest are veterans with:

- Deployment-related Health Disorders
- Post Traumatic Stress Disorder (PTSD)
- Substance Use Disorders
- Mental Health Disorders
- Stroke
- Chronic Illnesses
- HIV
- Spinal Cord Injuries

- Traumatic Brain Injuries
- Amputations
- Aging and Age-related Changes
- Underserved, high risk populations, e.g. women, homeless
- Sensory Disorders & Loss (esp. Blind Rehabilitation)

Within these special populations, the VA nursing research agenda includes:

**a. Maximizing the physical, mental, and social functioning of veterans and improving their quality of life.**

Examples of focus areas include, but are not limited to: community integration; palliative care; symptom management, e.g. pain, dyspnea, insomnia, fatigue, confusion, disruptive behaviors with dementia; rehabilitation and recovery; health promotion; patient education; self-management; or, genomics.

**b. Improving patient safety and health outcomes through nursing practice.**

Examples of focus areas include, but are not limited to: nursing-sensitive quality indicators; recruitment and retention; information systems or other technologies; work environment; or, emergency preparedness.

**c. Evaluating patient care delivery models and nursing systems of care**

Examples of focus areas include, but are not limited to: access to care; health disparities; care transitions; telehealth; care coordination; nursing roles; leadership and professional development; or, staffing models.

**d. Evaluating models for translation/implementation of evidence-based practice.**

Examples of focus areas include, but are not limited to: guidelines and protocols; facilitators and barriers; or, information systems.

**3. Pilot studies.**

Good research requires careful planning; often, a pilot study is part of this plan. The term “pilot study” is defined for this solicitation as a small, preparatory investigation designed not to test research hypotheses, but rather to test protocols, data collection instruments, sample recruitment strategies, and gather other information prior to a larger study, in order to improve the latter’s quality and efficiency.

Characteristics of a pilot study include the following:

- Designed to answer the question “Is a full scale trial/experiment worth pursuing?”;
- Must provide details on how the decision to pursue further study will be made;

- Should justify the number of participants in the pilot;
- Gives evidence for designation as a “pilot study” by addressing logistical issues, including, but not limited to:
  - Simultaneous testing, standardization, and modification of study protocols;
  - Checking reliability and validity of results;
  - Identifying effectiveness of human subjects protections and data security measures
  - Establishing estimates of variances, correlation, and/or differences for use in power calculations that will guide sample size for the full study;
  - Evaluating cost or timeliness of the full study.

#### **4. Eligibility.**

**NRI:** Junior nurse researchers with the earned doctorate who hold a VA appointment of at least 5/8 time are eligible to apply. A junior scientist is defined for the purpose of this solicitation as one who has not been a PI on a VA merit review award, R01 research grant, or similar substantial peer-reviewed grant or award. Investigators who have completed all course requirements for the doctorate may request a special exception of eligibility requirements; please contact the NRI Scientific Program Manager for guidance.

**NRI pilot option:** Eligibility requirements for junior nurse researchers are the same for NRI pilot study proposals as they are for full NRI proposals. Nurse researchers who have a history of previous, substantial independent funding may apply for the NRI pilot option to support a pilot study in a substantially and significantly different area of inquiry. Although a mentor is not required in this case, the study team should include appropriate expertise in the new area.

VA requires that a single PI be designated as the point of contact and recipient of funds. If additional PI's are part of the research team, a Leadership Plan must be submitted (see Instructions for designating multiple PI's in the VA Application Guide). All PI's of a proposed research study must meet VA eligibility criteria before funding is initiated (see VHA Handbook 1200.15).

Any questions about eligibility may be referred to the NRI Scientific Program Manager.

#### **5. Mentor Requirements.**

PIs must be guided by a Mentor with an earned doctorate in nursing, medicine or another health care or health services related discipline.

- a. The Mentor must be on the staff of the VA medical center and/or on the faculty of the affiliated university. It is essential that the Mentor have research experience, a significant history of independent research funding as a PI, publications in peer-reviewed journals, and be willing to commit, in writing, to guiding the nurse investigator's development for the duration of the award.
- b. If the Mentor is not employed by VA, the PI needs an additional Mentor who has a paid VA appointment and experience with VA research funding, policies, and procedures.
- c. The Mentor's role is to guide the nurse PI with respect to
  - i. Developing a successfully funded proposal
  - ii. Assisting with ongoing challenges inherent in the conduct of research
  - iii. Ensuring the successful completion and dissemination of the research
  - iv. Developing the mentee as a fully independent, funded VA nurse investigator
  - v. Any other requirements specific to the VA system and its research program.

## **6. Budget.**

Full NRI proposals may request up to four years of funding. Projects that exceed \$300,000 in any one year or a total of \$900,000 will not be accepted without a previous, written waiver approved by the portfolio manager and the Director, HSR&D Service (see Appendix for submission requirements). NRI pilot grants may be one or two years with a total maximum budget of \$50,000. The research design is expected to be efficient and appropriate with all budget categories well justified.

All VA awards are subject to the terms and conditions, cost principles, and other considerations described in the VHA Handbook for each Research and Development Service. In preparing project budgets, applicants are reminded to adhere to ORD guidelines regarding allowable use of research funds and restrictions on the use of research funds for equipment, software development, and clinical salaries.

## **8. Review and Selection Process**

NRI reviews are administered by the Health Services Research and Development Service (HSR&D) on behalf of the Office of Research and Development. HSR&D

employs a system of rigorous scientific review to ensure the scientific and technical merit of individual research projects and the integrity of its programs. Each application is evaluated by a multidisciplinary group of experts appropriate to the content, design, and methods proposed. The recommendations of the review panel, the priority scores for approved projects, and reviewers' specific comments guide the decisions of VA research administrators regarding which projects to fund.

As part of the initial merit review, all applications will:

- Undergo a selection process in which those applications deemed to have the highest merit will be discussed and assigned a priority score. Generally if the primary, secondary and tertiary review scores are 30 or greater, the proposal will not be reviewed by the full panel.
- Receive a written critique.
- Receive a second level of review by the Chief Research and Development Officer and his/her designees.

### **Review Criteria**

Prior to each review meeting, each reviewer independently prepares a written critique for each proposal to which the reviewer is assigned as primary, secondary, or tertiary reviewer. These critiques address the general review criteria listed below as well as NRI-specific criteria. These critiques (with reviewer identifiers removed) are sent to the applicant, along with notification of the review outcome and a summary of reviewer comments written by HSR&D staff.

**(1) Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study.** NRI allows a total of three proposal submissions: the original submission and two resubmissions. If the proposal is a re-submission, the applicant will have received detailed comments on the previous proposal. Any subsequent proposal is expected to highlight changes made in response to such feedback or to defend the earlier plan.

**(2) Scientific Significance and Originality.** Reviewers assess the scientific significance, theoretical foundation, and originality of the stated goals, objectives, and specific research questions and/or hypotheses. Reviewers consider what is proposed in relation to information and/or pilot data that the investigator provides regarding prior work (by self and others), as well as information from other sources that relates to the scientific significance and likely contribution of the proposed work.

(3) **Methods.** Reviewers assess the appropriateness of the research design and specific methods proposed for conducting the research. The following list contains some of the elements that reviewers consider, as applicable to the particular project, and in accordance with their particular expertise:

- a) Study design (e.g., retrospective vs. prospective, experimental, quasi-experimental, etc.).
- b) Approach (quantitative, qualitative, mixed methods).
- c) Theoretical model and conceptualization of key components.
- d) Population and sample, sampling plan, and/or comparison groups.
- e) Statistical power.
- f) Key variables and their measurement.
- g) Data analysis plan.
- h) Data collection issues, including respondent burden.
- i) Definition and feasibility of any intervention.
- j) Recognition and appreciation of methodological issues that may arise (e.g., sources of bias, confounding variables, recruitment and retention problems, crossovers, Hawthorne effect, psychometric issues, etc.).

(4) **Adequacy of Data.** Reviewers address the adequacy of data for the proposed study. For primary data, reviewers consider the adequacy of the proposed data collection instrument(s) or the plan for developing and testing new instruments, as well as the feasibility and appropriateness of data collection procedures. Regarding secondary data, issues include appropriateness, availability, accuracy, and completeness. Applicants proposing to use existing databases need to provide evidence of familiarity with these, and an awareness of the idiosyncrasies and limitations of the data. Reliability, validity, and adequacy of quality control procedures are important issues, for all types of data.

(5) **Project Organization and Management.** Reviewers consider the:

- a) Distribution of roles and responsibilities across project staff,
- b) Justification of full-time equivalent (FTE) allocations for each project year,

- c) Plans for coordinating multiple participants, tasks, or sites,
- d) Reasonableness of the timeline showing important benchmarks and products, and
- e) General feasibility of the management plan.

(6) **Investigator Qualifications.** The primary reviewer assesses the expertise of each investigator and each major consultant, including their professional credentials, institutional position, role in the project, expertise (especially as reflected in publications), and relevant experience. All reviewers assess the combined strength of the team in relation to the objectives of the project and determine whether it encompasses all needed skills and competencies. If the proposal is an approved dissertation proposal, the application should include a letter from the Chair of the Dissertation Committee or from the Dean or Doctoral Program Director of the school.

(7) **Role and fit of the Mentor:** The Project Management Plan of the NRI proposal narrative should include a detailed explanation of the specific role and or purpose of the Mentor(s), as well as the intended relationship with the PI (mentee). Specifically address the following:

1. The availability of the mentor
2. The frequency of meetings with the PI (mentee) and research team
3. The research, methodological, and/or substantive topical knowledge brought to this project by the Mentor.

(8) **Human Subjects.** Reviewers consider whether the study places human subjects at risk of physical or psychological harm and the adequacy of provisions to minimize risk, protect participants' privacy and the confidentiality of their records or responses, ensure informed consent, and minimize respondent burden. **NOTE:** *In considering human subjects issues, reviewers may question the decision of an IRB and may impose a stricter standard (see VHA Handbook 1200.5).*

(9) **Inclusion of Women and Minorities.** Review of each proposal's compliance with VA policy regarding the inclusion of minorities and women in the study population is the responsibility of the R&D Committee at each VA facility and VA human studies subcommittees. The HSR&D reviewers are also responsible for considering the adequacy of representation, and they do not need to concur with a decision by the R&D Committee.

(10) **Facilities and Resources.** Reviewers evaluate the adequacy of facilities and

resources to carry out the proposed study. The proposal must include evidence of support from the applicant's VA facility, support from any additional study site(s), and documentation of any agreements with consultants, or commitment of non-VA resources to the study.

(11) **Budget.** Project budgets need to be appropriate to the proposed work, sufficiently detailed, and well-justified. Reviewers assess the reasonableness of the project timeline and costs allocated to major budget categories. Personnel costs, and whether projects are staffed appropriately, are key considerations. Items that appear to be outliers, line items that change markedly from one year to another, identical total annual requests, and large amounts for equipment, travel, or subcontracts are scrutinized. **NOTE:** *Prior to any funding decisions, all projects under consideration also undergo administrative review of budgets by HSR&D research administrators. This review ensures that VA research funds are not used for any inappropriate purposes, to include patient care, travel to conferences, indirect/overhead expenses, salaries of Title 38 employees, and development projects that lack a strong evaluation component.*

(12) **Importance of the Problem Addressed.** Reviewers assess the importance of the problem or question that the proposed research seeks to address, in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public. The research should be designed to maximize the eventual application of findings and conclusions, and must be veteran-centric. **NOTE:** *Importance of the problem is assessed independently of the investigator's approach.*

(13) **Contribution to VHA.** Reviewers consider the expected contribution of findings of the proposed research to improving the quality, effectiveness or efficiency of health care in VA, or its potential to improve the health status of veterans. This includes consideration of the adequacy of the investigator's plans for translating findings into practice.

## 7. Funding Decision

- a. Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:
  - Scientific merit of the proposed project as determined by peer review.
  - Availability of funds.
  - Relevance of program priorities.
- b. The merit review score, which is based on significance, approach, innovation, environment, and mentoring will serve as the main determinant for identifying proposals that will be considered for funding. Projects scoring outside the



funding line may be funded at the discretion of the Chief Research and Development Officer

- Ultimately, the Chief Research and Development Officer will make the final selection of projects to be funded.

## 8. Post-review Notification of Review Results

(a) **Preliminary Notification.** The HSR&D review staff contacts the ACOS for R&D at each VA facility that submitted one or more proposal(s) to communicate the review committee's recommendation on each proposal from that facility.

### (b) Written Notification

- Written notification of the results of merit review generally are sent to the facility Director within 6 weeks after each review meeting. The notification letter includes the review committee's recommendation (i.e., approval or disapproval) and priority score. **NOTE:** *Priority scores should not be construed as funding decisions.* With the notification letter, the facility Director, ACOS for R&D, and the PI will receive a summary statement that outlines the main points of the reviewers' discussion and any administrative concerns. The PI and ACOS for R&D also receive a de-identified copy of all written critiques.
- Written notification regarding project funding generally are sent to the facility Director after each review meeting. Copies are sent to the PI, ACOS for R&D, VISN Director, and the CoE, REAP, TREP, GRECC, or MIRECC Director, if applicable.

(c) **Questions about Reviews and/or Conditional Approvals.** The NRI Scientific Program Manager is available to discuss questions about the individual critiques, the summary statement, or a conditional approval.

(d) The NRI uses the “**Just-in-Time**” information concept including IRB, DSMB, and OMB approvals and VA data safety certifications.

## 9. Proposal Submission.

(1) Intent to Submit. HSR&D requires notification of an investigator's intent to submit a proposal for merit review. The responsibility for a complete, properly formatted, and timely submission of HSR&D's Intent to Submit and a proposal abstract lies with the R&D Office at the originating VA facility. The Intent to Submit and Abstract must be submitted by the designated deadline in order for a proposal to be reviewed.

**Proposals that have not complied with this requirement will not be accepted for review.**

(2) Project Submission. A proposal must be submitted by the PI through the Associate Chief of Staff (ACOS) for R&D and medical center Director. The most current information regarding submission procedures can be found at HSR&D's website: <http://www.hsr.d.research.va.gov/> or in communications from CO to the ACOS/R&D's office.

(3) Format and Deadlines. Current information as to the correct format and current submission deadlines can be found at HSR&D's website: <http://www.hsr.d.research.va.gov>.

## **10. Annual Reporting Requirements.**

NRI requires three types of regular reports for every research and pilot project: annual progress report (abstract); copies of all publications based on the funded work; and a final report. Approval of future funding is contingent on the investigator's adherence to these critical requirements. For additional information and details regarding investigator reporting requirements, please consult your local R&D office.

## **11. Contact Information.**

Initial questions should be directed to the PI's Center of Excellence or VAMC Office of R&D. We encourage subsequent scientific/programmatic inquiries concerning the NRI and welcome the opportunity to answer questions from potential applicants. Questions may be directed to Kate Bent, RN, PhD, CNS, Scientific Program Manager, Nursing Research Initiative (202) 254-0248.

Joel Kupersmith, MD  
Chief Research and Development Officer

## **APPENDIX A**

### **NRI AMENDMENT TO “HSR&D INVESTIGATOR-INITIATED RESEARCH INSTRUCTIONS FOR APPLICANTS”**

1. All investigators submitting a proposal under the Nursing Research Initiative (NRI) program must follow the Health Services Research and Development (HSR&D) Website instructions for Intent to Submit instructions and proposal submission also found in Handbook 1204.1.
2. List the Mentor(s) under Personnel as co-investigator(s) for VA employee or under All Other as a consultant if non-VA.
3. Budgets should reflect the relevant Service’s funding policies.
4. Include in the Project Management Plan of the Proposal Narrative a detailed explanation of the specific role and or purpose of the Mentor(s), as well as the intended relationship with the PI (mentee). Specifically address the following:
  1. The availability of the Mentor(s)
  2. The frequency of meetings with the PI (mentee) and research team
  3. The research, methodological, and/or substantive topical knowledge brought to this project by the Mentor