DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Office of Research and Development
Health Services Research and Development Service
Washington DC 20420

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Program Announcement

SOLICITATION OF APPLICATIONS FOR
HEALTH SERVICES RESEARCH AND DEVELOPMENT
PILOT PROJECTS

1. **Purpose.** The Veterans Health Administration (VHA) Health Services Research and Development Service (HSR&D) invites applications for Pilot Projects. Funds provided under this initiative are for preliminary investigation prior to full-scale proposals to strengthen the evidence for a larger HSR&D research study or assure the research objectives are feasible. This solicitation is open to investigators who satisfy the eligibility requirements.

2. **Background.** HSR&D leadership and the Scientific Merit Review Board (SMRB) identified the need for pilot data to support principal investigators in submitting quality proposals for review. Completing pilot projects prior to submission of full-scale proposals is expected to enhance the development of the larger proposal and assist investigators with refining study research objectives, designs and methods to better address HSR&D priority areas or specific research topics. HSR&D solicitations and contact information are available at: http://www.hsrd.research.va.gov/funding/solicitations.cfm.

3. **Goals.** Funded HSR&D Pilot Program projects are expected to:

   i. Support development of preliminary studies to strengthen the likelihood of success for full-scale proposals;

   ii. Provide opportunities for investigators to explore novel approaches to research design and methods through small-scale research initiatives;

   iii. Allow funding for the study of such areas as refining of surveys or questionnaires; documenting rates of subject participation and drop-out; establishing the interest level of particular groups of potential subjects in proposed interventions; validating data sets constructed from multiple sources; confirming a hypothesis with limited data; conducting a "mini-version" of a potential multi-center randomized trial at a single site; or test the feasibility of new protocol designs, data collection instruments, sample recruitment strategies or gather other information needed to propose a larger or more complex study.

4. **Eligibility.** Proposed principal investigators must hold at least a 5/8ths VA appointment at the time of funding, fulfilled their obligations to complete a final report for any previous HSR&D funded projects and have followed all requirements for reporting publications. No requests for waivers of eligibility will be considered. Pilot projects may only have one principal investigator.

5. **Application Requirements.**

   a. All intended pilot projects must be submitted through the ART website ITS system (http://art.puget-sound.med.va.gov/) for review consideration according to HSR&D merit review submission instructions(Detailed Instructions for Preparing Scientific Merit Review Applications), and via www.Grants.gov through the ACOS/R&D Office. No exceptions will be permitted.

   b. The Principal Investigator is responsible for all aspects of pilot projects including responsibility for compliance with applicable VA requirements for human subject research, information security, and privacy.

   c. Principal Investigator must:

      i. Have at least a 5/8ths VA appointment and be eligible to conduct research in VA;
      ii. Not submit more than one pilot project per review cycle;
      iii. Communicate with the Associate Chief of Staff for Research and Development (ACOS/R&D) and obtain proposal endorsement (i.e., signature on submission);
      iv. Collaborate with co-located HSR&D or QUERI research groups.

   d. Applications should include:

      i. Table of Contents (not included in page limit);
      ii. Narrative research plan (not to exceed 10 pages limit) describing:
         a. The objectives of the proposed work and how it will contribute to the quality, design or conduct of a larger proposal;
         b. The next steps in planned research (and ultimate anticipated contributions);
         c. The expertise of key project personnel and how the project team will complete the work in a timely manner with high quality data;
         d. The timeline for proposed activity (no more than one year) displayed in a GANTT chart;
      iii. References (not included in the total page limit);
      iv. Endorsement from the Medical Center Director and ACOS/R&D (not included in the total page limit).

6. **Expected Pilot Budget.** Total funding cannot exceed $100,000. In planning project budgets, applicants are reminded to adhere to HSR&D guidelines regarding

allowable use of research funds for specific items and restrictions on the use of research funds for IT developmental initiatives (see VHA Handbook 1204.1, Paragraph 7, HSR&D Funding for "Development" [Scientific Research and Development Projects]). Budget pages are not included in the total page limit.

7. **Reporting Requirements.** Pilot projects require submission of a **Final Report** (that includes a final abstract) through the ART website (http://art.puget-sound.med.va.gov/) 90 days after the project end date. PIs should refer to HSR&D guidelines for report submission instructions for details (Final Report Instructions). The final abstract will be used on the HSR&D website once the project is complete.

8. **Anticipated Awards and Funding Period.** HSR&D expects to approve proposals that receive fundable scores based upon scientific merit, VA priorities, programmatic needs, and the potential for making a substantial contribution to HSR&D and VHA. Approved pilot projects will be funded for up to **one** year, contingent on available funds. Before funding may begin, customary Just-in-Time (JIT) requirements apply including IRB, OMB, Clinical Trial Registration and/or DSMB tracking. Oversight needs should be clearly identified in the proposal.

9. **Evaluation Criteria.** Applications will be evaluated on the basis of the following criteria.

    a. **Administrative Review Criteria.** Pilot applications are expected to meet the following minimum administrative review criteria to be considered for scientific merit review:

        i.   Eligibility requirements (section 4 above);
        ii. Application endorsement by Medical Center Director and ACOS/R&D; and
        iii. Only **one** PI and a budget total up to **$100,000** for the one year project.

    b. **Scientific Review Criteria.** Pilot application evaluations will include:

        I.   The scientific quality and potential outcome of the pilot study in itself to strengthen the evidence for a larger project or assure its feasibility; and
        II. The importance of the anticipated larger project to VHA and VHA research, based on the rationale presented by the investigators; and
        III. The perceived value of the pilot project relative to the cost.

    c. **Scoring Ranges.** Reviewers will be instructed to provide one score that incorporates their assessment according to the following factors:

        i.   **Significance** – Project objectives are important to VHA and VHA research and address important scientific question/area; project shows potential to expand knowledge including negative or unanticipated findings.
        ii. **Approach** Methods are appropriate to the stated objectives; use of appropriate research design/methods for addressing research questions.

Analyses of the findings or data may vary according to scope and complexity of the research aims; however, the research plan is not expected to consider every possible element of research design or methods that might be anticipated in a full-scale project.

   iii. **Innovation** – Project has perceived value based on innovation; will provide foundation to address new concepts and/or gaps in the research area to facilitate a larger study.

   iv. **Organization** and **Environment** – Project management and timeline are appropriate to achieve research aims and objectives by conclusion of funding; resources (e.g., equipment, staff) to ensure completion of project; IRB/IUCAC/Biosafety committee oversight sufficient.

   v. **Qualifications** - Principal investigator and research team have appropriate knowledge/background for project.

Scientific Merit Parameters

Using the above factors, the scientific merit of a proposal should be assigned a score corresponding to the following:

1.0 – 1.9 Excellent	Proposed research will contribute to addressing an important research question or scientific area with an insufficient knowledge base. Research goals, aims and objectives are stated clearly and research design/methodology is well-matched to the scope of the project. Research has high potential for innovation. Potential findings will be highly relevant to future studies that could advance the health and healthcare of veterans. Resources listed suggest a very high probability of the project's completion.
2.0-2.9 Good	Proposed research addresses important scientific area. Research goals, aims and objectives are stated clearly and the research design/methodology is generally appropriate to the scope of the project. Potential findings will have some relevance to future studies that could advance the health and healthcare of veterans. Resources listed suggest a high probability of the project's completion.
3.0-3.9 Fair	Proposed research addresses a valid area of investigation. Research goals, aims and objectives are stated clearly, but research design/methodology contain key flaws that should be corrected within the scope of the project. Potential findings may have some relevance to future studies that could advance the health and healthcare of veterans. Resources listed suggest the project could be completed.
4.0-5.0 Poor	Research goals, aims and objectives not clear and/or research design/methods contain significant flaws. It is doubtful that potential findings would be relevant to future research, or that larger studies would advance the health and healthcare of veterans. It is unclear whether the resources listed are sufficient to ensure project completion.

d. **Funding Decisions.** Funding decisions will be made by the Director, HSR&D, based upon the applicant's scientific merit score, VA priorities, programmatic needs, potential to lead to a larger research initiative and the potential for making

a substantial contribution to HSR&D and VHA. Funding decisions also will be contingent on availability of funds.

e. **Impact on HSR&D Research Centers.** Approved pilot project funding will be considered toward HSR&D Research Centers (Centers of Excellence [CoE] and Research Enhancement Award Programs [REAP]) eligibility according to HSR&D criteria (http://www.research.va.gov/funding/solicitations/docs/2009-CoE-HSRD.pdf).

10. **Submission Guidelines**. Applications that are not compliant with the eligibility requirements or submission guidelines will not be reviewed.

a. **Intent to Submit.** Applications will be accepted only from Principal Investigators who submit their pilot information in the ART website Intent to Submit system (http://art.puget-sound.med.va.gov/) according to HSR&D guidelines and submission timelines.

b. **Proposal Submission.** Only applications from PIs who submitted their Intent to Submit information will be accepted for review. No exceptions.

c. **Administrative Checklist**. Attachment A contains the checklist used by HSR&D to verify that the application is complete. Applicants and ACOS/R&D offices are advised to review the application and complete the checklist to ensure that the requested information is provided.

11.   **Inquiries**. Questions may be directed to Noelle Newman at (202) 461-1524 or Noelle.Newman@va.gov. To inquire about eligibility, contact Robert Small, BS (202) 461-1515 or robert.small@va.gov.

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