OVERVIEW OF SUPPORT FOR SCIENTIFIC RESEARCH AND DEVELOPMENT PROJECTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides procedures on support for scientific research and development projects.

2. SUMMARY OF MAJOR CHANGES: The principal changes in this document clarify and incorporate additional information on funding programs within Health Services Research and Development Service (HSR&D). Specific new information includes:

a. Paragraph 3, which provides the common procedures regarding investigator requirements, application procedures and review policies for HSR&D support of scientific research and development projects.

b. Paragraph 4, which includes general requirements and guidelines for Letters of Intent and Concept Papers for submission to HSR&D.

c. Paragraph 5, which provides general guidance and instructions regarding submission of proposals for support through the HSR&D.

d. Paragraph 6, which provides guidance on the merit review process as implemented by HSR&D.

3. RELATED DIRECTIVES: VHA Handbook 1200.5, VHA Handbook 1200.9, VHA Handbook 1200.18, and VHA Directive 1204.

4. RESPONSIBLE OFFICE: The Health Services Research and Development Service (124) is responsible for the contents of this VHA Handbook.

5. RESCISSION: This VHA Handbook rescinds VA Manual M-3, Part III, Chapter 1 and Chapter 3, dated November 12, 1985.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working date of May 2007.

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Under Secretary for Health

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CONTENTS

OVERVIEW OF SUPPORT FOR SCIENTIFIC RESEARCH AND DEVELOPMENT PROJECTS

PARAGRAPH PAGE

1. Purpose 1

2. Project Types 1

a. IIR (Investigator-Initiated Research) 1
b. SDR (Service-Directed Research) 1
c. NRI (Nursing Research Initiative) 2

3. Application Requirements 2

a. Eligibility 2
b. LOI (Letter of Intent) 2
c. Full Proposal 2

4. LOIs and Concept Papers 3

a. Scope 3
b. Rationale 3
c. General Requirements 3
d. Review Schedule 3
e. Review Results and Next Steps 4
f. Inquiries and Additional Information 4

5. Project Proposals 4

a. Requirements for Principal Investigators (PIs) 4
b. Required Approvals 5
c. General Instructions 5

6. Merit Review 6

a. Scope 6
b. Implementation 7
c. General Review Criteria 8
d. Reviewers Recommendations and Priority Scores 10
e. Post- review Notification of Review Results 10
f. Appeals 11

PARAGRAPH **PAGE**

7. HSR&D Funding For "Development" 12

a. Scope 12
b. Appropriate HSR&D IIR Support 13
c. Non-appropriate HSR&D IIR Support 13

APPENDICES

A Letter of Intent (LOI) Guidelines A-1

B Instructions for Preparing Research Proposals B-1

C Sample Format for Health Services Research and Development Application Checklist C-1

D Health Services Research and Development Scoring Guideline D-1

OVERVIEW OF SUPPORT FOR SCIENTIFIC RESEARCH AND DEVELOPMENT PROJECTS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook presents the common policies and procedures regarding investigator requirements, application procedures, and review policies. ***NOTE:*** *Exceptions and any requirements that are unique to each type of project are specified in the appendices.*

2. PROJECT TYPES

Project support from the Health Services Research and Development Service (HSR&D) is based on scientific merit review and program relevance. The same basic principles apply to all types of projects that HSR&D considers for funding: Investigator-initiated Research (IIR), Service-directed Research (SDR), and Nursing Research Initiative (NRI) Projects. HSR&D project support is available through three funding mechanisms, described as follows:

a. **IIR**

(1) The IIR program enables eligible Department of Veterans Affairs (VA) clinicians and social scientists to pursue their personal intellectual goals while advancing HSR&D research priorities and contributing to the quality, effectiveness, and efficiency of VA health care. The IIR program spans the traditional areas of health services research (cost, quality, and access) as well as emerging areas and current topics (e.g., patient safety). Most projects are multi-disciplinary in approach, involving a team of researchers with expertise in a variety of clinical specialties and academic disciplines. Many of these studies involve data collection at multiple sites to enhance generalizability and the eventual translation of the findings into practice. IIRs may receive funding for up to 5 years, and there is no pre-set funding cap. ***NOTE:*** *However, solicitations for particular categories of IIRs may impose limits on duration and total cost.*

(2) Periodically, HSR&D publishes program announcements or other types of research solicitations to inform the field regarding particular research priorities and opportunities within the IIR program. Collectively, HSR&D refers to these announcements as "special solicitations." Special solicitations are distributed to the field via FAX and are posted on HSR&D's webpage. The announcement's expected "lifespan," specific receipt and review dates, any special requirements, and expected investment are specified. Review may be carried out by the Scientific Review and Evaluation Board as part of its regular deliberations, or by an ad hoc review subcommittee with more specialized expertise. Unless the solicitation identifies an exception, all policies and procedures presented in this Handbook are applicable.

b. **SDR.** Periodically, HSR&D publishes "targeted" solicitations to invite proposals that address a specific research or development need identified in Central Office. These solicitations are distributed to the field via fax and are posted on HSR&D's webpage. Depending on the purpose of the research and the timeframe for completion, eligibility to apply may be restricted (e.g., to investigators at established HSR&D Centers) or there may be special requirements (e.g., matching funds). Each SDR announcement includes receipt and review dates, who may apply,

and specific requirements. For most SDR solicitations, HSR&D's intention is to fund only one project. Review of required SDR Concept Papers serves as a screen to identify the most competitive applicants, who are then invited to submit full proposals. ***NOTE:*** *Unless the solicitation identifies an exception, all procedures presented in this Handbook are applicable.*

NOTE: *IIR and SDR provide mechanisms for funding projects that may be programmatically part of another activity. For example, some IIR and SDR projects are part of the Quality Enhancement Research Initiative (QuERI). As such, they may be funded through separate accounts; however, all follow the basic policies and procedures set forth in this handbook. Any exceptions, for example, in funding limits, due dates, or who may apply, are specified in the applicable solicitation.*

c. **NRI**

(1) NRI is a research and capacity-building program that HSR&D manages for the Office of Research and Development (ORD). Program goals include expanding the pool of nurse investigators in VA and facilitating the development of nurses' research skills. The Principal Investigator (PI) for all NRI projects must be a clinically-active nurse and, in most cases, the PI must have a preceptor or mentor. In other respects, NRI adheres to the same general application and review policies and procedures as HSR&D's IIR program.

(2) The program announcement for NRI is reissued periodically to incorporate any changes in research priorities or administrative requirements. Eligible nurse investigators interested in applying should refer to the current NRI announcement, available on HSR&D's website. Letters of Intent for NRI projects are reviewed monthly, along with LOIs for the IIR program. NRI proposals are reviewed twice each year, by a subcommittee of the Scientific Review and Evaluation Board. NRI projects may not exceed 4 years of funding or a total cost of $750,000. ***NOTE:*** *The applicant needs to indicate whether the proposed research is most pertinent to the interests of HSR&D, Medical Research Service (MRS), or the Rehabilitation Research and Development (RRD) Service.*

3. APPLICATION REQUIREMENTS

a. **Eligibility.** Only "eligible" individuals may serve as the Principal Investigator (PI) or co-Principal Investigator (co-PI) on a VA-funded research project (see VHA Handbook 1200.15). A prospective PI who is not currently eligible may submit an LOI for IIR or NRI, or a Concept Paper for SDR, but eligibility must be established before a full proposal will be reviewed. For NRI projects, there is an additional requirement that the PI must be a nurse who is engaged in clinical work in VA.

b. **LOI.** All types of HSR&D projects, and the NRI program administered by HSR&D, use a two-step review process requiring applicants to submit and gain approval of a LOI or Concept Paper prior to submitting a full proposal. LOI policy and procedures are detailed in paragraph 4 of this Handbook and in the associated appendices.

c. **Full Proposal.** All HSR&D projects use VA Form 10-1313-13, VA Research and Development Programs, pages 1-8, with only minor differences across project types. The specific forms that must be included (and guidance for completing them), as well as page limits

for the narrative sections, are detailed in App. B). Proposals for all HSR&D projects must be submitted through formal channels, consistent with all current instructions, and received by the specified due dates.

4. LOIS AND CONCEPT PAPERS

a. **Scope**

(1) Investigators seeking support for a research project through the IIR program of VA's HSR&D, or the NRI, administered by HSR&D, must first submit a LOI. HSR&D's SDR program requires a similar document, referred to as a Concept Paper. These brief, preliminary proposals are reviewed in order to determine relevance to program goals and soundness of the research plan. Approval of the LOI or Concept Paper is a prerequisite to submitting a full research proposal to HSR&D.

(2) The LOI or Concept Paper is to be submitted by the PI through the local Research and Development (R&D) office. The required signature of the Associate Chief of Staff (ACOS) for R&D signifies local review and ensures, at a minimum, local support and conformance to current VA Central Office guidelines. ***NOTE:*** *In addition, applicants are strongly encouraged to obtain local assistance or review regarding scientific and technical issues.*

b. **Rationale.** HSR&D's requirement that investigators gain approval of an LOI or Concept Paper prior to preparation of a full proposal is designed to assist investigators as well as program administrators. Specifically, this preliminary review serves to:

(1) Identify and, when indicated, redirect proposed research that is not appropriate to the goals of HSR&D or VA.

(2) Improve the quality of research proposals, and the likelihood of their success, by identifying major issues or problems early in the project's development.

(3) Support HSR&D program planning by alerting administrators to research projects that are under development.

c. **General Requirements.** All LOIs and Concept Papers must be prepared and submitted in accordance with current instructions and received by the applicable due date. Required forms, allowable length, formatting requirements, and number of copies may differ across programs. For IIR and NRI, see Appendix A of this document. For SDRs, instructions are contained in each announcement. ***NOTE:*** *Investigators need to clearly identify the type of project for which they are applying and to ensure the LOI or Concept Paper is directed to the intended program within HSR&D.*

d. **Review Schedule**

(1) HSR&D accepts LOIs for IIR and NRI projects throughout the year. LOIs received by the last working day of any month are reviewed during the following month. Investigators may submit only one LOI per month. ***NOTE:*** *Special IIR solicitations and SDR announcements may specify limited receipt dates or a unique review schedule for LOIs and Concept Papers.*

(2) Whenever possible, applicants are advised to submit the LOI at least 3 months ahead of the intended proposal deadline, in order to allow time for review, notification of results, and development of the full proposal.

e. **Review Results and Next Steps**

(1) **Notification.** For IIRs and NRI projects, LOI review results (approval or disapproval) is communicated via telephone or e-mail to the office of the ACOS for R&D and the PI within 1 week of the review. Written notification, including highlights of reviewers' comments, will be mailed within approximately 4 weeks. For SDRs, results of Concept Paper review will be provided as specified in the pertinent announcement.

(2) **Proposal Submission.** Once notified of LOI approval, applicants for IIR and NRI are encouraged to submit a full proposal by the closest reasonable proposal deadline. LOI approval expires if three proposal deadlines pass and a full proposal has not been submitted. ***NOTE:*** *IIR proposals responding to a special HSR&D announcement may have a more limited timeframe. For SDRs, proposal deadlines are indicated in the pertinent solicitation.*

(3) **Revision of LOI or Concept Paper**

(a) For the IIR and NRI program, an LOI that is disapproved may be revised and resubmitted, one time. Any revised LOI is expected to explicitly address issues raised in the initial review and to identify all changes in the proposed plan.

(b) Revision and resubmission of an SDR Concept Paper is generally not an option.

f. **Inquiries And Additional Information.** The local VA R&D office should be the investigator's first point of contact for information about LOIs and Concept Papers. Representatives of the local R&D office may direct inquiries to the HSR&D LOI Program Manager or to the SDR Program Manager at VA Central Office.

5. PROJECT PROPOSALS

This paragraph provides general guidance regarding submission of proposals for support through HSR&D (see App. A).

a. **Requirements for PIs**

(1) **Eligibility**. The PI and any co-PI of a proposed research study must meet VA eligibility criteria (see VHA Handbook 1200.15).

(2) **Good Standing**. Investigators must fulfill their obligation to complete a final report for any previous HSR&D-funded project before a new proposal will be considered.

(3) **Co-Principal Investigators.** HSR&D encourages designation of a single PI, but will permit one co-PI. The same requirements and responsibilities apply equally to the PI and any

co-PI. In written communications between VA Central Office and the field, the PI of record is HSR&D's single contact.

(4) **Human Subjects Protection Training**. All individuals applying for VA research project funding as PI or co-PI are required to complete an approved course in human subjects protection. Documentation concerning this training is to be submitted along with any research proposal (see VHA Handbook 1200.5).

b. **Required Approvals.** All proposals submitted to HSR&D must be approved by the R&D Committee at the VA facility and by the Institutional Review Board (IRB) of each site involved in the study.

(1) **Research and Development Committee**. See VHA Handbook 1200.1.

(2) **IRB**. Most HSR&D studies involve human subjects or the use of personal data. To ensure proper protections, proposals for all such studies must be approved by the IRB at all designated project sites. Documentation of approval (or exemption) must be submitted with the proposal. When IRB schedules preclude this, HSR&D will accept the required documentation up to 30 days following the proposal due date. If project sites are not all selected by the proposal submission deadline, the PI must outline the plan for obtaining IRB review as each site is selected and must submit documentation of these IRB actions to HSR&D promptly. In addition, every site included in the proposed research must hold a current Assurance of Compliance with provisions of the Federal Common Rule. ***NOTE:*** *Recognized Assurances currently include a Multiple Projects Assurance (MPA) issued by the Office of Human Research Protection (OHRP), Department of Health and Human Services, a Federal Wide Assurance (FWA), or a VA MPA contract.*

(3) **HSR&D LOI.** Unless responding to an HSR&D announcement that states an exception, a proposal must be developed based on an approved HSR&D Letter of Intent and received while that approval is still "active" (see subpar. 4e).

c. **General Instructions**

(1) **Receipt Dates**. IIR and NRI application deadlines are November 1 and May 1 of each year, for review by HSR&D's Scientific Review and Evaluation Board (SREB) in January and June, respectively. The same receipt dates apply for new and revised applications. Special IIR solicitations may announce other receipt dates.

(2) **Proposal Limit**. A proposed PI may submit only one application to HSR&D per review cycle, and an application that is submitted to HSR&D may not be submitted to any other component of VA's ORD (i.e., Medical Research Service (MRS), Rehabilitation Research Service (RRS), or Cooperative Studies).

(3) **Revised Proposals**. Proposals that are approved by HSR&D's Scientific Review and Evaluation Board (or one of its subcommittees), but are not funded, may be revised and submitted for a new review. A revised proposal is expected to address explicitly the issues raised by reviewers of the previous proposal. Resubmissions need to be received within 1 year of the original submission date. No more than two revisions are permitted. Any second

resubmission (third version of an application) will undergo administrative review to determine whether the changes are sufficient to warrant reconsideration by the SREB. ***NOTE:*** *If a proposal is disapproved, or if too much time has elapsed, the investigator must start over with a new LOI.*

(4) **Withdrawal.** A PI who wishes to withdraw an application from consideration must notify the HSR&D Assistant Director, Scientific Review by telephone and in writing.

(5) **Designated PI.** The proposed PI, or "applicant," is the individual who will have principal responsibility for the scientific and technical direction of and the completion of the research. Designation of a single PI is preferred; however, HSR&D permits one Co-PI. ***NOTE:*** *Central Office-initiated communications from HSR&D are directed to a single PI.*

(6) **Proposal Content and Format.** Proposals are to be prepared using required VA Forms 10-1313, pages 1-8, merit review forms, and in accordance with all current instructions. Detailed information is provided Appendix A. Applications must be complete upon arrival in VA Central Office. Once received, additional or replacement information will not be accepted unless requested by HSR&D. The responsibility for a complete and timely submission lies with the R&D Office at the originating VA facility. ***NOTE:*** *An incomplete application may be returned without review.*

(7) **Local Approvals.** All required forms, approvals, and endorsements must be submitted by the PI's VA facility. If a PI transfers to another VA facility after the application has been submitted, new approvals and endorsements must be obtained. ***NOTE:*** *The PI, through the R&D office, needs to notify the HSR&D Assistant Director, Scientific Review about an expected transfer, and recognize that it may delay review of the application, or start of the project.*

(8) **Off-site Research.** An investigator who seeks permission to perform research outside of a VA medical center, VA-owned or VA-leased space, must request a waiver to perform the research off-site (see Handbook 1200.16).

(9) **Intellectual Property, i.e., Inventions and Transfer of New Scientific Discoveries.** Refer to VHA Handbook 1200.18.

(10) **Inquiries.** Questions about the application process should be directed to the ACOS for R&D or Coordinator for R&D at the applicant's facility. ***NOTE:*** *If additional information is needed, contact HSR&D's Office of Scientific Review (124F) at 202-408-3661.*

6. MERIT REVIEW

This paragraph provides guidance on the merit review process as implemented by HSR&D.

a. **Scope**

(1) 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, from inside and outside VA, who constitute the SREB or one of its subcommittees. The recommendations of the review board, the priority

scores for approved projects, and reviewers' specific comments guide the decisions of VA research administrators regarding which projects to fund.

(2) The scientific review process is the foundation for effective communication with applicants for HSR&D research support. Reviewers' assessments and suggestions are communicated to applicants to help them understand the board's recommendation, to improve already strong projects, and to assist applicants who may wish to revise and resubmit their application.

b. **Implementation**

(1) **SREB and Subcommittees**

(a) HSR&D merit review is carried out by the SREB and several subcommittees. SREB is a multidisciplinary panel of experts, with approximately 20 members, each of whom is appointed for a 3-year term, plus a non-voting chairperson. Members are researchers and clinicians from within VA and external to VA (non-VA members constitute approximately 60 percent). If additional expertise is required beyond that readily available on the SREB, one or more *ad hoc* reviewer(s) with appropriate expertise is to be recruited to supplement the review.

(b) Each subcommittee of SREB is chaired by a current member of SREB and populated by VA and non-VA researchers with expertise appropriate to the program. For example, the standing Nursing Research Subcommittee includes individuals with expertise in medicine and rehabilitation as well as health services issues related to nursing. Review of proposals responding to special HSR&D solicitations, is frequently by an *ad hoc* subcommittee of SREB with expertise appropriate to the topic.

(c) SREB is a chartered VA committee that is subject to rules of the Federal Advisory Committee Act (FACA). In accordance with FACA requirements, HSR&D announces each review meeting in the Federal Register, and the public is invited to observe the opening announcements and instructions. During review of the research proposals, deliberations are confidential, and the meeting is closed to the public. As a learning opportunity, HSR&D may permit VA researchers to observe portions of the review session that are closed to the general public.

(2) **Review Schedule**

(a) SREB reviews IIR proposals twice each year, in January and June.

(b) SDR proposals and IIR with special receipt dates (specified in the applicable announcement) are reviewed within 3 months of the proposal receipt date.

(3) **Reviewer Responsibilities**

(a) Each proposal is assigned to reviewers with appropriate expertise to review the scientific merit of the proposal, with one member designated as the primary reviewer, one as secondary reviewer, and one as tertiary reviewer. Care is taken to avoid reviewers having a real or perceived conflict of interest (and, if a conflict is identified, assignments are changed). All non-

conflicted reviewers are invited to participate in the review of every application, whether or not it is specifically assigned to them and to vote on recommendations regarding approval or disapproval.

(b) 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 (see subpar. 6c) as well as any special criteria that may be included in a particular research solicitation. These critiques (with reviewer identifiers removed) are eventually sent to the applicant, along with notification of the review outcome and a summary of reviewer comments written by HSR&D staff.

c. **General Review Criteria**

(1) **Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study.** Almost every applicant will have received comments regarding the importance, design and/or methods of the proposed study, based on their presentation in a LOI or Concept Paper. 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.

(7) **Human Subjects.** Reviewers note whether or not a study involves human subjects or data with personal identifiers and, if so, whether VA requirements for IRB review and approval have been met. 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).*

(8) **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.

(9) **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.

(10) **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 1 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 staff. This review ensures that VA research funds are not used for any inappropriate purposes, to include patient care, salaries of Title 38 employees, and development projects that lack a strong evaluation component.*

(11) **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. ***NOTE:*** *Importance of the problem is assessed independently of the investigator's approach.*

(12) **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.

d. **Reviewer Recommendations and Priority Scores**

(1) At the conclusion of discussion on each proposal, reviewers make a motion to recommend approval, conditional approval, disapproval, or (occasionally) deferral, and then vote on the motion. The vote of the majority carries. For all approved and conditionally approved proposals, individual reviewers then assign a priority score, ranging from 10 (strongest) to 50 (weakest). The committee's recommendation for each proposal and the mean priority score, are critical elements in funding decisions made by the Director, HSR&D. ***NOTE:*** *The definitions reviewers use in making recommendations and assigning priority scores appear in Appendix A.*

(2) Each merit review session is independent. In the case of a proposal that has been revised and resubmitted, it is possible that reviewers will raise different or new issues concerning the proposed research, and this may result in a less favorable recommendation than in the previous review.

e. **Post-review Notification of Review Results**

(1) **Preliminary Notification.** Within 10 days following each review meeting, 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.

(2) **Written Notification**

(a) Written notification of the results of merit review must be 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 decision.* Copies of this letter must be sent to the PI, ACOS for R&D at the facility, the Veterans Integrated Service Network (VISN) Director, and the Director of the Center of Excellence (CoE) or Research Enhancement Award Program (REAP), if applicable. 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.

(b) Written notification regarding project funding must be sent to the facility Director within 10 weeks after each review meeting. Copies are sent to the PI, ACOS for R&D, VISN Director, and the CoE or REAP Director, if applicable.

(3) **Questions about Reviews and/or Conditional Approvals.** HSR&D's Assistant Director, Scientific Review, is available to discuss with the PI any questions about the individual critiques, the summary statement, or a conditional approval.

f. **Appeals**

(1) In limited circumstances, the PI for a project that is disapproved may appeal the recommendation of the review board and request a new review of the current proposal. An appeal may be appropriate when, in the opinion of the investigator, the board did not understand the research, missed relevant points, or was biased. A discrepancy between the conclusions of previous and current reviewers, unless due to an error or oversight by reviewers, is not grounds for an appeal. ***NOTE:*** *The appeals process is designed to uncover potential procedural errors, not to resolve differences on scientific points of view between the applicant and the reviewers.*

(2) The appellant needs to prepare a formal letter rebutting specific points that indicate possible misunderstanding or misinterpretations of the proposal, or bias on the part of the scientific reviewers. The summary statement provided to the applicant is the only document acceptable as the basis for an appeal. All information contained in the appeal must have been part of the original proposal. ***NOTE:*** *Data obtained since the original review or any additional information can not be included.*

(3) The appeal document must be submitted through the local R&D Committee, ACOS for R&D, and submitted together with a supporting letter from the facility director, to the Director, HSR&D. Any appeal should be received by HSR&D within 6 weeks of formal notification of the review results. The original and five copies of the appeal are to be sent to the Director, Health Services Research and Development (124F), VA Central Office, 810 Vermont Avenue, NW, Washington, DC, 20420.

(4) If HSR&D determines that the appeal is appropriate, staff arranges for a new review by individuals with the relevant expertise, who were not involved in the disputed review. This ad hoc review group makes a new recommendation regarding approval or disapproval to the

Director, HSR&D, and assigns a new priority score if the proposal is approved. This recommendation and score must be promptly communicated to the medical center Director and PI.

7. HSR&D FUNDING FOR "DEVELOPMENT"

NOTE: *This policy applies to all applications seeking support of developmental work through HSR&D IIR program. To the extent possible, determinations of eligibility for HSR&D-IIR funding will be made at the stage of LOI review, and applicants will be notified promptly if their request is deemed inappropriate.*

a. **Scope.** The mission of the HSR&D Service includes the support of scientifically meritorious and VA-relevant research and development. Scientific activity that yields new knowledge (research) and work resulting in new products (development) are often interdependent; and HSR&D receives proposals that include elements of both. This mission statement clarifies the nature and extent of "developmental" work that may be supported with HSR&D funds.

(1) In determining what developmental work (and, similarly, what research) is appropriate for potential funding through HSR&D's IIR program, the distinction between "efficacy" and "effectiveness" is the key.

(2) HSR&D-IIR funding support is appropriate for projects focused on products, procedures and practices ("interventions"), if there is evidence that they are safe and efficacious (i.e., they work in controlled settings). HSR&D-IIR funds are also appropriate for studies of interventions that have been widely adopted in practice, even if evidence of efficacy is lacking. Studies of such interventions may evaluate their effectiveness (i.e., whether they work in the "real world") or issues related to their quality, use, outcomes, and cost.

(3) In general, HSR&D-IIR support is not appropriate for projects whose goal is to develop a new product of the types (see subpar. 7c) because efficacy is unknown. However, some such products may be produced or refined in conjunction with the conduct of an IIR project. In addition, HSR&D-IIR support is appropriate for the development of new methods and tools for research, and the evaluation of clinical care when the validity of existing tools has not been determined or when appropriate tools do not exist.

(4) Developmental work that is not appropriate under HSR&D's IIR program may be appropriate for support by HSR&D through the SDR program or when the Director, HSR&D, identifies a specific need and issues a call for proposals.

(5) All developmental work supported through HSR&D's IIR program is expected to:

(a) Meet established standards of scientific peer review and applicable review criteria.

(b) Be submitted simultaneously with a well-developed evaluation plan.

(c) Constitute a relatively small portion of the total time and budget requested for the complete project (i.e., development plus evaluation).

b. **Appropriate HSR&D IIR Support**. HSR&D IIR support is appropriate for, but not limited to, development of the following.

(1) Measures of quality of care.

(2) Measures of functional status.

(3) Measures of cognitive status.

(4) Methods for risk adjustment.

(5) Methods for measuring or estimating costs.

(6) Methods to elicit patient preferences.

c. **Non-appropriate HSR&D-IIR Support.** HSR&D-IIR support is not appropriate for development of the following:

(1) Clinical practice guidelines.

(2) Computer algorithms or reminder systems.

(3) Databases or registries.

(4) Computer software.

(5) Clinical or surgical techniques.

(6) Diagnostic tests.

(7) Drugs.

(8) Educational materials (for patients or providers).

(9) Equipment.

(10) Medical devices.

NOTE: *Products such as those listed in the preceding become appropriate subjects of HSR&D-IIR research once they are developed, and there is some evidence of their efficacy or validity. For example, IIR research might focus on implementation of clinical practice guidelines, evaluation of outcomes related to a new drug, or adaptation of a computerized reminder system for use in VA.*

LETTER OF INTENT (LOI) GUIDELINES

NOTE: *These Letter of Intent (LOI) guidelines pertain to projects submitted for funding through (Health Service Research & Development Service's (HSR&D) Investigator-Initiated Research (IIR) program and the Nursing Research Initiative (NRI). For Service-Directed Research (SDR) projects, which may require a "Concept Paper," instructions are contained in the individual announcement.*

1. REQUIRED CONTENT

a. **LOI Cover Page.** The LOI Cover Page (Department of Veterans Affairs (VA) Form 10-1313-13, VA Research and Development Programs) must be filled out completely and signed by the Associate Chief of Staff (ACOS) for Research & Development (R&D) or the R&D Coordinator, or designee. ***NOTE:*** *Item 7, the signature of the medical center Director is not required.*

(1) In sections 1 and 3 of the Cover Page, indicate the Service and program for which the LOI is intended. If the LOI is responding to a specific announcement, check "Response to Specific Announcement" and enter the title of the announcement. For LOIs submitted to the IIR program, but not in response to any specific HSR&D announcement, check "Merit Review." For LOIs submitted to the Nursing Research Initiative (NRI) program, check the "Other" box and specify "NRI."

(2) In section 2 of the Cover Page, indicate if the LOI is new or revised and, if revised, write in the project number of the initial LOI.

(3) In completing section 5, include the social security number for the PI (and any co-PI).

b. **Outline.** The LOI is to be presented in outline form; be specific and concise. Include each of the following items in the order presented below, using each as a heading. ***NOTE:*** *Items Sections 1-10 may not exceed a total of three pages.*

(1) **Principal Investigator.** Type the Principal Investigator's (PI's) name in the upper right-hand corner of each page.

(2) **Project Title.** The title should be informative and concise (maximum 72 characters).

(3) **Purpose.** Specify the objective(s) of the proposed research and explain how these relate to long-term goals.

(4) **Scientific Rationale.** Identify the theory or conceptual framework that supports the hypothesis(es), expected findings or results, and/or proposed approach.

(5) **Focus**

(a) Specific research question(s). State these in the form of testable research hypothesis(es), if applicable.

(b) Intervention. If the research involves an intervention, identify and briefly

describe it. Indicate what is known about the efficacy and availability of this intervention. ***NOTE:*** *HSR&D intervention studies address effectiveness and/or cost effectiveness of treatments for which efficacy has already been established.*

(c) Product. If a measure or research tool is to be developed, validated, or refined, identify and describe it. For any other type of product, indicate its current status in terms of stage of development and availability.

(6) **Anticipated Impact.** What will be the practical impact of this research (e.g., better patient health or functioning, more consistent use of "best practices," improved access to care, reduced cost, etc.)? Will the findings or results be useful throughout VA? Will they be generalizable beyond VA?

(7) **Methods**

(a) Study Design and Approach. Indicate whether the study is, for example, a randomized controlled trial, case-control, or observational study. Does it involve new analytic techniques or qualitative methods? ***NOTE:*** *Most epidemiological studies are more appropriate for consideration by the Epidemiology Review Committee, managed by VA's Medical Research Service.*

(b) Population and Sample, Including Control Group, if applicable. Indicate key characteristics of each, including major inclusion and/or exclusion criteria. Indicate expected sample size and the number of study sites providing patients or patient data.

(c) Type(s) of Data. Identify what types of primary data are to be collected and the source of any secondary data to be used (e.g., specific clinical or administrative databases).

(d) Analysis Plan. Provide a concise description, identifying analytic techniques, unit of analysis, time points, and key variables.

(8) **Key Participants.** Note that HSR&D encourages designation of a single PI and no project may have more than one co-PI. For each individual, indicate their principal discipline or specialty. ***NOTE: For NRI (only):*** *Identify the preceptor or mentor, and that person's expertise.*

(9) **Resource Request.** Indicate expected project duration and estimated total cost. ***NOTE:*** *For IIRs, there is no pre-set cost limit; the project period may be up to 5 years. NRI projects are limited to 4 years and a total cost of $750,000.*

(10) **Statement of Disclosure.** Provide a brief (i.e., one or two line) statement confirming the absence of a financial or contractual relationship between the PI (or any member(s) of the proposed research team) and any organization or individual involved in the study, which might constitute a real or perceived conflict of interest. If such a relationship or contract does exist, full disclosure must be provided.

c. **Supplemental Pages**

(1) **References.** Submit up to one page of pertinent references.

(2) **Additional NRI Requirement.** For NRI, include either: A one-page summary of the qualifications of the preceptor (and mentor, if applicable), including their most relevant publications and a description of their planned commitment to provide guidance throughout the proposed project; or clear evidence that the PI is sufficiently experienced so as not to require a preceptor.

d. **Format.** Every page (including permitted supplemental pages) must be formatted according to the following specifications:

(1) **Margins.** Set all margins to at least one-inch.

(2) **Font.** Use a font size that precludes more than 15 characters per inch (i.e., usually 12-pitch).

(3) **Spacing.** Single space.

2. SUBMISSION. Only complete LOI packages, in the specified format, will be forwarded to reviewers. Appendices, letters of support, and/or any additional pages (including references beyond one page) will not be forwarded to reviewers or retained by HSR&D. LOIs received on or before the last day of a month will be reviewed the following month.

a. **Who Submits**. The LOI is to be submitted by the PI through the local R&D office. The required signature of the ACOS for R&D signifies that the LOI has undergone local review ensuring, at a minimum, local support and conformance to current VA Central Office guidelines. ***NOTE:*** *Applicants are strongly encouraged to obtain local assistance or review regarding scientific and technical issues as well.*

b. **What to Submit**. The complete LOI package consists of the LOI Cover Page, LOI Outline (sections 1-10), and up to one page of references.

c. **Where to Send**. Mail (do not send by facsimile or e-mail) the original complete LOI package (do not send additional copies), to:

LOI Program Manager (124-I)
Health Services Research and Development Service
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, DC 20420

d. **Re-Submitting an LOI**. An LOI that has been disapproved may be revised and resubmitted (one time only). A revised LOI must be accompanied by a cover letter, not exceeding one page, that addresses the major concerns of the previous reviewers.

3. REVIEW CRITERIA. LOI review emphasizes relevance to the mission and current priorities of VA and HSR&D (or NRI), and addresses key scientific issues. Approval or disapproval is based on the following criteria:

a. The purpose, focus, and approach are clear.

b. The anticipated findings or results of the proposed study will contribute to improvements in the health of veterans or the quality of VA health care.

c. The proposed work fits within the scope of HSR&D or NRI and will make a contribution to established program areas and/or current priorities.

d. The proposed study is grounded in an appropriate conceptual framework and will advance knowledge. ***NOTE:*** *This is research.*

e. Key aspects of the study design are specified, and they appear to comprise an appropriate approach. ***NOTE:*** *LOI review regarding methods focuses on major issues only; however, review of the full proposal must include detailed evaluation of research methods.*

f. The research does not raise concern about any ethical issue or undue patient burden.

g. For NRI LOIs only**:**

(1) The LOI shows that the preceptor (and mentor, if applicable) is (are) sufficiently qualified and committed to provide the necessary guidance and support in developing and completing the proposed research; or

(2) Clear evidence is presented showing that the PI is sufficiently experienced so as not to require a preceptor.

4. NOTIFICATION OF REVIEW RESULTS

a. The ACOS for R&D and PI will be notified of review results (approval or disapproval) within one week of the review. Notification letters will be mailed to the VA medical center Director with a copy to the ACOS for R&D, the Network Director, PI and, where applicable, the Director of the HSR&D, the Center of Excellence (CoE) or Research Enhancement Award Program (REAP) within approximately 4 weeks of review. Additionally, the Chief Consultant, Nursing Strategic Healthcare Group, will receive notification regarding each NRI LOI.

b. Notification regarding approval or disapproval summarizes the rationale for the recommendation and may contain additional comments for the investigator to consider in further development of the project.

5. ADDITIONAL INFORMATION

a. The local VA R&D office should be the investigator's first point of contact for information about HSR&D and NRI programs and requirements.

b. The R&D Webpage (http://www.va.gov/resdev) contains information about HSR&D program priorities, including all active research solicitations; as well as information about review of LOIs and full proposals.

c. Inquiries may be directed to the HSR&D LOI Program Manager, at (202) 408-3661.

INSTRUCTIONS FOR PREPARING RESEARCH PROPOSALS

***NOTE*:** *These instructions pertain to all applications submitted to the Health Services Research and Development Service (HSR&D) for the Investigator-Initiated Research (IIR) program, Service-Directed Research (SDR) program, and the Nursing Research Initiative (NRI).*

1. FORMAT

a. Applications must be on Department of Veterans Affairs (VA) Forms 10-1313-1 through 10-1313-8, VA Research and Development Programs, VA form 10-1223, Report on Subcommittee on Human Studies and, if applicable, VA form 10-1086, VA Research Consent Form. These are available at local VA Research and Development (R&D) offices, through PROMISE, and on the web at www.va.gov/resdev.

b. Type all pages single-spaced, with at least 1-inch margins on all sides. Use a font no smaller than 11-point to ensure good reproduction and easy reading. An application with low quality or undersized print will be returned without review.

c. Number all pages, in the bottom right-hand margin, showing Principal Investigator (PI) last name and the page number (e.g., Smith-1 to Smith-87). Number consecutively, starting on VA Form 10-1313-1, Merit Review Application, and ending with the last page of the supporting documents.

d. Securely fasten each copy of the proposal with a spring clip, centered in the top or left-hand margin.

2. CONTENTS OF THE APPLICATION PACKAGE

a. **Required Items**

(1) The single-sided original of all required forms (VA Form 10-1313-1 through VA 1313-8, and VA Form 10-1223), the proposal narrative, all supporting documents, and the HSR&D Application Checklist, in the format described in Appendix C.

(2) Thirty double-sided copies of the entire application.

(3) One additional copy of VA Form 10-1313-1, and VA Form 10-1313-2, Summary Description of Program, copied back-to-back.

(4) An electronic abstract (in Microsoft Word), either on a disk or as an e-mail attachment. Either mail the abstract on diskette with the rest of the application, or e-mail the abstract to: HSR&D.abstracts@mail.va.gov.

(5) If this is a revised proposal In a letter (not exceeding three pages, placed in front of the proposal narrative, and addressed to the Director, HSR&D), the PI must indicate how the revised

proposal differs from the previous one. Revised applications are expected to respond fully to any previous critiques. All substantive changes and additions to the narrative must be identified by the use of *italics*.

b. **Optional Items**

(1) Proposed data collection instrument(s).

(2) Appendixes.

(3) A letter (addressed to the HSR&D Assistant Director, Scientific Review) identifying two or more scientists who are qualified to review the application. For each nominee, provide name, degree, title, affiliation, areas of expertise, and complete contact information.

3. DETAILED INSTRUCTIONS FOR COMPLETING FORMS

a. **VA Form 10-1313-1, Merit Review Application**

(1) **Item 1 (Tab No.).** Leave blank.

(2) **Item 2 (Application Number).** Enter the 3-letter prefix and first 5 digits of the 6-digit project number, as assigned to the approved Letter of Intent (LOI). Enter the 6th digit of the project number to indicate whether this is the first (-1), second (-2), or third (-3) time the proposal is being submitted for review.

(3) **Item 3 (Review Group).** Enter "HSR&D" and identify the specific announcement (if any) to which this proposal responds.

(4) **Item 4 (Review Date).** Leave blank.

(5) **Item 5 (Facility No.).** Enter the PI's and, if applicable, Co-Principal Investigators (co-PI)'s VA medical center or facility number.

(6) **Item 6 (Location of Health Care Facility).** Provide the complete mailing address, including the PI's routing symbol, for the VA facility identified in Item 5. For multi-site studies, on a separate page, list the same information for any additional sites.

(7) **Item 7 (Social Security Number).** Enter the PI's social security number only on the original copy.

(8) **Item 8 (Date of Last Submission).** Enter the date (if any) on which this proposal was previously submitted to HSR&D for merit review. If none, enter "N/A."

(9) **Item 9 (Principal Investigator(s), Degree(s), and Telephone Number).** Enter the PI's (and Co-PI's) last name in capital letters, followed by first name, middle initial, and degree(s) and phone numbers for each.

(10) **Item 10 (Program Title).** Enter the project title. The title may not exceed 72 characters (including spaces) and should be as specific and descriptive as possible. If the title does not match that of the approved LOI or most recent submission of this proposal, type "NEW TITLE" above the title.

(11) **Item 11 (Amount Requested each Year).** Enter the total funding requested for each project year and for the entire project. Note that most IIR projects do not have a pre-set funding limit, but none may exceed 5 years in duration. Some IIR solicitations or program announcements may specify a different limit on project duration or cost. ***NOTE:*** *Projects funded through the NRI may not exceed 4 years, or a total cost of $750,000.*

(12) **Item 12 (VA Employment Status).** Indicate current or expected VA employment status for the PI (and Co-PI). PIs and Co-PIs who have less than a 5/8-paid VA appointment must have an approved eligibility letter (see VHA Handbook 1200.15).

(13) **Item 13 (VA Salary Source).** Indicate salary source for PI (and for Co-PI).

(14) **Item 14 (Type Program).** Check "NEW."

(15) **Item 15 (Program or Cost Center).** Print "824" / "134."

(16) **Item 16 (Primary Program Area/ Primary Specialty Area).** For PI (and Co-PI), indicate primary and secondary research interests, using the options contained in the "Page 18" instructions in PROMISE.

(17) **Item 17 VA Hospital Service and Section.** Complete for PI (and Co-PI).

(18) **Item 18 (Academic Rank, Department, Affiliation).** Complete for PI (and Co-PI).

(19) **Item 19 (Program Use).** Check YES or NO for each item.

(20) **Item 20 (Summary of Research Support).** Provide requested information for PI (and Co-PI), beginning with the current fiscal year.

(21) **Item 21 (Date Entered on Duty).** Enter date of PI's (and Co-PI's) entry to VA duty, or expected date, if appointment is pending. (If there has been a break in service, give date of most recent appointment.)

(22) **Signature Blocks.** Original, dated signatures of the PI and the ACOS for R&D or Coordinator for R&D (or designee) are required. The latter certifies that the application is administratively complete and that all required reviews have been conducted.

b. **VA Form 10-1313-2, Summary Description of Program**

(1) **At the Top of the Form, Check "PROJECT."** Enter the PI's name and the project title. Keywords. From the National Library of Medicine's Medical Subject Headings (MeSH), select at least three that identify the scientific discipline or research area(s) emphasized in the

proposed research. ***NOTE:*** *The accuracy of these codes is very important. The codes assist HSR&D administrators in analyzing and describing the research portfolio and in selecting appropriate reviewers.*

(2) **Brief Statement of Research Objectives (Abstract).** Provide a concise (500 words or less), informative description of the proposed study, suitable for publication. The abstract should begin with a clear statement of the rationale and objective(s) of the proposed research. It must then identify the research design (e.g., randomized controlled trial, case-control study, observational study, etc.); principal source(s) of data; principal type of analysis (e.g., outcomes assessment, decision modeling, cost-effectiveness, qualitative, etc.); population to be studied (veteran status, gender, age, ethnic or racial minority, etc.); and the expected contribution of the research to VA and others.

c. **Table of Contents.** List all sections of the application (including any appendices) and the initial page number for each. Place the Table of Contents immediately after VA Form 10-1313-2.

d. **VA Form 10-1313-3, Current Funds and First Year Request**

(1) At the top of the form, check "Project." Enter PI's name and project title.

(2) Under Personnel, starting with the PI, list all individuals who will work on the project, including those for whom no salary support is requested. Enter name and academic or professional degree(s).

(3) Physicians, dentists, nurses and other Title 38 employees may not receive salary support from VA research funds except with the express prior approval of the Chief R&D Officer.

(4) Clerical support may not be included as study personnel unless their work can be justified as an integral part of project activities.

(5) Intergovernmental Personnel Act (IPA) appointments should not be listed under Personnel. IPAs should be listed under All Other.

(6) Under Role in Program, indicate whether the named individual is a co-PI, investigator, research assistant, etc. Also indicate each person's grade and step.

(7) Under Percent Effort, list the percent of time (Full-time Equivalent(FTE)) to be devoted to the project by each named participant. Ensure that no person's individual time commitments total more than 100 percent.

(8) Current Year Funds refers to any R&D funds allocated by VHA Central Office available to the named individuals during the 12 months preceding the requested start date.

(9) First Year Requested Funds refers to funds requested for the first 12 months of the proposed project (funding period typically starts 5 months after proposal submission). VA Research funds cannot be used to cover the costs of patient care except in very special

circumstances. Also, the policy regarding use of research funds for "development" specifies that such work should comprise a minor part of the total project; and HSR&D projects that include development of some type of product must include a strong evaluation component.

(a) Salaries, including fringe benefits (not to exceed the percent allocated in the medical center research budget for fringe benefits in the Initial Target Allowance (ITA) guidelines for the fiscal year in which the proposal is being submitted or the most recent available), for all personnel to be paid from R&D personal services funds. Requested salary support must be commensurate with the percent of effort. The salaries of clinical nurse and physician investigators will not be covered by research funds. ***NOTE:*** *For NRI, which stipulates that the PI must be a nurse, this means that the PI's salary cannot be paid by research funds.*

(b) Cost of Consultant Services, if any. Current VA rules and regulations limit consultant payments to $500 per consultation or $2,500 per year, exclusive of expenses. Higher amounts must be approved by the Secretary of Veterans Affairs.

1. **Consultation-related Costs.** Consultation-related costs other than professional fees (e.g., consultant travel) should be listed under All Other Expenses.

2. **Curriculum Vitae and Letter.** A curriculum vitae and letter from each proposed consultant, indicating agreement to consult and detailing the nature of the consultation, should be included in the supporting documents.

3. **Equipment Costs.** Equipment costs, if any. List each item of equipment to be purchased. Estimated equipment costs should be consistent with current VA procurement policies and contracts.

4. **Cost of Supplies.** Cost of Supplies, if any. Itemize by major category, e.g., office supplies, printing, etc..

5. **All Other Expenses.** Itemize by major category, e.g., travel, rent, contract fees, IPAs, etc. (see Handbook 1204.5). List estimated travel costs, noting that all requested travel must be related directly to the conduct of the research. Separate the estimates for government employees and other persons, and use government contract airfares and current per diem rates whenever appropriate. Travel and registration costs associated with conference attendance should not be requested. ***NOTE:*** *If the project is funded, HSR&D will consider requests for such travel, especially to present study findings, on a case-by-case basis.* Project funds may not be requested for the purchase of books, journals, reprints, professional membership dues, or cost of manuscript preparation.

e. **VA Form 10-1313-4, Estimated Expenses**

(1) At the top of the form, check "Project."

(2) Personnel. All personnel costs should be straight-lined for the duration of the project. Do not request funds for expected cost-of-living increases, within-grade increases or promotions.

(3) Consultant Services through Total Operating Expenses. For each category, indicate total cost in each project year. Annual costs shown on VA Form 10-1313-3, Current Funds and First Year Request, must match those shown on VA Form 10-1313-4, Estimated Expenses.

(4) Justification of items page 3. Provide detailed justification for each item listed on Form 1313-3, using continuation sheets if necessary. Indicate total FTE requested each year. For each proposed consultant, indicate the nature of the service to be performed, the fee per consultation, the number of consultations, and the amount requested for consultant travel and per diem. Provide justification for each item of equipment, indicating the availability of similar equipment at your facility and nearby research space, and include the cost of maintenance. Travel estimates should be broken out by year, separately for VA employees, employees of other Federal agencies, and project participants who are not government employees. Indicate the destination and purpose of all requested travel. When appropriate, provide a breakout of the project budget by phase and year.

f. **Gantt Chart.** Present the project timeline in Gantt Chart form (see this App. par. 8).

g. **VA Form 10-1313-5, Biographic Sketch.** Complete a VA Form 10-1313-5, for each investigator and collaborator. Start with the PI (and co-PI), followed by co-investigators and other key professional staff (i.e., all persons who will participate in the design, performance, and professional direction of the proposed research, except consultants). Do not submit curricula vitae. For advanced degrees and specialty training, indicate academic discipline(s) and field(s).

h. **VA Form 10-1313-6, Bibliography.** For each investigator and collaborator, provide a chronological list of the most important and pertinent publications (not exceeding two pages and not including publications still in preparation or presentations). Separate technical reports and published abstracts from full articles. Identify any publications that resulted from recent VA research support. If any member of the research team has no publications to report, submit Form 10-1313-6, marked "NONE."

i. and j. **VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending), and and VA Form 10-1313-8, Investigator's Total VA and Non-VA Research Development Support**

(1) Complete a VA Form 10-1313-7 and a VA Form 10-1313-8 for each investigator and collaborator listed on Form 10-1313-3 whose percent of effort on the proposed project is greater than 5 percent. Include all current research funding and all pending requests. For any member of the research team with no current or pending research support, submit forms 1313-7 and 1313-8 marked "None."

(2) Describe on VA Form 10-1313-8 every item listed on VA Form 10-1313-7.

(3) For each investigator and collaborator with any non-VA pending research application(s) or ongoing non-VA funded research project(s), submit project abstract(s) and indicate the percent of effort for all years that overlap with the proposed project. Insert these pages behind VA Form 10-1313-8.

k. and l. **VA Form 10-1223, Report of Subcommittee on Human Studies, and VA Form 10-1086, VA Research Consent Form, and Related Documentation**

(1) Proposals for studies involving human subjects will not be reviewed unless or until approved by the VA facility's Subcommittee on Human Studies or, if none, by the institutional review board (IRB) of the affiliated university. A current (not older than 1 year) VA Form 10-1223 must be submitted along with any university IRB approval form. Review by the Human Studies Subcommittee is to include consideration of compliance with VA policy requiring the inclusion of minorities and women unless an exception has been approved. If the IRB or the VA Subcommittee on Human Studies has found the proposal exempt from review for human subjects' considerations, this finding must be noted in the comments section of VA Form 10-1223. ***NOTE:*** *For multi-site studies, include documentation of IRB approval for each site that has been identified. For sites not yet identified, IRB approval must be forwarded as soon as the site is selected.*

(2) If the human subjects review requires evidence of subjects' informed consent, submit VA Form 10-1086 or a VA-approved university informed consent form.

(3) On a separate page, submit certification of completion of human subjects protection training. ***NOTE:*** *This training is required for each PI and Co-PI every 3 years.* Provide a brief description of the content of the training session.

4. PROPOSAL NARRATIVE

a. The narrative is the heart of the application and the focus of merit review. It must include sufficiently comprehensive and detailed information about the rationale for, goals and methods of, the proposed research to permit serious consideration of the scientific and technical merit of the proposed research. In a clear, well-organized, self-contained narrative, the applicant must explain what is proposed, how it will be done, and why it is important. ***NOTE:*** *The narrative is expected to address any substantive and methodological concerns identified by reviewers of the LOI or any previous version of the proposal.*

b. The full narrative (i.e., see following subpar. 4b(1) through 4b(6)) may not exceed 25 pages. Include:

(1) **Research Objectives (approximately 1 page).** State:

(a) The immediate and long-term objectives; and

(b) The hypothesis(es) or key research question(s).

(2) **Background of Context (approximately 2-3 pages).** Provide evidence from the literature and any pilot studies addressing:

(a) The scientific rationale and theoretical framework for the proposed research. Discuss relevant research, completed or underway (inside and outside VA).

(b) The context in which the study will be conducted and results applied.

(c) How or why this study will succeed in answering questions that have eluded other researchers (e.g., better design, larger sample, longer followup, etc.).

(3) **Significance (approximately 1-2 pages).** Discuss how the proposed research will extend scientific knowledge or enhance the state-of- the-art, and how the results of the study will be useful to VA (and, if applicable, outside VA). Consider the following questions:

(a) How common, serious, or urgent is the problem this research addresses?

(b) How will the proposed research extend knowledge and/or contribute to improved quality, effectiveness or efficiency of VA health care or the health of eligible veterans? How will it enhance health care management or clinical decision-making?

(c) What or who are the audiences for the results of the research, and how might they use the information or product(s)?

(4) **Methods (approximately 15 pages).** Describe the research plan completely and in detail, including the basic study design, sampling plan, control or comparison groups, methods for data collection and analysis, and specific techniques and measures. Specify the kinds or sources of data to be used, how hypotheses will be tested, aggregate and subgroup analyses, and provisions for assuring data quality and adherence to the study protocol. Address:

(a) How is the study design suited to the specific research question(s) and population? What are the advantages and disadvantages of this approach?

(b) Where will the study take place? Why is this setting or geographic location appropriate? Will the results be generalizable to other places or populations?

(c) What are the characteristics of the study population? How will the sample be selected and what steps will be taken to secure and retain the needed number of subjects (and controls, if applicable)? What steps will be taken to ensure adequate representation of women and minorities? What is the estimated sample size and how was it derived? What assumptions were made regarding the magnitude of the expected treatment effect? At what level of power can inferences be drawn?

(d) Identify and define the dependent and independent variables and explain their selection. How will the major variables be measured and how will they be linked in the analysis? Comment on the reliability, validity, and appropriateness of the proposed measures for the study population. ***NOTE:*** *If new or unpublished measures are to be used, the data collection instruments must be submitted as part of the appendix.*

(e) What is the data collection strategy and timeline? What are the potential problems in collecting data and controlling data quality? How will these problems (e.g., missing data, respondent drop-out, interviewer bias) be addressed?

(f) What is the strategy for data analysis? Outline the planned analyses, indicating which variables will be used in which analyses and the order in which analyses will be done (do not merely name proposed statistical tests). What are the strengths and limitations of this analytic strategy?

(g) How will the findings or products of this research be disseminated? Discuss conditions or barriers to implementing the eventual findings or products, and identify any plans and promising mechanisms (beyond professional publications) to facilitate dissemination and implementation.

(5) **Project Management Plan (1-2 pages).** Describe:

(a) The project management plan and timeline (referring to the Gantt Chart).

(b) The facilities and resources required, indicating which are available and which would be obtained if the project is funded. Include space, data processing capacity, access to subjects, access to VA staff and major equipment and/or supplies.

(c) The role and tasks of each member of the research team and how their work will be coordinated.

(d) Any proposed collaboration with institutions or investigators outside the PI's facility and how the work will be coordinated. Include a description of the role of consultants, contractors, and other non-VA employees. Along with the letters of endorsement, include a letter from each person who is from outside the PI's facility, indicating their agreement to participate.

(6) **References.** List complete bibliographic information for all cited references. ***NOTE:*** *Reference pages do not count as part of the 25-page limit.*

5. SUPPORTING DOCUMENTS

a. **Privacy of Information Statement.** All applications must include a letter from the facility Privacy Officer (usually the Chief, Medical Administration Service) identifying the PI's name and project title and providing evidence of due regard for the Privacy Act of 1974 (Public Law 93-579) and intent by the PI to comply. The statement must be signed, dated, and the signer identified by name, title, and affiliation.

b. **Studies Involving Animals, Biosafety Issues, or Radiation.** Studies involving animals, potential biohazards, or radiation have special requirements. Refer to VHA Handbooks 1200.7 and 1200.8 for instructions related to animal protocols and required committee approvals.

c. **Letters of Endorsement.** All letters of endorsement must include the PI's name, project title, and VA facility. They need to be addressed to the Director, HSR&D, and are to be signed and dated. Letters are required from:

(1) The chairperson of the R&D Committee. If the PI is the chairperson of the R&D committee or subcommittee, an appropriate alternate should sign. This responsibility may not be delegated to the Administrative Officer or ACOS for R&D.

(2) The Director of the PI's VA facility and, if the research has Network implications, the Network Director. The letter must indicate that the proposal is not being submitted to any VA funding source other than HSR&D. It should document the Director's understanding that employee appointments and funding for projects supported by R&D are for the duration of the project only. The letter also must indicate the Director's recognition of the potential impact of the proposed research on the facility (including, for example, use of space, equipment, or release time).

(3) Each participating or affected organizational element, institution, collaborator, and consultant indicating their concurrence and their specific role in the project. For consultants (only), also include curricula vitae.

d. **Appendixes.** Information that is critical to the review of the application must be contained in the proposal narrative. Appendices are for material that was prepared, by the applicant or others, independent of the current proposal.

(1) **Data Collection Instruments.** For HSR&D applications proposing the use of unpublished data collection instruments, copies of the instrument(s) should be submitted whenever possible. There is no page limit for instruments; however, if they are multiple or long, applicants may submit sample questions or partial instruments.

(2) **Other Selected Material.** Other selected material that explains or documents a proposed method that is new or unpublished. Total length may not exceed 10 pages.

(3) **Appendix Pages**

(a) All appendix pages are to be numbered consecutively with the rest of the application and included in the Table of Contents.

(b) All appendices must be submitted at the same time as the rest of the application.

6. APPLICATION CHECKLIST

The "HSR&D Application Checklist" (see App. C) appears on the final page of these instructions (detach or photocopy). The checklist is to be completed by the administrative contact for the proposal (i.e., ACOS or Administrative Officer for R&D), who is responsible for ensuring that the proposal is complete.

7. ADDRESS FOR HSR&D APPLICATION PACKAGES

Send complete application package via U.S. mail or commercial delivery to: Health Services Research and Development Service (124F), Department of Veterans Affairs, 1400 Eye Street, NW, Suite 780, Washington, DC 20005. Phone: (202) 408-3661. FAX: (202) 275-0020.

8. SAMPLE GANTT CHART

Project Title: Comprehensive Outcomes of Smoking Cessation in VA					
	Project Period (Fiscal Years)				
	Dates: October 1, 2002 through March 31, 2005				
Activity	**2002**	**2003**	**2004**	**2005**	**2006**
Design questionnaire	---				
Identify respondents	--				
Initial data collection	--------	--			
Analyze results		--------			
Write report		-----			
Refine procedures (based on survey results)		-----			
Collect follow up data		--	----		
Analyze results			-----		
Write articles				----	
Write final report				---	

SAMPLE FORMAT FOR
HEALTH SERVICES RESEARCH AND DEVELOPMENT APPLICATION CHECKLIST

1. Prerequisites:
- ❑ Eligibility of Principal Investigator (PI)(s) established or waiver requested
- ❑ Letter of Intent has been approved and is "active"
- ❑ All sites covered under a current Assurance of compliance with Common Rule
- ❑ PI and/or Co-PI not on Department of Health and Human Services (DHHS) Office of Research Integrity sanctions list

2. Package includes, in the following order:
- ❑ Self-addressed postcard for acknowledgement of receipt
- ❑ For multi-site studies, a separate page that lists all sites in the study
- ❑ VA Form 10-1313-1, Merit Review Application
- ❑ VA Form 10-1313-2, Summary Description of Programs
- ❑ Table of Contents
- ❑ VA Form 10-1313-3, Current Funds and First Year Request
- ❑ VA Form 10-1313-4, Estimated Expenses
- ❑ Project Timeline (Gantt Chart)
- ❑ VA Form 10-1313-5, Biographic Sketch
- ❑ VA Form 10-1313-6, Bibliography
- ❑ VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support (Current and Pending)
- ❑ VA Form 10-1313-8, Investigator's Total VA and Non-VA Research and Development Support
- ❑ VA Form 10-1223, Report of Subcommittee on Human Studies, dated and signed
- ❑ IRB approval for all project sites
- ❑ Certification of completion of human subjects protection training
- ❑ VA Form 10-1086, VA Research Consent Form, if applicable
- ❑ If a resubmission, letter from PI identifying significant changes (max.3 pages)
- ❑ Narrative (no more than 25 pages)
- ❑ Animal Research Protocol Statement, if applicable
- ❑ Biohazard Statement, if applicable
- ❑ Privacy of Information Statement *
- ❑ Research and Development (R&D) Committee Review of Proposal *
- ❑ Letters:
  - (1) Transmittal, from VA medical center Director *
  - (2) Endorsement, from each participating organizational element or institution *
  - (3) Endorsement from each collaborator *
  - (4) Endorsement, and curriculum vitae, from each consultant *

3. Optional: Appendices, including data collection instrument(s)

4. Format and numbers of copies:
- ❑ All pages are numbered consecutively
- ❑ One original of all application materials, with required signatures
- ❑ Single copy of VA Form 10-1313-1 and 10-1313-2, copied back-to-back
- ❑ 30 copies of entire application, including any appendices, copied back-to-back, and securely fastened

* *Original signature required.*

HEALTH SERVICES RESEARCH AND DEVELOPMENT SCORING GUIDE

1. Approval. Approval indicates that the proposed study has potential to produce original, valid, and useful findings regarding one or more important research question(s). The priority score, ranging from 10 to 50, indicates reviewers' overall enthusiasm based on their combined assessment of the study's technical and/or scientific merit, innovation, and importance.

SCORE	ENTHUSIASM	CRITERIA
10 – 15	**Exceptional**	The proposed study is exceptional both in terms of technical/ scientific merit and importance of the research question(s). The results of the study, if carried out as described, would almost certainly contribute to improved health care and the advancement of health services research. Suggested changes, if any, reflect differences of opinion or specialized knowledge on the part of one or more reviewers, not problems or errors in the proposal.
16 – 22	**High**	The proposed study has high to exceptional importance and high to exceptional technical/scientific merit. Any flaws warranting attention are few, minor, and can be easily corrected without further review.
23 – 34	**Moderate**	The importance of the research question(s) is moderate to exceptional, and the overall strengths of the study clearly outweigh its weaknesses; however, one or more significant flaw(s) reduces reviewers' enthusiasm. The research plan needs further development in general or specific changes in approach or methods.
35 – 40	**Marginal**	The importance of the research question(s) is moderate to exceptional, but one or more flaw(s) in design or approach seriously threaten the originality, validity, usefulness, or feasibility of the study. The problems may be remediable in a revised proposal.
41 – 50	**Low**	The research question(s) have only low to moderate importance, and the number or nature of technical/scientific problems do not contribute to reviewers' enthusiasm. A successful revision would entail fundamental changes in conceptualization and approach.

2. Conditional Approval

a. The importance of the research question(s) is "high" or "exceptional" and the plan is solid, but specific technical or scientific issue(s) diminish reviewers' enthusiasm for the project. The

required modification(s) are discrete and limited, and addressing them would not involve fundamental redesign of the study. Further, the limited number and relative simplicity of the required modifications make it reasonable for the investigator to provide the requested response within 4 weeks of receiving the review notification.

b. When reviewers recommend Conditional Approval, they assign a score to represent their overall enthusiasm for the study as if the investigator has made appropriate changes to address the required modifications or to justify the original approach.

c. The investigator's response to the required modification(s) will be reviewed by health Services Research and Development (HSR&D) staff and may be reviewed by one or more reviewers when additional expertise is needed. The individual(s) conducting this review will make a recommendation as to whether the investigator's response is satisfactory.

d. If the investigator cannot respond within 4 weeks, or if the response does not satisfy reviewers, a new proposal (but not a new Letter of Intent (LOI)) must be submitted.

3. Deferral

a. Without additional information and/or clarification regarding specific, limited issues, reviewers cannot make a recommendation whether to approve or disapprove the project.

b. The investigator will be given the opportunity to respond to reviewers' questions. This response will be added to the current proposal for reconsideration at the next scheduled review meeting.

c. No priority score is assigned.

4. Disapproval. No Priority Score is assigned, and it indicates one or more of the following:

a. The study is not original.

b. The research question(s) have only trivial importance or relevance to Department of Veterans Affairs (VA) health care.

c. The research plan has a "fatal flaw."

d. An irremediable error in the scientific design precludes valid findings.

e. Proposes unethical or hazardous procedure, which is irremediable.

f. Completion as described is infeasible.

g. The cumulative effect of several non-fatal flaws precludes the validity or usefulness of the findings.