

## SCIENTIFIC RESEARCH AND DEVELOPMENT PROPOSALS

**1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook describes policies that govern scientific proposals that are submitted to Health Services Research and Development Service (HSR&D) for funding.

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

a. General guidelines for Concept Papers for submission to HSR&D; for submission of proposals for support; for the merit review process as implemented by HSR&D; and for funding for developmental proposals.

b. The common procedures regarding investigator requirements, application procedures, and review policies for HSR&D support of scientific research and development proposals.

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

**4. RESPONSIBLE OFFICE.** The Health Services Research and Development Service (124) is responsible for the contents of this VHA Handbook. Questions may be referred to (202) 254-0207, or by facsimile at (202) 461-1500.

**5. RESCISSION.** VHA Handbook 1204.1, dated May 15, 2002, is rescinded.

**6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before December 31, 2013.

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## SCIENTIFIC RESEARCH AND DEVELOPMENT PROPOSALS

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook describes the procedures that pertain to scientific research and development proposals submitted to Health Services Research and Development Service (HSR&D) for funding, including types of projects, investigator eligibility, application procedures, and scientific merit review.

### 2. PROJECT TYPES

Project support from 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. HSR&D project support is available through two funding mechanisms:

a. **Investigator-Initiated Research (IIR)**. The IIR Program enables eligible Department of Veterans Affairs (VA) clinicians and social scientists to pursue their research goals that advance HSR&D priorities and contribute 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., post-deployment health). 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.

b. **Service-Directed Research (SDR)**. Periodically, HSR&D invites submission of proposals that address a specific research or development need identified by VA Central Office. 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). SDR Concept Papers are reviewed to identify the most competitive applications; Principal Investigators (PI) are then invited to submit a full proposal.

### 3. SPECIAL INITIATIVES AND SOLICITATIONS

Periodically, HSR&D publishes special research solicitations, initiatives, or other types of program announcements to inform the field regarding research priorities and opportunities. These announcements are communicated to the office of Associate Chief of Staff (ACOS) for Research and Development (R&D) at the facility and are posted on HSR&D's web site at: (<http://www.hsrd.research.va.gov>). The announcements expected "lifespan," submission deadlines and review dates, any special requirements, and expected investment are specified. The HSR&D Scientific Merit Review Board (SMRB) may review proposals 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.

a. **Nursing Research Initiative (NRI)**. The NRI, managed by HSR&D for the Office of Research and Development (ORD), solicits proposals from VA nurse investigators who are in the early stages of their research careers to conduct a mentored research project, leading to independence in the PI role. All ORD Services (Biomedical Laboratory Research and Development (BLR&D), Clinical Sciences Research and Development (CSR&D), Rehabilitation Research and Development (RR&D), and HSR&D) accept investigator-initiated proposals as part of the NRI program. NRI proposals adhere to the same application and review policies and procedures as proposals submitted to HSR&D's IIR Program.

(1) Junior nurse researchers with an earned doctorate who hold a VA appointment of at least 5/8 time are eligible to apply. PIs must be guided by a Mentor with a doctorate in nursing, medicine, or another health services related discipline.

(2) The applicant needs to indicate whether the proposed research is most pertinent to the interests of HSR&D, BLR&D, CSR&D, or RR&D. Approved proposals are funded according to the respective Service's funding limits.

(3) The program announcement for NRI is reissued periodically to incorporate any changes in research priorities or administrative requirements. Eligible nurse investigators interested in applying need to refer to the current NRI announcement, available on HSR&D's web site at: (<http://www.hsrd.research.va.gov>).

b. **Quality Research Enhancement Initiative (QUERI)**. QUERI is an ORD initiative, managed by HSR&D, designed to translate research findings, in collaboration with clinical leadership, into optimal patient outcomes and system-wide improvements.

(1) **Service-Directed Proposals (SDP)**. HSR&D invites submission of proposals for projects implementing research into practice to improve care delivery. SDP Concept Papers are reviewed to identify the most competitive applications; PIs are then invited to submit a full proposal. Full proposals must follow guidance provided in the relevant solicitation. Full proposals are reviewed by an ad hoc review panel with appropriate scientific expertise.

(2) **Service-Directed Research (SDR)**. Periodically, HSR&D invites submission of proposals that address a specific research or development need identified by VA Central Office. Depending on the purpose of the research and the timeframe for completion, eligibility to apply may be restricted (e.g., to investigators at established Centers) or there may be special requirements (e.g., matching funds). SDR Concept Papers are reviewed to identify the most competitive applicants, who are then invited to submit full proposals. Full proposals must follow the guidance provided in the relevant solicitation and adhere to the same application policies and procedures as proposals submitted to HSR&D's IIR Program. Full proposals are reviewed by an ad hoc review panel with appropriate scientific expertise.

(3) **Rapid-Response Projects (RRP)**. HSR&D invites submission of pilot projects, pre-implementation projects, small projects that follow-up on recently completed implementation efforts, or projects that respond to a VHA priority issue. Proposals are reviewed by an ad hoc review panel with appropriate scientific expertise.

#### 4. APPLICATION REQUIREMENTS

a. **Eligibility.** Only “eligible” individuals may serve as the 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 a proposal for consideration; however, eligibility must be established before funding for an approved proposal is initiated.

b. **Merit Review Application.** Guidance for preparing a Merit Review application is provided in the VA ORD SF 424 (R&R) Application Guide, which can be found at: <http://www.research.va.gov/funding/electronic-submission.cfm>. Merit Review application requirements for all HSR&D funding must be:

(1) Submitted through formal channels, consistent with all current instructions, and received by the specified due dates.

(2) Strictly adhered to in order for Merit Review applications to be reviewed. **NOTE:** *Applicants are strongly encouraged to obtain assistance from their local research office regarding administrative, scientific, and technical issues.*

#### 5. CONCEPT PAPERS

a. Some solicitations require submission of a Concept Paper. These brief, preliminary papers are reviewed in order to determine relevance to program goals and soundness of the research plan. Approval of the Concept Paper is a prerequisite to submitting a full research proposal to HSR&D.

b. The Concept Paper is to be submitted by the PI through the local R&D office. The required signature of the ACOS for R&D signifies local review and ensures, at a minimum, local support and conformance to current VA Central Office guidelines.

c. All Concept Papers must be prepared and submitted in accordance with instructions published in the announcement and received by the applicable due date.

d. Scientific merit review is conducted by an ad hoc panel of peer reviewers.

e. Results of the Concept Paper review are provided to the applicant; however, revision and resubmission of the Concept Paper are not generally options.

f. Once notified of Concept Paper approval, the applicant is encouraged to submit a full application package by a pre-specified deadline. Full proposals must follow guidance provided in the relevant solicitation and adhere to the same application policies and procedures as proposals submitted to HSR&D’s IIR Program.

## 6. MERIT REVIEW APPLICATIONS

This paragraph provides general guidance regarding submission of Merit Review applications for support through HSR&D. Specific guidance is provided in the VA ORD SF 424 (R&R) Application Guide, which can be found at:

<http://www.research.va.gov/funding/electronic-submission.cfm>. *NOTE: Applicants are strongly encouraged to obtain assistance from their local research office regarding administrative, scientific, and technical issues.*

### a. **Requirements for Principal Investigator (PI)**

(1) **Eligibility.** Any PI of a proposed research study must meet VA eligibility criteria before funding is initiated (see VHA Handbook 1200.15). A prospective PI who is not currently eligible may submit a proposal for consideration; however, eligibility must be established before funding for an approved proposal is initiated.

(2) **Good Standing.** Investigators must fulfill their obligations to complete final reports for any previous HSR&D-funded projects and have followed all requirements regarding properly reporting publications before a new proposal is reviewed.

(3) **Multiple PIs on a Project.** HSR&D allows up to three PIs to be recognized on the proposal. Request for multiple project PIs must be approved by the Director, HSR&D, prior to the submission of the proposal. Responsibility and accountability for the conduct of the project is shared equally by each PI. One PI, designated as the “Corresponding PI” is responsible for communicating with HSR&D staff about project-related scientific, administrative, and ethical issues and for being the point of contact for communications from VACO. It is the responsibility of the Corresponding PI to disseminate communication from VACO to the other PIs and project staff.

(4) **Human Subjects Protection Training.** All individuals applying for VA research project funding are required to complete an approved course in human subjects protection. Once a proposal using human study participants has been approved for funding, all study personnel listed on the project must take currently required Human Subjects Protection training. All training must meet current ORD human subjects protection requirements. It is the responsibility of the ACOS for R&D to ensure that all study personnel have received human subjects protection training, to maintain the original training certificates locally, and to ensure that all annual training requirements are met. For multi-site studies, it is the responsibility of the ACOS for R&D, at each site, to maintain the original training certificates and to ensure that all annual training requirements are met for study personnel located at each facility.

(5) **Certification of Storage and Security of VA Research Information.** The PI must certify that the use, storage, and security of all research information collected for, derived from, or used during the conduct of the research is in compliance with all VA and VHA requirements. A copy of the “Principal Investigator’s Certification “Storage and Security of VA Research Information” is required prior to funding and is available on the ORD web site at:

<http://www1.va.gov/resdev/resources/policies/cybersecurity.cfm>. Any questions regarding this issue needs to be directed, using electronic mail, to: [researchdata@va.gov](mailto:researchdata@va.gov).

b. **Required Approvals.** All proposals submitted to HSR&D must be approved by the local R&D Committee, and if human subjects are involved, by the Institutional Review Board (IRB) at the VA facility.

(1) **R&D Committee.** See VHA Handbook 1200.1.

(2) **IRB.** Most HSR&D studies involve human study participants or the use of personal data. To ensure proper protections, proposals for all studies involving human study participants must be approved by the IRB. IRB approval at each site of a multi-site study must be obtained before funds are distributed to that site. It is the PI's responsibility to renew IRB approval annually for active projects. Every site included in the proposed research must hold a current Assurance of Compliance with provisions of the Federal Common Rule.

c. **General Instructions**

(1) **Intent to Submit.** HSR&D may require notification of an investigator's intent to submit a proposal for merit review. The responsibility for a complete, properly formatted, and timely submission of HSR&D's Intent to Submit information and a proposal abstract lies with the R&D Office at the originating VA facility. The Intent to Submit and Abstract must be submitted by the designated deadline in order for a proposal to be reviewed. Proposals that have not complied with this requirement will not be accepted for review. *NOTE: Current information as to the correct format and current submission deadlines can be found at HSR&D's web site at: <http://http://www.hsr.d.research.va.gov>.*

(2) **Receipt Dates.** Application deadlines for review by HSR&D's Scientific Merit Review Board (SMRB) are posted on HSR&D's web site at: <http://www.hsr.d.research.va.gov>. The same receipt dates apply for new and revised applications.

(3) **Proposal Limit.** A PI may submit more than one application to HSR&D per review cycle; however, an application that is submitted to HSR&D may not be submitted to any other component of VA's ORD (i.e., BLR&D, CSR&D, or RR&D).

(4) **Revised Proposals.** Proposals that are approved by HSR&D's SMRB (or one of its subcommittees), but are not funded, may be revised and submitted for a new review.

(a) A revised proposal is expected to address explicitly the issues highlighted in the Summary Statement, which were raised by reviewers of the previous proposal.

(b) HSR&D allows a total of three proposal submissions: the original submission and two resubmissions. All resubmissions need to be received within 2 years of the original submission date (five annual merit review cycles). If the proposal has not been funded within 2 years of the original submission date, the project will not be reviewed.

(5) **Withdrawal.** Withdrawal of an application once Intent to Submit information has been submitted requires formal notification by the ACOS for R&D to VA Central Office. *NOTE: An e-mail notification from the ACOS for R&D is acceptable.* The contact person for this communication is the Merit Review Program Manager (124R).

(6) **Corresponding PI.** The Corresponding PI, or "applicant," is the individual who has principal responsibility for the scientific and technical direction of and the completion of the research. The Corresponding PI is responsible for the appropriate expenditure of project funds and for ensuring that the project and staff complies with all governing regulations.

(7) **Communication.** All communication about the proposal must be directed to the ACOS for R&D with a copy to the Corresponding PI. It is the responsibility of the Corresponding PI to ensure that all communications are forwarded to project staff.

(8) **Proposal Content and Format.** Proposals are to be prepared using current instructions and required Merit Review forms. Once a proposal has been received, additional or replacement information or supporting letters 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. An incomplete or non-compliant application may be returned without review.

(9) **Regulations Governing Research Involving Human Subjects.** All research involving human subjects must comply with all Federal regulations and VA requirements that address the protection of human subjects. The Common Rule is codified by VA at 38 CFR Part 16, and by the Department of Health and Human Services (HHS) at 45 CFR Part 46, Subpart A., and VHA Handbook 1200.5.

(a) Monitoring Safety. All interventional proposals submitted to HSR&D must contain a research plan that includes adequate provisions for monitoring the data collected to ensure the safety of human subjects (38 CFR 16.111 (a)(6)). The plan must include establishing a Data Monitoring Committee (DMC). In addition, interventional studies that are multi-site and randomized may require oversight by HSR&D's Data Safety and Monitoring Board (DSMB). The research plan must include a plan for reporting DSMB or DMC findings to the IRB. The IRB must always carefully review the proposed data and safety-monitoring plan.

(b) Data Safety Monitoring Plan. The data safety monitoring plan must include the information that is to be collected and the information to be sent to the DMC or the DSMB. It must be based on the level of risk and at minimum contain:

1. What safety information will be collected including adverse events and serious adverse events.
2. How the safety information will be collected (what case report forms, what study visits, etc.).
3. The frequency of data collection (when safety data collections starts and how it will be collected such as at study visits, through telephone calls with participants).

4. Procedures for reporting adverse events to the IRB.
5. The frequency of periodic review of cumulative safety data.
6. The statistical tests for the safety data to determine if harm is occurring.
7. Provision for the oversight of safety data, such as by the DMC or DSMB.
8. Conditions that will trigger an immediate suspension of investigational treatments.

(c) Data Monitoring Committee (DMC) or Data Safety Monitoring Board (DSMB).

Dependent on the risk, single site studies may be monitored by a local DMC. Multi-site, randomized interventional studies may need to be monitored by HSR&D's DSMB. The charge of the DMC or DSMB must include:

1. Determining the continued safety of research subjects based on the data submitted to the DMC or DSMB.
2. Meeting at least once per year. *NOTE: HSR&D or the IRB may determine that the DMC or DSMB must meet more frequently based on the potential risks to the subjects.*
3. The written report and minutes of the DMC or DSMB must be forwarded to the PI, the IRB and HSRD within 14 days of each meeting.

(10) **Funding Consideration.** HSR&D gives special consideration to proposals that are responsive to targeted priority research areas specified in HSR&D's solicitations. Current solicitations describing research priorities are available on HSR&D's web site at: <http://www.hsr.d.research.va.gov> . The PI must indicate if the proposal is responsive to a particular solicitation. Reviewers and HSR&D Scientific Program Managers evaluate whether the justification provided by the PI adequately supports identifying the proposal as responsive to a particular solicitation.

(11) **Local Approvals.** All required forms, approvals, and endorsements must be submitted by the PI's VA facility.

(12) **Transfer of PI.** The PI, through the local R&D office, must notify the assigned HSR&D Scientific Program Manager in advance of an expected transfer to another facility. The PI must recognize that a transfer may delay review of the application or the start of the project. If a PI transfers to another VA facility after an application has been submitted, new approvals and endorsements must be obtained.

(13) **Off-site Research.** An investigator who plans 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).

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

(15) **Inquiries.** Questions about administrative issues on the application process need to be directed to the Office of the ACOS for R&D or Coordinator for R&D at the applicant's facility. The Administrative Officer or ACOS for R&D may communicate with the Scientific Merit Review Program Manager if clarification or additional information is required. Questions regarding scientific issues may be directed to the appropriate Scientific Program Manager.

## 7. MERIT REVIEW

This paragraph provides guidance on the merit review process as managed 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 proposals and the integrity of its programs. Each application is evaluated by a multidisciplinary group of experts, from inside and outside VA, who constitute the SMRB or one of its subcommittees. The recommendations of the SMRB, the priority scores for approved proposals, and reviewers' specific comments guide the decisions of VA research administrators regarding which proposals to fund. In addition, VA research administrators consider VA priorities, responsiveness of the proposed work to solicitations, and the significance and importance of the research to veterans and veterans' health care.

(2) The scientific review process is essential to funding the best science. Reviewers' assessments and suggestions are communicated to applicants to help them understand the SMRB's recommendations, to improve already strong proposals, and to assist applicants who may wish to revise and resubmit their application.

### b. Scientific Merit Review Board (SMRB)

#### (1) **SMRB and Subcommittees**

(a) HSR&D merit review is carried out by the SMRB, consisting of several subcommittees. Each subcommittee has a chairperson. SMRB consists of a multidisciplinary panel of experts, each of whom is appointed for a 4-year term. Members are researchers and clinicians from within VA and external to VA with expertise appropriate to the review group. If additional expertise is required beyond that readily available on the SMRB, ad hoc reviewer(s) with appropriate expertise are utilized.

(b) SMRB 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 attend the opening announcements and instructions. During review of research proposals, deliberations are confidential, and the meeting is closed to the public. **NOTE:** *As a learning opportunity, HSR&D may permit VA researchers to observe portions of the review session that are closed to the general public. Observers must adhere to the same confidentiality and conflict of interest policies as the reviewers.*

**(2) Review Schedule**

- (a) SMRB reviews IIR proposals at least twice each year.
- (b) SDR and IIR proposals with special receipt dates are reviewed as specified in the relevant solicitation.

**(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. All reviewers who identify a real or perceived conflict of interest are recused from the review and discussion of the identified proposal with which they have a conflict. All reviewers without a conflict of interest are expected to read and participate in the review of each 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 they are 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 sent to the applicant, along with notification of the review outcome and a summary of the discussion at the review meeting written by HSR&D staff.

**c. General Review Criteria**

**(1) Adequacy of Response to Previous Feedback Provided by HSR&D Regarding the Proposed Study.** If the proposal is a re-submission, the applicant will have received detailed comments on the previously submitted proposal. Any subsequent proposal is expected to highlight changes made in response to such feedback or to defend the earlier plan.

**(2) Responsiveness to Research Priorities Solicitations.** HSR&D may give special funding consideration to proposals that are responsive to HSR&D or ORD solicitations for research.

- (a) Investigators must indicate if a proposal is responsive to a particular solicitation.
- (b) Reviewers evaluate whether the justification provided by the investigator adequately supports identifying the proposal as responsive to a particular solicitation.

**(3) Scientific Significance and Originality**

(a) Reviewers assess the scientific significance, theoretical foundation, and originality of the stated goals, objectives, and specific research questions or hypotheses.

(b) Reviewers consider the proposed research 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.

(4) **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 versus prospective, experimental, quasi-experimental, etc.);
- (b) Analytical approach (quantitative, qualitative, mixed methods);
- (c) Theoretical model and conceptualization of key components;
- (d) Population and sample, sampling plan, or comparison groups;
- (e) Statistical power. *NOTE: Power calculations need to be described in terms of clinical significance, if appropriate;*
- (f) Key variables and their measurement;
- (g) Data analysis plan;
- (h) Data collection issues, including respondent burden; and
- (i) Definition and feasibility of any intervention.

(5) **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. Secondary data issues to be considered 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. For all types of data, reliability, validity, and adequacy of quality control procedures are important issues.

(6) **Project Organization and Management.** Reviewers address the overall organization and management of the project to evaluate whether the initiation, conduct, and completion of the proposed research are feasible. Factors that may be considered are:

- (a) Distribution of roles and responsibilities across project staff;
- (b) Justification of Full-time Equivalent (FTE) employee 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.

(7) **Investigator Qualifications.** Reviewers assess the expertise of each investigator and each major consultant, including 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.

(8) **Study Participants.** Reviewers consider the risk to benefit ratio of the study, analyzing whether the study places human participants at risk of physical or psychological harm and evaluating 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. In considering human study participant issues, reviewers may question the decision of an IRB and may impose a stricter standard (see VHA Handbook 1200.5).

(9) **Inclusion of Women and Minorities.** VA mandates that all research proposals reviewed and funded by ORD include women and minorities in their study populations to the extent possible. 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.

(a) This requirement is a criterion considered during the scientific peer review of all research proposals. HSR&D reviewers are also responsible for considering the adequacy of representation, and they may not concur with a decision by the local R&D Committee. In recognition of the importance of the inclusion of these groups in VA research, as well as the challenges in recruiting sufficient numbers of veterans from these groups in order to conduct statistically-valid analyses, investigators are encouraged to consider special recruitment efforts and oversampling of these study populations in all research proposals that have relevance to women and/or minority veterans. This would include research that can inform and improve the health and health care of women veterans and/or minority veterans; for diseases, disorders, conditions and services that are particularly relevant, or of disproportionate or special impact; or where there are known or potential gender and racial, ethnic, and cultural disparities or differences. It is anticipated that additional sampling will facilitate analyses by gender, race and ethnicity, enabling subgroup analyses and additional research findings by gender and minority group. These analyses will lead to improved interventions to reduce disparities among veterans.

(b) The SMRB continues to assess whether investigators have made a substantive effort to include women and/or minorities in their research proposals. This policy applies to all research activities involving human subjects or human specimens and/or tissues conducted completely or partially in VA facilities or in approved off-site locations.

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

(11) **Budget.** Project budgets need to be appropriate to the proposed work, sufficiently detailed, and well-justified. Reviewers assess the reasonableness of the project timeline and costs allocated to major budget categories. Personnel costs and whether proposals 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. Prior to any funding decisions, all proposals under consideration will undergo administrative review of budgets by HSR&D staff. This review ensures that VA research funds are not used for any inappropriate purposes, such as patient care, salaries of Title 38 employees, and development proposals that lack a strong evaluation component.

(12) **Importance of the Problem Addressed.** Reviewers assess the importance of the problem or question that the proposed research seeks to address, in terms of its prevalence, severity, urgency, cost, etc., for VA and the general public. The importance of the problem is assessed independently of the investigator's approach.

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

d. **Reviewer Recommendations and Priority Scores**

(1) At the conclusion of discussion on each proposal, reviewers make a motion to recommend approval, conditional approval, or disapproval, 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. The committee's recommendation for each proposal and the mean priority score are critical elements in funding decisions made by the Director, HSR&D.

(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 a previous review.

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

(1) **Preliminary Notification.** 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 priority score for each proposal from that facility. Priority scores should not be construed as funding decisions. Funding decisions are based on scientific merit review score, responsiveness to funding priorities, veteran centricity, and availability of funds.

(2) **Written Notification of Review Results**

(a) Written notification of the results of merit review generally is sent to the ACOS for R&D within 6 weeks after each review meeting. The notification includes the review committee's recommendation (i.e., approval, conditional approval, or disapproval), priority score, and funding decision (unless the proposal received conditional approval). Copies of the letter are sent to the Corresponding PI and the Director of the Center of Excellence (CoE) or Research Enhancement Award Program (REAP), if applicable. Included with the notification letter, is 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 redacted copy of all written critiques with identifiers removed.

(3) **Questions about Reviews and/or Conditional Approvals.** HSR&D's assigned Scientific Review Administrator 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 either disapproved or approved but not funded after three proposal reviews may appeal the recommendation of the review board and request a new review of the current proposal. The appeals process is to be used only to contest potential procedural errors, not to resolve differences on scientific points of view between the applicant and the reviewers. An appeal may be appropriate when, in the opinion of the investigator, the SMRB did not understand the research, missed relevant points, or was biased. A discrepancy between the conclusions of previous and current review SMRB, unless due to an error or oversight by reviewers, is not grounds for an appeal.

(2) The appellant needs to prepare a formal letter that identifies the specific points of 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. The appeal must be based only on information that was part of the original proposal; incorporation of new data is not allowed.

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

(4) If HSR&D determines that the appeal is appropriate, staff will arrange for a new review by scientists with relevant expertise, who were not involved in the disputed review. The review is based on the original proposal as provided to the review board. Additional information and clarification, including the PI's rebuttal letter, are not shared with the ad hoc reviewers. This ad hoc review group makes a recommendation regarding approval or disapproval to the Director, HSR&D, and assigns a priority score if the proposal is approved. This recommendation, priority score, and HSR&D Director's decision will be promptly communicated to the facility Director, ACOS for R&D, and PI.

## 8. HSR&D FUNDING FOR “DEVELOPMENT”

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. The following guidance clarifies the nature and extent of “developmental” work that may be supported with HSR&D funds.

(1) HSR&D-IIR funding support is appropriate either for developing new methods and tools for conducting research or for evaluating existing methods and tools.

(2) All development work supported through HSR&D’s IIR program is expected to:

- (a) Meet established standards of scientific peer review and applicable review criteria; and
- (b) Be submitted with a well-developed evaluation plan.

b. **Appropriate HSR&D IIR Support for Development.** 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, and
- (7) Efficacy studies of processes of health care delivery (but not efficacy studies of new or evolving clinical procedures).

c. **Non-appropriate HSR&D IIR Support for Development.** HSR&D-IIR support is not appropriate for:

- (1) Synthesizing existing evidence into clinical practice guidelines or patient or provider educational materials,
- (2) Computer algorithms or reminder systems, databases or registries, or computer software, unless specific to a scientific research aim,

(3) Clinical or surgical techniques or diagnostic tests unless related to specific process of health care delivery,

(4) Drugs, equipment, and 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.*

d. **Exceptions**

(1) Development that normally would not be funded but constitutes a relatively small portion of the total time and budget requested for the entire project may also be appropriate for HSR&D funding (i.e., minor development with the primary focus on evaluation).

(2) 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.