DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF RESEARCH & DEVELOPMENT

HEALTH SERVICES RESEARCH AND DEVELOPMENT PROGRAM GUIDE, 1204.01

As of January 1, 2017, the Health Services Research and Development (HSRD) Merit Review Award Program Directive (1204), Handbook (1204.01) and Operational Procedures (1204.05) have been replaced with this HSR&D Program Guide. This Program Guide replaces all prior official ORD guidance to the Health Services Research and Development Program.

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CONTENTS

HEALTH SERVICES RESEARCH & DEVELOPENT PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) Program Guidebook describes the infrastructure and operations of the VA Health Services Research and Development (HSR&D) Program as well as procedures that pertain to scientific research and development proposals submitted to HSR&D for funding consideration, including project types, investigator eligibility, waiver requirements, application procedures, and scientific merit review.

2. HSR&D ORGANIZATION

Recognizing the need to maintain and build a strong pool of investigators, HSR&D makes a significant investment in the operation of programs to build health services research capacity within VA.

a. **Centers.** HSR&D provides infrastructure support, including costs for some personnel, supplies and equipment, and for locally initiated research activities to sites through its Center of Innovation (COIN) mechanism. COINs develop their own research agenda in consultation with VA national operations' program partners and collaborate with local universities, medical schools, and schools of public health. Each HSR&D COIN has a large, multidisciplinary team of investigators with the intellectual resources and logistical support to develop and pursue long-term programs of research and to nurture young investigators. COINs are awarded and renewed based on competitive review, and include a strong national pool of clinician and non-clinician researchers, available both as potential collaborators or consultants to other researchers in VA and throughout the health services research community, and as advisers to HSR&D Central Office. More information on HSR&D Centers is available at http://www.hsrd.research.va.gov/centers/default.cfm

b. **Quality Enhancement Research Initiative (QUERI).** QUERI is a systematic, national effort that supports VHA in the more rapid implementation of research into practice using quality improvement methods in order to improve veteran care. While administratively housed under HSR&D, QUERI is funded through clinical dollars, enabling QUERI to deploy more time-sensitive, non-research protocols in response to national VA priorities, per VHA Handbook 1058.05 VHA Operations Activities That May Constitute Research. QUERI funds a national network of Programs that address cross-cutting VHA priority goals, including women's health, mental health, homelessness, rural health, care coordination, long-term care, medication safety, antimicrobial resistance, pain management, and personalized care. QUERI also co-funds with operations' leaders Partnered Evaluation Initiatives that focus on national evaluations for high-priority topics, including caregiver support, health equity, and diffusion of innovative technologies. QUERI Evidence Synthesis Program (ESP) Centers provide VA leaders with comprehensive, timely syntheses of targeted topics that inform clinical best practices and policy. More information is available at: http://www.queri.research.va.gov/

c. **Resource Centers.** HSR&D's Resource Centers provide technical assistance and consultative services to VA researchers and others in Central Office and the field.

Each of the Resource Centers provides specific expertise such as knowledge of organizational and management issues, the use of VA databases (and big data) in research, and the conduct of economic analyses. HSR&D's extensive research dissemination program is also managed by a Resource Center.

3. HSR&D MERIT REVIEW

Project support from HSR&D is based upon 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 primarily through two funding mechanisms: Investigator Initiated Research (IIR) mechanisms which include research on VA-relevant topics identified by the investigators or developed in response to one of HSR&D's program announcements highlighting current research priorities; and Service-Directed Research (SDR) projects, which are responses to specific research or development needs identified by HSR&D, ORD, or other offices within VHA, to strengthen or complement VA's health services research enterprise.

a. **Investigator-Initiated Research (IIR).** The IIR Program enables eligible Department of Veterans Affairs (VA) clinicians and non-clinician 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 (e.g., health care organization, cost, quality, and access), as well as emerging areas and current topics (e.g., implementation science, post-deployment health, community-based care, etc.). 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. A pilot IIR mechanism is also available. For more information on current HSR&D research priorities please visit: http://www.hsrd.research.va.gov/.

b. **Career Development Awards (CDA).** HSR&D's Career Development program is an intramural funding mechanism designed to attract, develop, and retain talented VA-ORD researchers in areas of particular importance to VA. In this Program both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to advance awardees toward independence as funded VA-ORD scientists. Implicit in all Career Development applications is the understanding that the applicants plan to continue their careers within VA. The CDA award provides salary and project funds (to eligible applicants) to support a three- to- five year program of research career development and mentoring. Applicants must demonstrate a high degree of potential in their area of interest and a strong VA commitment. By the end of the CDA, it is anticipated that the awardees will have competed for independent research funding and have secured long-term appointments at the VA.

c. **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). SDRs may involve a planning phase in which concept papers are solicited to support specific research and development work (e.g., research methods/measurement development, data source acquisition and validation, program tools etc.). Concept papers are reviewed to identify the most competitive applications; Principal Investigators (PIs) are then invited to submit a full proposal.

d. **Other HSR&D Solicitations.** HSR&D also publishes special research solicitations to inform the field regarding research priorities and opportunities. These announcements are communicated to the office of the Associate Chief of Staff (ACOS) for Research and Development (R&D) at the facility and are posted on HSR&D's website at: http://www.hsrd.research.va.gov/). 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 program guide are applicable.

4. HSR&D APPLICATION REQUIREMENTS

This paragraph provides general guidance regarding submission of Merit Review, Service-directed Research, CDA, or other 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. A 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 staff.

(4) **Human Subjects Protection Training.** All individuals applying for VA research project funding are required to complete an approved course in human subject research 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 subject research protection training. All training must meet current ORD human research subjects' protection requirements. It is the responsibility of the ACOS for R&D to ensure that all study personnel have received human subject research 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) **Required Approvals.** All proposals submitted to HSR&D must be approved by the local R&D Committee and by the Institutional Review Board (IRB) at the VA facility if the study meets the definition of human subject research, before a start date is confirmed and funding is disbursed to the field.

(a) R&D Committee**.** See VHA Handbook 1200.01.

(b) IRB**.** Most HSR&D studies involve interactions with human subject research participants or the use of their personal identifying data. To ensure proper protections, proposals for all studies involving human subject research participants or their personal identifying data 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 Federal Wide Assurance (FWA) of Compliance with provisions of the Federal Common Rule.

b. **General Instructions for Proposals.**

(1) **Intent to Submit**. HSR&D requires notification of an investigator's intent to submit a proposal for merit review. The responsibility for a complete, properly formatted, and timely submission of HSR&D's Intent to Submit 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:*** *Information as to the correct format and current submission deadlines can be found at HSR&D's web site at: http://http://www.hsrd.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.hsrd.research.va.gov . The same receipt dates apply for new and revised (resubmissions) 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., QUERI, BLR&D, CSR&D, or RR&D)**.**

(4) **Revised Proposals.** Proposals that receive highly competitive scores from an HSR&D SMRB subcommittee and are recommended for approval, but are not funded, may be revised and submitted for a new review. A revised proposal is expected to

explicitly address the issues highlighted in the Summary Statement, which were raised by reviewers of the previous proposal. 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 approved requires formal notification by the ACOS for R&D to HSR&D VA Central Office. ***NOTE:*** *An e-mail notification from the ACOS for R&D is acceptable.* The contact person for this communication is the Scientific Merit Review Program Manager (10PH).

(6) **Communication.** All communication about the proposal from HSR&D will 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.

(7) **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.

(8) **Regulations Governing Research Involving Human Subjects**. Research involving human subjects must comply with all Federal regulations and VA requirements that address the protection of human subjects in research. 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.

(9) **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) and plans for ensuring data privacy/security. In addition, interventional studies that are multi-site and randomized may require oversight by HSR&D's Data and Safety 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.

(10) **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:

(a) What safety information will be collected including adverse events and serious adverse events? How the safety information will be collected (what case report forms, what study visits, etc.)?

(b) The frequency of data collection (when safety data collections start and how it will be collected such as at study visits, through telephone calls with participants).

(c) Procedures for reporting adverse events to the IRB.

(d) The frequency of periodic review of cumulative safety data.

(e) The statistical tests for the safety data to determine if harm is occurring.

(f) Provision for the oversight of safety data, such as by the DMC or DSMB.

(g) Conditions that will trigger an immediate suspension of investigational treatments.

(h) 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 a process for determining the continued safety of research subjects based on the data submitted to the DMC or DSMB, and plans for meeting at least once per year. ***NOTE:*** *HSR&D or the IRB with oversight authority for the study may determine that the DMC or DSMB must meet more frequently based on the potential risks to the subjects.* 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.

(11) **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: www.hsrd.research.va.gov

(12) **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.

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

(14) **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.

(15) **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 full waiver to perform the research entirely off-site or a partial waiver to perform the research off-site part-time (e.g., one specific component of the research cannot be completed within the VA).

(16) **Intellectual Property.** For information on Invention Disclosures and Transfer of New Scientific Discoveries. Refer to VHA Handbook 1200.18

(17) **Inquiries.** Questions about administrative issues pertaining to the application

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

5. MERIT REVIEW PROCESS

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 are maintained. Each application is evaluated by a multidisciplinary group of experts, from inside and outside VA, who constitute the Scientific Merit Review Board (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. 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 applications.

a. **HSR&D SMRB and Subcommittees.** 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. SMRB is a chartered VA advisory 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.

b. **Review Schedule.** SMRB reviews IIR proposals at least twice each year. SDR and IIR proposals with special receipt dates are reviewed as specified in the relevant solicitation.

c. **Reviewer Responsibilities.** 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. 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.

d. **Review Criteria.** *Refer to specific HSR&D solicitations (RFAs) for 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 Priority Solicitations.** HSR&D may give special funding consideration to proposals that are responsive to HSR&D or ORD solicitations for research. Investigators must indicate if a proposal is responsive to a specific solicitation. Reviewers evaluate whether the justification provided by the investigator adequately supports identifying the proposal as responsive to the specific solicitation.

(3) **Scientific Significance and Originality.** Reviewers assess the scientific significance, theoretical foundation, and originality of the stated goals, objectives, and specific research questions or hypotheses. 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, 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 Employee (FTEE) 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 1200.05).

(9) **Inclusion of Women and Racial/Ethnic groups.** VA mandates that all research proposals reviewed and funded by ORD include women and members of

different racial/ethnic groups in their study populations to the extent possible. 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 veterans and those of different racial/ethnic groups.

(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.

(a.) Request for a **waiver to exceed the current published budget cap** must be approved in advance of application submission and included as an attachment to the application in Grants.gov. *Refer to specific HSR&D solicitations (RFAs) for instructions on waiver preparation.*

(b.) Request for a **waiver to exceed 30% of total project costs for IPAs** must be approved in advance of application submission and included as an attachment to the application in Grants.gov. *Refer to specific HSR&D solicitations (RFAs) for instructions on waiver preparation.*

(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 VA.** 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.

e. **Reviewer Recommendations and Priority Scores.**

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. 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.

f. **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.** Written notification of the results of merit review generally is sent to the ACOS for R&D. 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, if applicable, the Director of the Center of Innovation (COIN). 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 Officer is available to discuss with the PI any questions about the individual critiques, the summary statement, or a conditional approval.

g. **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.

(4) Any appeal needs to be received by VA Central Office HSR&D **within 6 weeks of written notification of the review results**.

(5) The original appeal must be sent to the Director, HSR&D (10PH), VA Central Office, 810 Vermont Avenue, NW, Washington, DC, 20420, with copies via VA email to the Director, Deputy Director, Administrative Officer and the Scientific Merit Review Board Program Manager.

(6) 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 upon 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.

6. POST-AWARD PROCESS

a. Communication with HSR&D Central Office.

Field-initiated written communication with VA Central Office regarding any HSR&D activity needs to be signed by the Medical Center Director or Chief Executive Officer, and addressed to the appropriate person within HSR&D. In addition to requirements of the Office of Research and Development (ORD) for routing written communications through the facility Associate Chief of Staff (ACOS) for Research and Development (R&D), correspondence to HSR&D VA Central Office from a site where there is a co-located HSR&D Center of Innovation (COIN) needs to be routed through that HSR&D Center's Principal Investigator (PI). All formal communications are to be sent to the primary addressee using VA e-mail.

(1) In limited circumstances, investigators may initiate contact with HSR&D VA Central Office staff. Advice needs to be sought first from the facility ACOS for R&D, the Administrative Officer (AO) for R&D or the HSR&D COIN PI, if the investigator is at a site with a co-located HSR&D Center. Investigator-initiated contact with HSR&D VA Central Office staff is appropriate when the matter concerns professional or scientific issues.

b. Circumstances Requiring Formal Communication.

Requests for all types of R&D program or project support require concurrence by the facility ACOS for R&D and the signature of the medical center Director. Formal written communication includes, but is not limited to:

(1) Requests for supplemental project funding,

(2) Requests for bridge or other supplemental funding,

(3) Requests to transfer funding from one site to another,

(4) Requests to transfer a project from one site to another,

(5) Requests for a change in PI,

(6) Requests for major changes in project objectives,

(7) Requests for no-cost extensions affecting award termination date, and

(8) Appeals of decisions affecting resources.

(a) In addition, HSR&D requires a formal written request for all types of HSR&D program or project support, including COIN and investigator travel, and for any significant change in a funded project (see par. 8). All formal communication regarding HSR&D matters requires concurrence by the facility ACOS for R&D and the HSR&D Center PI (if applicable), and the signature of the medical center Director.

(b) HSR&D must be notified by the ACOS for R&D, through the facility Director, prior to research staff participation in any Congressional testimony, or other important project assignments, work group tasks, or other activities requested by VHA Central Office, the Veterans Integrated Service Network (VISN), etc.

c. **Exceptions**. Requests for resources that do not require approval by the medical center Director include:

(1) Requests for supplemental funds to cover actual travel costs related to VA Central Office-directed travel; and

(2) Responses to oral inquiries initiated by ORD or HSR&D.

d. **Informal Communication.** Informal communication includes in-person or telephone conversations and e-mail correspondence. Facility R&D staff, or HSR&D Center administrative staff, may initiate informal contact with HSR&D's staff assistants for field operations or the appropriate HSR&D program manager for advice, technical assistance, or guidance. E-mail communications may be included as part of the project file documentation.

7. FINANCIAL OPERATIONS

a. **Project Funding.**

Within approximately 8 weeks of each scientific review meeting, HSR&D notifies applicants regarding funding of projects. Decisions to fund a research project are based on the recommendations of the applicable merit review panel, the priority score, program

priorities, and the availability of funds. Human subject research may not commence nor will funds be disbursed to the field until all Just-in-Time documentation has been received by HSR&D. Multi-year activities are funded with the expectation that support will continue through the entire period approved by the review board; however, support beyond the current fiscal year is contingent upon HSR&D's future budget and on the project's satisfactory progress. The Director, HSR&D, makes all funding decisions, and all decisions are final.

(1) **Disbursement.** All funds disbursed within a given fiscal year are expected to be obligated by end of the fiscal year. If there is a delay in expending funds, HSR&D finance must be notified as soon as possible, but no later than July 1st.

(2) **Use.** Project funds must be used for the purposes described in the proposal application.

b. **Travel**

(1) **Locally-Directed Travel.** HSR&D travel funds are very limited. Locally-directed travel is allocated to the VA medical center for approved, designated purposes. The Medical Center Director may authorize employee travel expenditures from funds allocated by HSR&D in accordance with VA policies. Authorized travel from HSR&D funds must be for:

(a) Travel essential for the conduct of a research project. Funds for travel that is necessary for the conduct of a project need to be itemized in the proposal budget and must be approved prior to allocation of funds.

(b) Participation in, or oversight of, multi-site research.

(c) Attendance at a professional meeting to present HSR&D data, or to participate in an organized discussion of medical, scientific, or technical subjects pertinent to the investigator's HSR&D work.

(d) Training in the use of specialized R&D equipment and techniques.

(e) Informal exchange of medical, scientific, or technical information, including training in relevant areas or equipment use.

(2) **Centrally-directed Travel.** Centrally-directed travel is provided when HSR&D requests an employee to attend a meeting, training session, or similar activity. Centrally-directed travel requires concurrence by the medical center Director before funds are provided by HSR&D. Field facilities must provide HSR&D with an estimate of the travel costs. Final adjustments to travel estimates are due in HSR&D within 30 days of completion of travel.

(3) **Travel to Present Scientific Findings.** Travel funds may be requested to present research findings at a professional meeting. A formal request must be submitted to the Director, HSR&D through appropriate channels. The request must include a clear

and detailed justification and an estimate of all costs associated with the travel. The PI must present results from the investigator's currently-funded Merit Review project. Approval must be obtained prior to initiation of travel and is limited to one trip for each funded project.

(4) **Foreign Travel Requests.** Requests for foreign travel funds or authorization must follow current VA local and national policies.

(5) **Other Travel Requests.** Travel requested by an employee for any other purpose (not previously described) intrinsic to the HSR&D program requires prior approval by the Director, HSR&D. This category includes travel for certain committee meetings and for permanent transfer station of HSR&D employees. The request, approved by the medical center Director, must include the reason for travel, mode of travel, dates of travel, estimated cost for per diem and expenses, and transportation costs. Requests must be directed to the Director, HSR&D, through appropriate channels at least 30 days prior to the travel date. Any adjustment to estimated cost is due in VA Central Office within 30 days of completion of travel. *HSR&D follows ORD policy and procedures regarding employee travel, outlined in VHA Handbook 1200.2.*

8. HSR&D REPORTING REQUIREMENTS

a. **Project Abstract.** The PI for each project funded by HSR&D is responsible for submitting a brief initial, annual, and final progress report (Project Abstract). Initial Project Abstracts are due at the time of funding; annual Project Abstracts are due on the funding anniversary date; final Project Abstracts are due with the final report. Abstracts are published on the HSR&D web site and serve as a source of information for VA Central Office responses to Congressional and other inquiries. ***NOTE:*** *Current HSR&D guidance regarding content, format, and the process for submitting Project Abstracts is available on HSR&D's Web site at: http://www.hsrd.research.va.gov*

b. **Final Report.** The PI for each project funded by HSR&D is responsible for submitting a Final Report for the project. The Final Report is due to the Director, HSR&D within 90 days following the project's official completion date. Current instructions on required format and content for the Final Report can be found at HSR&D's Web site at: http://www.hsrd.research.va.gov. A PI who has not submitted a Final Report by the deadline will not receive funding for any new HSR&D project until the Final Report has been received. In addition, new proposals will not be accepted for Merit Review until the Final Report has been received.

c. **HSR&D Center Annual Report.** The PI of each HSR&D Center is responsible for submitting an annual report to HSR&D each December. The report describes the resources, activities, and accomplishments of the center for the prior fiscal year and outlines plans for the current fiscal year. HSR&D Center Annual Reports are submitted electronically using HSR&D's information management system and must conform to the format and content guidance provided as part of the submission process.

d. **Career Development Awardee Annual Progress Report.** The progress of each

Research Career Development awardee must be reviewed annually by the awardee's mentor, with concurrence of the COIN PI, if applicable, and the ACOS for R&D. In addition, each awardee must submit a brief summary of accomplishments during the year. This report must be sent to the Director, HSR&D, in specified format, within 30 days of the awards start date anniversary. In addition, awardees need to submit a recent photograph and updated bio sketch, for inclusion on the HSR&D web site and the annual yearbook. ***NOTE:*** *Specific instructions regarding content and format for these items are issued each year.*

e. **Publication notifications.** All HSR&D-supported PIs are responsible for notifying VA Central Office when a paper has been accepted for publication, regardless of the source of funding for the project. A copy of the accepted manuscript must also be provided. In addition, PIs are responsible for notifying VA Central Office when a major scientific presentation is planned, regardless of the funding source for the investigator's salary or the research project. ***NOTE:*** *Detailed information on the notification process can be found at HSR&D's Web site at: http://www.hsrd.research.va.gov.*

f. **Sanctions.** Sanctions may be imposed on investigators or centers if they fail to submit required reports in a timely and accurate manner.

9. PROJECT MODIFICATIONS

Current instructions on required format and content for requesting Project Modifications can be found at HSR&D's Web site at: http://www.hsrd.research.va.gov.

a. Once HSR&D funding is initiated, investigators must obtain formal approval from the Director, HSR&D, for any significant change such as: the approved project research plan, objectives, methods, budget, time, key personnel, or site(s). HSR&D strongly encourages PIs to limit requests for project modifications to one modification request during the study period and will consider additional requests for modifications only under extenuating circumstances.

h. Requests for project modifications must be submitted by the medical center Director, through the ACOS for R&D and the HSR&D Center PI (if applicable) to the Director, HSR&D. To permit careful review, all modification requests must be submitted as soon as the need becomes apparent and, in all cases, at least 3 months prior to the effective date of the proposed change.

i. **Sabbaticals.** HSR&D funded PIs planning to enter into sabbaticals during active project periods are required to submit a request for a project modification no less than 6 calendar months prior to initiation of the sabbatical for approval to participate in the sabbatical during the project period. The request should include a plan for continuing the research while on sabbatical, temporarily suspending the research, or transferring the research to another PI for an interim period of time. Failure to notify HSR&D about a pending sabbatical may result in termination of HSR&D funding for the project.

j. Justification for the requested modification must be clear, detailed, and should contain appropriate supporting documentation, including revised budgets, timelines,

letters of support, etc., as applicable.

k. If additional information is required, the PI has 30 days from the date of communication to respond to the request; if this deadline is not met, the request may be disapproved. Unusual or extraordinary circumstances that preclude a response by the deadline must be discussed with the Scientific Program Manager for the project.

APPROVED:

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David Atkins, M.D., M.P.H.
Acting Deputy Chief Research and Development Officer