

OPERATIONAL PROCEDURES FOR ACTIVITIES SPONSORED BY THE HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook provides specific guidance for activities sponsored by Health Services Research and Development (HSR&D) Service including policies and procedures related to: communication with Department of Veterans Affairs (VA) Central Office; financial operations, including funding decisions and investigator travel; investigator eligibility; monitoring of HSR&D projects and programs; investigators' reporting obligations and requests for modifications to approved projects. *NOTE: This Handbook supplements VHA Handbook 1200.2.*
- 2. SUMMARY OF CHANGES.** This VHA Handbook updates current procedures.
- 3. RELATED DIRECTIVES.** VHA Directive 1204 and VHA Handbooks 1204.1, 1204.3, 1200.2, 1200.4, 1200.15, 1200.18, and 1200.19.
- 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) 461-1500, or by facsimile at (202) 254-0461.
- 5. RESCISSIONS.** VHA Handbook 1204.5, dated April 16, 2002, is rescinded.
- 6. RECERTIFICATION.** This Handbook is scheduled for recertification on or before the last working date of September 2013.

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1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides specific guidance for activities sponsored by Health Services Research and Development (HSR&D) Service including policies and procedures related to: communication with Department of Veterans Affairs (VA) Central Office; financial operations, including funding decisions and investigator travel; investigator eligibility; monitoring of HSR&D projects and programs; investigators' reporting obligations and requests for modifications to approved projects. This Handbook supplements VHA Handbook 1200.2.

2. COMMUNICATION WITH HSR&D CENTRAL OFFICE

a. General Rule

(1) Field-initiated written communication with VA Central Office (VACO) regarding any HSR&D activity needs to be signed by the facility Director or Chief Executive Officer, and addressed to the appropriate person within HSR&D (see VHA Handbook 1200.2). 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 VACO from a site where there is a co-located HSR&D Center (Center of Excellence (CoE), Research Enhancement Award Program (REAP), or Resource Center) needs to be routed through that HSR&D Center's Principal Investigator. All formal communications are to be sent to the primary addressee using United States (U.S.) mail or commercial delivery, unless communication by e-mail has been requested by HSR&D.

(2) In limited circumstances, investigators may initiate contact with HSR&D VACO 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 Center Principal Investigator, if the investigator is at a site with a co-located HSR&D Center. Investigator-initiated contact with HSR&D VACO staff is appropriate when the matter concerns professional or scientific issues;

b. Circumstances Requiring Formal Communication

(1) 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 facility Director. Formal written communication includes, but is not limited to, the following:

- (a) Requests for supplemental project funding;
- (b) Requests for bridge or other supplemental funding;
- (c) Requests to transfer funding from one site to another;
- (d) Requests to transfer a project from one site to another;

- (e) Requests for a change in Principal Investigator (PI);
- (f) Requests for major changes in project objectives;
- (g) Requests for no-cost extensions affecting award termination date;
- (h) Appeals of decisions affecting resources; and

(i) Notification of medical center staff participation in any major 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.

(2) In addition, HSR&D requires a formal written request for all types of HSR&D program or project support, including Centers 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 Principal Investigator (if applicable), and the signature of the facility Director.

c. **Exceptions.** Requests for resources that do not require approval by the facility 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 (see VHA Handbook 1200.2) also apply for 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.

3. 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. 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) 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) 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 facility Director may authorize employee travel expenditures from funds allocated by HSR&D in accordance with Department of Veterans Affairs (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. Travel funds are allocated based on the recommendations of the Scientific Merit Review Board or HSR&D staff.

(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 facility 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, as described in subparagraph 2b. 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 and/or authorization must follow current VA local and national applicable policies, under the jurisdiction of the Chief Academic Affiliations Officer (14).

(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 permanent transfer station of HSR&D employees. The request, approved by the facility 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.

NOTE: HSR&D follows ORD policy and procedures regarding employee travel, outlined in VHA Handbook 1200.2.

c. **Information Technology.** Information and guidance regarding current policies and procedures for information technology purchases and leasing are disseminated by ORD's finance office. Information technology purchases and leasing include: hardware, software, telecommunications, supplies and materials, and personnel. Information technology expenditures must be used for the items described in the proposal budget.

4. ELIGIBILITY FOR HSR&D SUPPORT

HSR&D implements the eligibility policy and procedures presented in VHA Handbook 1200.15. Exceptions to the basic requirement that all PIs hold at least a 5/8ths VA appointment are very rare, and in no case, is an exception made without approval of the Chief R&D Officer.

NOTE: Questions may be directed to HSR&D's Eligibility Coordinator.

5. FIELD RESPONSIBILITY FOR MONITORING HSR&D-FUNDED ACTIVITIES

HSR&D expects all the research projects and activities it sponsors to be carried out according to the plan presented in the approved proposal. The local R&D Office needs to assist VA Central Office in this goal by monitoring investigators' progress and by ensuring compliance with HSR&D and ORD policies and procedures. The R&D Office needs to monitor funded research projects to ensure that problems that threaten adherence to the approved research plan or completion within the approved time and budget are identified early and VA Central Office is notified immediately of potential problems. The R&D Office must make every effort to assist investigators in resolving issues that threaten the successful completion of the funded research.

a. **Obligation of Funds.** All funds dispersed 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.

b. **Adherence to Approved Budget.** Project funds must be used for the purposes described in the proposal application.

6. 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 website 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 website at: <http://www.hsr.d.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 website at: <http://www.hsr.d.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 Principal Investigator of each HSR&D Center is responsible for submitting an annual report to HSR&D each November. 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 CoE Principal Investigator, 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 biosketch, for inclusion on the HSR&D website and the annual yearbook. **NOTE:** *Specific instructions regarding content and format for these items are issued each year.*

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

7. REQUIRED NOTIFICATION REGARDING PUBLICATION OR PRESENTATION OF RESEARCH FINDINGS

All HSR&D-supported Principal Investigators 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, Principal Investigators 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 website at: <http://www.hsr.d.research.va.gov>. VHA Handbook 1200.19 provides general guidelines on notification of publications or presentation of research findings.*

8. PROJECT MODIFICATIONS

a. Once HSR&D funding is initiated, investigators must obtain formal approval from the Director, HSR&D, for any significant change in the approved project research plan, objectives, methods, budget, time, key personnel, or site(s). HSR&D will consider only one modification request during the study period.

b. All requests for project modifications must be submitted by the medical center Director, through the ACOS for R&D and the HSR&D Principal Investigator (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.

(1) Justification for the requested modification must be clear, detailed, and contain appropriate supporting documentation, including revised budgets, timelines, letters of support, etc., as applicable.

(2) If additional information is required, the Principal Investigator 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.

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