

April 16, 2002

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

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook provides Health Services Research and Development (HSR&D)-specific guidance regarding policies and procedures related to: communication with Department of Veterans Affairs (VA) Central Office; financial operations, including funding decisions and investigator travel; investigator eligibility; and monitoring of HSR&D projects and programs, including investigators' reporting obligations.
- 2. SUMMARY OF MAJOR CHANGES:** This Handbook represents the first comprehensive, HSR&D-specific document that addresses the program areas of: communication with Department of Veterans Affairs (VA) Central Office; financial operations, including funding decisions and investigator travel; investigator eligibility; and the monitoring of HSR&D projects and programs, including investigators' reporting obligations.
- 3. RELATED DIRECTIVES:** VHA Directive 1204, VHA Handbooks 1200.1, 1200.2, 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.
- 5. RESCISSIONS:** VHA Directive 10-95-036, dated March 1995, and VA Manual M-3, Part III, Chapters 1 and 2, dated November 1985, are rescinded.
- 6. RECERTIFICATION:** This document is scheduled for recertification on or before the last working day of April 2007.

S/ by Dennis H. Smith for
Robert H. Roswell, M.D.
Under Secretary for Health

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

1. PURPOSE

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

NOTE: This Handbook supplements VHA Handbook 1200.2.

2. COMMUNICATION WITH HSR&D CENTRAL OFFICE

a. General Rule

(1) Guidance regarding formal, field-initiated communication with VHA Central Office is delineated in VHA Handbook 1200.2. Consistent with that, field-initiated written communication with VA Central Office regarding any HSR&D activity should be over the signature of the facility Director or Chief Executive Officer, and addressed to the appropriate person or program within HSR&D. In addition to requirements of the Office of Research and Development (ORD) for routing written communications through the Associate Chief of Staff (ACOS) for Research and Development (R&D), correspondence to HSR&D Central Office from a site or an affiliate site where there is an HSR&D Center of Excellence (CoE) or Research Enhancement Award Program (REAP) should be routed through that Director. All formal communications are to be sent to the primary addressee via United States (U.S.) mail or commercial delivery. An unofficial copy may be sent by FAX or e-mail, but this must be followed by the original communication.

(2) In limited circumstances, investigators may initiate contact with HSR&D central office staff. Investigator-initiated contact is appropriate when the matter concerns professional or scientific issues; however, advice should first be sought from ACOS for R&D and HSR&D CoE Director (if any). Investigators should seek local advice or technical assistance regarding all administrative matters.

b. Circumstances Requiring Formal Communication

(1) Requests for all types of R&D program or project support require concurrence by the ACOS for R&D and the signature of the medical center Director. 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.

(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 Network, 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. 5b). All formal communication regarding HSR&D matters requires concurrence by the ACOS for R&D, the HSR&D COE, or REAP Director (if applicable), and the signature of the facility Director.

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 VHA 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. Field facility R&D staff or HSR&D Center or REAP 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. HSR&D frequently uses printed e-mail communications to document project files.

3. FINANCIAL OPERATIONS

a. **Funding Decisions for Merit-reviewed Activities.** Within approximately 10 weeks of each proposal review meeting, HSR&D notifies applicants regarding funding of new projects. Decisions regarding initiation of all scientific activities are based on the recommendations of the applicable merit review panel and the priority score, plus current program priorities, and the availability of funds. 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 these decisions are final.

b. Employee Travel

(1) **Locally Directed Travel.** Locally directed travel is paid from funds specifically allocated to the VA medical center for that purpose. The medical center Director may authorize employee travel expenditures from allocated funds in accordance with VA policies. Authorized travel from R&D funds is for the purpose(s) of:

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

(b) Informal exchange of medical, scientific or technical information, including receiving instruction in applicable topics.

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

(d) Participation in multi-facility research and development other than when the travel is centrally directed.

(e) Travel essential for the conduct of a research project.

(2) **Centrally Directed Travel.** When an authorized individual in VHA Central Office requests an employee to attend a meeting, training session, or similar activity related to R&D, such travel requires concurrence by the medical center Director and funds will be provided by VHA Central Office. Field facilities must provide VHA Central Office with an estimate of the travel costs. Final adjustment to travel estimates are due in VHA Central Office within 30 days of completion of travel.

(1) HSR&D travel funds are very limited. Funds for travel that is necessary to the conduct of a project should be itemized in the budget proposal and may be approved for that purpose. Travel funds are allocated based on recommendations of the review board and/or HSR&D's budget staff.

(2) To obtain travel funds for purposes other than the direct conduct of the research (e.g., to present findings at a scientific meeting), a separate, formal request must be submitted to the Director, HSR&D (attention: 124G), 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. For HSR&D funding of investigator travel, the PI must present data analysis results from the investigator's currently funded Merit Review project. Approval must be obtained prior to commencement of travel and is limited to no more than one trip for the duration of the approved project period.

(3) **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.

(4) **Other Travel Requests.** Travel requested by an employee for any other purpose (not previously described) intrinsic to the R&D program requires prior approval by the Director of the

pertinent R&D Service at VHA Central Office. This category includes travel for certain committee meetings and permanent transfer of R&D employees. The request, approved by the medical center Director, will include the reason for, mode of and dates of travel, estimated per diem or expenses and transportation costs, and the amount of travel money required from VHA Central Office funds. Requests shall be directed to the Director of the appropriate R&D Service in VHA Central Office through established administrative channels at least 30 days prior to the travel date. Adjustment to funding is due in VHA 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.

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 Principal Investigators hold at least a five-eighths 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, 124-I, at 202-408-3671.*

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

HSR&D expects all research projects and activities it sponsors to be carried out according to the plan presented in the approved proposal. The local R&D Office should assist Central Office in this goal by monitoring investigators' progress and by ensuring compliance with HSR&D reporting requirements. The R&D Office needs to be aware if a funded research project encounters a problem that threatens adherence to the approved research plan or completion within the approved time and budget, and should notify VA Central Office of such problems and assist investigators in resolving them.

a. HSR&D Reporting Requirements

(1) **Project Annual Reports.** The PI for each project funded by HSR&D is responsible for submitting a brief annual progress report by October 15 of each year. These reports must follow current HSR&D guidance regarding content and format (instructions are issued each year). Investigators who are affiliated with an HSR&D CoE or Resource Center submit project annual reports electronically, through their center, to an HSR&D database called the Annual Report Template. Other investigators submit their reports through HSR&D's Special Projects Office in Perry Point, MD. These reports are included in HSR&D's annual Progress Reports Book, which is widely disseminated and is the primary source of information for VA Central Office responses to Congressional and other external inquiries.

(2) **Center Annual Reports.** The Director of each HSR&D CoE and Resource Center is responsible for submitting an annual report describing resources, activities, and accomplishments of the center. Due each year on October 15, the report covers the prior fiscal year and plans for the current fiscal year. Reports must follow current HSR&D guidance regarding content and format (specific instructions are issued each year). The report is submitted electronically using HSR&D's Annual Report Template. *NOTE: Annual project progress reports by each PI at the center are submitted at the same time.*

(3) **Career Development Awardee Annual Progress Reports.** The progress of each Research Career Development (RCD) awardee and Advanced Research Career Development (ARCD) awardee must be reviewed annually by the awardee's mentor, with concurrence of the CoE Director, if applicable, and the ACOS for R&D. In addition, each Career Development awardee and Career Scientist awardee who has completed 6 months or more of their award term is responsible for submitting a brief summary of accomplishments during the year. The report is to be sent to the Director, HSR&D, in specified format, by June 15th. In addition, each awardee is required to submit a recent photograph and updated biosketch, for inclusion in the annual edition of Career Development and Career Scientist Awardee. **NOTE:** *Specific instructions regarding content and format for these items are issued each year.*

(4) **Publication of Scientific Material.** General guidelines on this topic are contained in VHA Handbook 1200.19.

(5) **Project Final Reports.** The PI for each research project funded by HSR&D is responsible for submitting a project Final Report, conforming to the instructions contained in Appendix B. Final reports are due within 90 days following the project's official completion date.

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

b. **Project Modifications.** Once HSR&D funding is initiated, investigators must obtain formal approval from the Director, HSR&D, for any significant change in project objectives, methods, budget, time, key personnel, or site(s). All requests for project modifications must be submitted in writing by the medical center Director, through the ACOS for R&D and the CoE or REAP Director (if applicable) to the Director, HSR&D (attention: 124G). 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. Justification for the proposed modification must be clear, detailed, and contain appropriate supporting documentation, including revised budgets, timelines, letters of support, etc., as applicable. **NOTE:** *Procedures for requesting modifications to HSR&D funded projects are included as Appendix C.*

**REQUIRED NOTIFICATION REGARDING
PUBLICATION OR PRESENTATION OF RESEARCH FINDINGS**

NOTE: The Health Services Research and Development Service (HSR&D) has established the following requirements regarding notification of pending publications and presentations:

1. For all publications based on an HSR&D-funded or HSR&D-managed project

a. HSR&D requires a copy of the complete article as soon as it is accepted for publication.

b. Each item is to be sent, via e-mail, in a separate message, in the following format:

(1) Address to: vhacohsrd@mail.va.gov and to researchinfo@vard.org.

(2) In the e-mail "Subject" line, enter: "Pub," HSR&D Project No., and Principal Investigator (PI) last name. For example: "Pub, IIR 99-023, Smith."

(3) In the message, indicate the full journal name and the expected or approximate date of publication.

(4) Attach the full article (in Microsoft Word). Name the attachment using this format: Abbreviated journal name, date of acceptance, topic, and last name of HSR&D investigator. For example: "JAMA, 3-15-01, Quality, Greenberg."

c. "**Red Flag.**" Red flag the message if the article: discusses veterans specifically; compares the Department of Veterans Affairs (VA) to private sector health care; recommends actions or has major policy implications for VA leadership (i.e., Office of Research & Development (ORD), the Under Secretary for Health, and/or the Secretary of Veterans Affairs); or is likely to receive press or media coverage.

2. For all publications by an HSR&D-supported investigator, regardless of source of project funding: Follow all the instructions in preceding paragraph 1, except identify the "subject" as: "Pub," HSR&D Investigator, and PI last name". For example: "Pub, HSR&D Investigator, Smith."

NOTE: This applies to all articles by individuals (as sole or co-author) whose salary support is paid principally by HSR&D, e.g., all persons with active Career Development awards or Career Scientist awards, and non-clinician scientists who are part of an HSR&D center's staff.

3. For publications based on health services research NOT funded by HSR&D, when author's salary is NOT from HSR&D: Follow preceding instructions, with these exceptions:

a. Provide only copy of the abstract, as soon as the investigator is notified it is accepted.

b. In the e-mail "Subject" line, enter "Pub," funding source, and PI's last name. For example, "Pub, NIH, Kane."

4. Major presentations by HSR&D investigators

a. HSR&D requires notification of each major scientific presentation, as soon as it is accepted for presentation.

(1) This includes papers accepted for presentation at all national or international conferences if the:

(a) Paper is based on an HSR&D-funded or HSR&D-managed research project;

(b) Author (or co-author) receives major salary support from HSR&D.

(2) If the presentation is expected to receive press or media coverage, regardless of the source of the author's salary support or the research project, notification of HSR&D is required.

b. Follow these instructions:

(1) Address to: vhacohsrd@mail.va.gov and to researchinfo@vard.org.

(2) In the e-mail "Subject" line, enter "Talk," HSR&D Project No., and PI last name. For example: "Talk, IIR 99-023, Smith" or "Talk, NIH, Smith."

(3) Attach the abstract or paper (in Microsoft Word). Name the attachment using this format: Abbreviated name of chief conference sponsor, date of acceptance, topic, and investigator's last name. For example: "APHA, 3-15-01, Quality, Greenberg."

(4) "**Red Flag.**" Red flag the message if the presentation: discusses veterans specifically; compares the Department of Veterans Affairs to private sector health care; recommends actions or has major policy implications for VA leadership (i.e., ORD, the Under Secretary for Health, and/or the Secretary of Veterans Affairs); or is likely to receive press or media coverage.

**HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)
PROJECT FINAL REPORTS**

1. RESPONSIBILITY. The Principal Investigator (PI) for each research project funded by the Health Services Research and Development Service (HSR&D) is responsible for submitting a project Final Report:

a. Conforming to the instructions contained in this Appendix. **NOTE:** *A PI who has an overdue Final Report will not receive funding to initiate a new HSR&D project until the Final Report is received. In addition, HSR&D will not review a new proposal from a PI who has an overdue Final Report.*

b. To HSR&D through designated local officials whose signatures guarantee their awareness of the work and their approval of the Final Report.

2. PURPOSE. HSR&D project Final Reports serve the following purposes, they:

a. Provide documentation for HSR&D research investments;

b. Identify important research findings and appropriate audiences for dissemination;

c. Provide needed information that is not already available in another form; and

d. Give investigators a direct forum for communicating with HSR&D and Research and Development (R&D) about their work.

3. DATE OF SUBMISSION. Final Reports are due within 90 days of the project's official end date. Requests for additional time to prepare the Final Report must be submitted to the Final Reports Program Manager (124-I-2) through the Associate Chief of Staff (ACOS) for (R&D). **NOTE:** *Timely reporting is very important; extension requests are discouraged.*

4. RESPONSIBILITIES OF HSR&D. HSR&D is responsible for approving or disapproving the Final Report. HSR&D:

a. Conducts administrative and content review of each Final Report. In addition, the Report may be sent to one or more external reviewer(s) to help assess the validity, significance, and implications of the findings and to identify appropriate audiences for dissemination. If reviewers have any significant concerns about the Final Report, HSR&D will communicate these to the PI, and may require revisions.

b. Notifies the PI and ACOS for R&D when review of the Final Report is complete and shares with the PI any written critiques or recommendations. **NOTE:** *Prior to notification of approval by HSR&D, the Report is not to be distributed except to individuals who served on the research team.*

c. If, subsequent to approval of the Final Report by HSR&D, the PI materially changes any conclusions or recommendations, an amended report is to be submitted promptly.

5. FORMAT. Use at least 1-inch margins on all sides and a standard font no smaller than 11-point. Use single-sided copying, with each section starting on a new page. Include a Table of Contents, and number every page.

6. COMPONENTS. All HSR&D project Final Reports are to include the following sections: Title Page, Abstract, Highlights, Discussion of Project Changes (if applicable), Publications and/or Product List, and Full Publications. Together, these six parts provide a comprehensive, but concise description of what was done and what was found, as well as what the investigator thinks it means and what (if anything) HSR&D might do to help disseminate and/or implement the findings.

a. **Title Page**

(1) Identify as “Final Report for HSR&D project identification number.” On subsequent lines, list: project title, PI (and co-PI) name(s), dates of project funding period, and Report date.

(2) Include a disclaimer indicating that the Report presents the findings and conclusions of the author(s); it does not necessarily represent the Department of Veterans Affairs (VA) or HSR&D.

(3) At the bottom of the page, include a statement acknowledging HSR&D support in the following form: “This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service.” If applicable, also identify other sources of funding.

b. **Abstract**

(1) **Purpose.** The abstract submitted to HSR&D with the Final Report provides an at-a-glance summary of the project, in a very short, structured format.

(2) **Format.** Use the same format as specified for HSR&D annual progress reports (refer to current instructions). The Final Report abstract needs to be identical, in both format and content, to the final abstract entered into other VA databases. Compared with the initial project abstract or annual updates, the final abstract should use relatively more space for findings and/or results and impact, and less space for background, objectives and methods. Also, use appropriate verb tense, and enter “complete” in the Status line to make clear that the project is, in fact, complete.

NOTE: *Publications should not be cited in the abstract.*

c. **Highlights**

(1) **Purpose.** “Highlights” is the primary document used by HSR&D for dissemination of information about the study. Therefore, this document must include enough information about the purpose of the study and how it was conducted so that it can serve as a stand-alone summary to inform non-researchers. It needs to emphasize what was found or produced and the implications for clinical care, management, future research, and/or policy (as pertinent). The writing must be very clear. Important caveats or qualifications need to be indicated, and the language should be non-technical. **NOTE:** *The Highlights document is not an “executive summary” in that it is not expected to cover all aspects of the project.*

(2) **Format.** Highlights may not exceed three pages of text.

(3) **Content.** Include the following sub-sections:

(a) Background and Objectives. Indicate why the study was undertaken and list all objectives that were presented in the approved research proposal (up to 1/2 page).

(b) Design and/or Methods. Include information about the study design, intervention (if any), source(s) of data, site(s), sample, and generalizability of results (unless research methods were the focus of the study, this section should not exceed 1/2 page).

(c) Findings. Summarize findings related to each of the stated objectives. For each highlighted finding, identify the working paper or publication that contains details (approximately 1 page).

(d) Discussion and Implications. (Approximately 1 page.) Did you find what you expected? Do results have important implications for clinical care, health care policy, or future research? Are they likely to be controversial? Who needs to know? What do you recommend as next steps?

(e) Recommendations to HSR&D. Identify any unpublished finding that may warrant external review and/or early dissemination, and any published finding that may warrant special notice.

d. **Discussion of Project Changes** (if applicable)

(1) **Purpose.** To identify substantial ways in which the final work differs from the originally approved project and discuss the implications. **NOTE:** *Changes include planned activities that were not completed as planned, added activities, and revised activities.*

(2) **Format.** This section should not exceed 3 pages.

(3) **Content.** As pertinent, address the following:

(a) Objectives and/or Specific Aims. Significant changes in the scope of the project or specific aims, compared with the approved proposal.

(b) Methods. Significant changes in research design or methods, compared with the approved proposal.

(c) Resources and Personnel. Changes in the project budget, timeline, or key personnel compared with the approved proposal.

NOTE: *In accordance with HSR&D policy, major changes in the specific aims, methods, or budget require prior approval.*

e. **Publications and/or Product List**

This paragraph provides a comprehensive account of completed and planned publications, working papers, abstracts and other products resulting from this HSR&D-supported research project.

(1) **Format.** Using the headings in subparagraph e(2)(a) through e(2)(d), list all publications and products in chronological order. For publications, use New England Journal of Medicine bibliographic style.

(2) **Content.** List all items, completed and planned, resulting from this HSR&D-funded project, with actual or expected publication and/or completion dates. Do not include work that pre-dates the subject HSR&D project or that was solely supported by another source.

(a) **Publications and Working Papers.** Every HSR&D Final Report must include at least one publication or working paper addressing the main results of the project.

1. List all articles based on this project that are published or “in press.” For each, include the authors, title, journal (if applicable), actual or expected publication date (if applicable), and one statement addressing the focus or impact. **NOTE:** *For full papers go subparagraph 6f.*

2. List completed, unpublished working papers based on this project. For each, indicate whether or not it has been, or will be, submitted for publication. If so, does the article address time-critical information important to veterans’ health and health care? If submission for publication is not planned, what other type of dissemination is warranted, and who should be informed about it? (For example, if the paper is thought to lack interest outside VA, or is too detailed for journal publication, is it of importance to VHA policymakers or does it contain methodological detail that may interest other researchers?)

(b) **Abstracts and Presentations.** List all published abstracts and all presentations based on work supported by this HSR&D project. For published abstracts, include full citation. For presentations, list authors, title, location and date of presentation, and a single statement describing the focus or impact. If there is not yet a publication or working paper for this item, include the abstract in Section F.

(c) **Planned Publications.** List additional planned publications based on this HSR&D project (for which there is no completed working paper). For each, include authors, working title, focus and/or impact statement, and the anticipated date of manuscript completion.

NOTE: *PIs are reminded to acknowledge HSR&D support in all publications (including the project number), to notify HSR&D regarding acceptance, and to provide a copy, according to standard HSR&D policy. Also, subsequent to submission of the project Final Report, investigators should continue to notify HSR&D regarding any article(s) accepted for publication according to standard HSR&D policy.*

(d) **Other Products.** List any other products that resulted from the work supported by this HSR&D project. Examples include educational or training aids, computerized reminder systems, treatment algorithms, programs for abstracting and organizing Veterans Health Information

System and Technology Architecture (VISTA) data, etc. For each, give a very brief (one paragraph) explanation of the nature and potential use of this product and provide contact information for requesting details.

f. **Full Publications**

This paragraph provides full, journal-style publications, working papers, and submitted abstracts (when there is no corresponding manuscript) reporting results supported by this HSR&D project.

(1) **Format for Working Papers.** Each working paper is to be in standard journal style. Working papers may run longer than typical journal articles, but investigators are encouraged to be concise. Emphasis should be placed on methodological detail; it is expected that working papers will contain much more methodological detail and/or more detailed presentation of the data and results than usually presented in a final journal article. The background and discussion sections may be brief; however, they should include some information as to why the study was undertaken, how the results fit into the current literature, and the implications and limitations of the study's findings. Each working paper must include key references, but the background and discussion sections need not be as fully referenced as in a final publication.

(2) **Content.** Provide, in full, all papers that are published or in press, all papers that have been submitted, and all other completed working papers reporting results supported by this project. Include at least one publication or working paper containing the study's main results.

g. **Appendix (Optional).** The Appendix needs to be limited to critical information that is not available elsewhere.

7. SUBMISSION

a. **Transmittal Letter.** The Final Report must be approved by the local R&D Committee and transmitted to HSR&D through the ACOS or Coordinator of R&D. The transmittal letter must be signed by the: PI, ACOS for R&D, facility director, and chairperson of any project steering committee. In addition, if the PI is located at an HSR&D CoE or REAP, the letter must be signed by the Director of that unit. These signatures indicate that the Final Report accurately describes the research that was done and that it has undergone local review. The letter needs to include a description of the local review and summary of reviewers' conclusions.

b. **Copies**

(1) Submit the original and five complete, single-sided copies. **NOTE:** *If color printing is used, submit ten complete copies.* The original should be held together with a removable fastener. The copies must be bound or fastened securely and must have a protective cover. If not using a transparent cover, the cover must include all information contained on the title page. Place the transmittal letter immediately behind the title page.

(2) Also submit a complete electronic copy of the Final Report, including (if possible) articles identified in the Publications List. Use an IBM-PC compatible diskette, in the latest available version of Microsoft Word or Word Perfect for Windows. Label the disk with PI name, project

number, file name, and format, and date. The electronic file is to be a single document that matches the paper Report in every possible respect.

(3) Submit reports to:

Final Reports Program Manager (124-I-2)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, DC 20420

8. INQUIRIES

The PI's local R&D Office is the appropriate initial contact for inquiries about Final Reports. Other questions about submission and review of HSR&D Final Reports may be directed to: HSR&D Final Reports Program Manager at 202-408-3669.

MODIFICATION OF PROJECTS FUNDED BY THE HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)

1. Health Services Research and Development Service HSR&D expects all research projects it sponsors to be carried out according to the plan presented in the approved proposal. Once funding has started, investigators must obtain formal approval from the Director, HSR&D, for any significant change in objectives, methods, budget, time, key personnel, or location. Requests for changes must be submitted in writing by the medical center Director, through the Associate Chief of Staff (ACOS) for Research and Development (R&D) and the HSR&D Center of Excellence (CoE) or Research Enhancement Award Program (REAP) Director (if one) to the Director, HSR&D (124G), in conformance with the procedures outlined herein. A project that is changed without prior approval is at risk of early termination.

2. PROCEDURES FOR REQUESTING A MODIFICATION

a. 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. Review of requested project modification(s) generally requires between 30-60 days depending on the nature of the change and the type of review that is required. Requests for modifications that are administrative in nature, and budget requests up to 20 percent of the approved budget, will generally be reviewed by HSR&D staff. Changes in the research objectives or methods, other changes that may alter the science, and requests for more than a 20 percent budget increase, generally require review by one or more external expert(s).

b. All requested modifications must be submitted in writing, through appropriate channels, and with the lead time indicated. The justification for every request must address in detail any implications for personnel, budget, timeline, project feasibility (as applicable), and must include appropriate supporting documents such as new budget pages, Gantt charts, curriculum vitae (CVs), etc. Adequate information must be provided to permit reviewer(s) to determine why the change is necessary and to allow thorough evaluation of the request.

c. Requestors must send two complete copies of all materials, with a Modifications Cover Page, to:

Director, Health Services Research and Development Service
Attention: 124G
810 Vermont Avenue, NW
Washington, DC 20420

d. The following sections address issues related to particular types of requested modifications.

(1) **Change in Objectives.** Approval must be obtained to add, delete, or significantly alter the objectives of a funded project. The written request must provide a detailed explanation of the proposed change, its rationale and implications.

(2) Change in Methods

(a) Approval must be obtained to change any key component of the approved research plan. This includes, but is not limited to: sampling plan, source(s) of data, addition of another “arm” or comparison group, data collection instrument(s), data collection method(s), or analysis plan. A fundamental change in study design (e.g., elimination of a control group, use of retrospective instead of prospective data, etc.) is not permitted.

(b) The request for approval of methodological changes must include a clear description of how the proposed change differs from the approved approach, why a change is needed, and how the proposed change will resolve the problem.

(3) Change in Budget

(a) HSR&D approval must be requested in writing for any budget change. HSR&D will generally not approve a budget increase of more than 20 percent of the original approved project budget.

(b) A request for an increase in budget must include a description of the steps taken locally to address the budgetary issues, including use of local HSR&D, R&D, or other resources.

(4) **Increase in Time.** Investigators are expected to complete project work within the approved funding period and to notify HSR&D early regarding any significant delay. Formal approval is required to extend a project completion date, whether or not additional budget is also requested. All requests for additional time must be well justified, and the amount of time requested should be less than 6 months.

NOTE: Project final reports are due within 90 days of the official end date of the project period, and requests for additional time to prepare the final report should be rare. A delayed final report receipt date must be requested in writing and approved by the Director, HSR&D; however, a “Request for Modification” is not required for this purpose.

(5) Change in Key Personnel

(a) The Principal Investigator (PI) and Co-PI (if one) are responsible for carrying the funded project through its completion. A change in PI or co-PI may not be made without the approval of the Director, HSR&D. Supporting information submitted with any request to change a PI must be accompanied by a letter from the current PI indicating the PI’s agreement to relinquish responsibility for the project to the proposed new PI.

(b) Approval of VA Central Office also is required to change any other project participants who are responsible, in whole or in part, for the design, execution, or management of the project, and for any change in their time commitment to the project. Medical centers must provide a CV of the new participant(s) and other supporting documents to permit HSR&D to assess their qualifications, competing commitments, etc.

NOTE: For a funded project involving a mentor (e.g., Career Development, Nursing Research Initiative), HSR&D expects that the time commitment and geographic proximity of the awardee

and mentor remain as presented in the approved project. If either the awardee or mentor seeks a decrease in time commitment or transfer to another facility, formal approval must be obtained.

(6) Change in PI (or Co-PI) Employment Status

(a) If the VA employment status of the PI or Co-PI drops below a 5/8 paid appointment, an eligible VA investigator must replace that PI.

(b) The ACOS for R&D is responsible for notifying HSR&D of a change affecting PI eligibility within 2 weeks of their own receipt of this information. This notification must be accompanied by a request for approval of a new PI and supporting information (see preceding subpar. 2d(5)).

(7) Change in Location

(a) HSR&D projects are awarded to the medical facility where the PI is stationed at the time of the award. If the PI or co-PI is transferred to another VA facility, the project remains at the initial location unless or until approval is secured for transferring the project with the investigator. If the PI moves to another VA without requesting transfer of the project to the PI's new station, approval must be obtained from the Director, HSR&D before naming a new PI.

(b) A request for transfer of a project between facilities must include written documentation from the medical center Director of each facility agreeing to the transfer. However, final approval rests with the Director, HSR&D.

**REQUEST FOR MODIFICATION OF HEALTH SERVICES RESEARCH AND
DEVELOPMENT SERVICE-FUNDED PROJECT**

SAMPLE FORMAT OF COVER PAGE

1. Identifying Information

- a. Project Number _____
- b. Project Title _____
- c. Name of Principal Investigator _____
- d. Principal Investigator's Department of Veterans Affairs (VA) Facility _____
- e. Principal Investigator's Telephone No. _____

2. Request for a change in: *NOTE: Check all that apply.*

- a. _____ Research Objectives
- b. _____ Research Methods
- c. _____ Budget
- d. _____ Time
- e. _____ Key Personnel
- f. _____ Location

3. Preferred effective date of requested change _____

_____	_____
(Signature of Principal Investigator)	(Date)

_____	_____
(Signature of Center of Excellence or Research Enhancement Award Program Director (if applicable))	(Date)

_____	_____
(Signature of Associate Chief of Staff for Research and Development)	(Date)