

March 25, 2009

**VETERANS HEALTH ADMINISTRATION
HEALTH SERVICES RESEARCH AND DEVELOPMENT**

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Directive defines Health Services Research and Development (HSR&D) policy.
- 2. SUMMARY OF MAJOR CHANGES.** This VHA Directive incorporates additional information about conferences.
- 3. RELATED DIRECTIVES.** VHA Handbooks 1204.01 through 1204.05 and VHA Handbook 1200.4.
- 4. RESPONSIBLE OFFICE.** The Health Services Research and Development Service (124) is responsible for the contents of this Directive. Questions may be referred to (202) 461-1500, or by facsimile at (202) 254-0461.
- 5. RESCISSION.** VHA Directive 1204, dated April 15, 2002, is rescinded.
- 6. RECERTIFICATION.** This VHA Directive is scheduled for re-certification on or before the last working day of March 2014.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publication Distribution List 3/26/2009

**VETERANS HEALTH ADMINISTRATION
HEALTH SERVICES RESEARCH AND DEVELOPMENT**

1. PURPOSE

This Veterans Health Administration (VHA) Directive provides policy and guidance for Health Services Research and Development (HSR&D) Service programs. HSR&D program information is updated as necessary and is available at HSR&D's Web site at:

<http://www.hsrd.research.va.gov>.

2. BACKGROUND

a. HSR&D develops and manages a diverse, interdisciplinary, intramural research program targeted to address the health care needs of Veterans. HSR&D's mission is to advance knowledge and promote innovations in quality, effectiveness, efficiency, cost, and accessibility of health services to improve the health and care of Veterans. This mission is carried out through the support of scientifically meritorious and Department of Veterans Affairs (VA) relevant research and development. HSR&D fosters collaborations with other organizations to capitalize on unique VA opportunities to enhance program effectiveness and efficiency.

b. HSR&D-sponsored Health Services Research examines the organization, financing, management, and social factors of health care and their effects on health care delivery, quality, cost, access, and outcomes. VA Health Services Research focuses on understanding how to organize, deliver, and finance health care that is cost effective, meets the needs of Veterans, and ensures that the Veterans' health care system consistently provides the best care. It emphasizes research that has practical applications and that can assist patients, health care providers, managers, and policymakers.

c. HSR&D funding support is primarily for studies about health care services and health care delivery models that are available or feasible in regular clinical settings. The "laboratory" for health services research studies is the real world of clinical practice, where variations among patients, physicians, and other factors that affect health care cannot be fully controlled and may, themselves, be the focus of research. In general, studies involving treatments that are still regarded as experimental are not in the domain of health services research.

d. HSR&D also supports certain kinds of scientific "development." Proposals may include interdependent elements of scientific activity that yield new knowledge (research) and work resulting in new products (development). Most of this work focuses on the development of new measures or analytic techniques for use in health services research, or on the refinement, testing, or translation of existing research tools. Selectively, HSR&D also supports the development of certain other products, such as: computer software, patient registries, research databases, and educational materials. All development projects are bound by restrictions on the use of VA research funds for clinical equipment. All development work sponsored by HSR&D includes a plan for scientific evaluation (see VHA Handbook 1204.01).

3. POLICY. It is VHA policy that HSR&D funds and manages scientifically meritorious research and development to advance knowledge and promote innovations in quality, effectiveness, efficiency, cost and accessibility of health services to improve the health and care of Veterans and to serve as a national leader in the field of health care provision. HSR&D fosters collaborations with other organizations to capitalize on unique VA opportunities to enhance program effectiveness and efficiency. *NOTE: The requirements of any policies and operational procedures formulated in conjunction with this VHA Directive apply to all HSR&D activities conducted at VA facilities or by VA investigators, whether funded by VA or by other sources, or unfunded.*

4. RESPONSIBILITIES

a. **Director, HSR&D.** The Director, HSR&D Service, is the designated official, responsible to the Chief Research and Development Officer, for: HSR&D policy development, planning and coordination of activities, scientific review of research proposals, management of the research portfolio, budget formulation, and distribution of funds. The Director of HSR&D Service is responsible for:

(1) The three main types of HSR&D programs which include: programs that directly support scientific research and development, programs that build health services research capacity within VA, and programs that strengthen VA's health services research infrastructure. *NOTE: In addition, HSR&D manages some Research and Development (R&D)-wide programs for the Office of Research and Development (ORD) and other entities within VA.*

(2) Ensuring HSR&D:

(a) Sustains a superior environment of inquiry conducive to the highest quality research, education and patient care.

(b) Effectively integrates fundamental, translational, and clinical research to meet the health care needs of Veterans.

(c) Capitalizes on VHA's value as a national research asset.

(d) Leads and manages an effective and efficient health services research enterprise.

(e) Increases awareness and understanding of VHA's research contributions in the field of health services research.

(3) Ensuring the values guiding all HSR&D efforts include: scientific excellence, the ethical conduct of research, and protection of human subjects.

b. **Field Facility R&D Officer.** The facility R&D Officer, or designee, is responsible for:

(1) Ensuring that all research projects and activities sponsored by HSR&D are carried out according to the plan presented in the approved proposal; this includes:

(a) Monitoring investigators' progress and ensuring compliance with HSR&D and ORD policies and procedures.

(b) Monitoring 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.

(2) Notifying VA Central Office immediately of potential problems.

(3) Assisting investigators in resolving issues that threaten the successful completion of the funded research.

5. DEFINITIONS

a. **Direct Support of Research.** In HSR&D, direct support for scientific research and development is provided through two main categories of merit-reviewed research, the Investigator-Initiated Research (IIR) program and the Service-Directed Research (SDR) program. Adhering to the same general principles and procedures for scientific merit review, the IIR and SDR programs provide a flexible framework for support of research addressing a very wide range of topics and employing a range of approaches to address important health services research questions.

(1) Projects supported through the IIR mechanism 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.

(2) SDR projects 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.

b. **Capacity Building.** 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.

(1) **Centers.** HSR&D provides infrastructure support, including costs for some personnel, supplies and equipment, and for locally initiated research activities to sites. Each HSR&D Center of Excellence (CoE) develops its own research agenda, is affiliated with a Medical Center, and collaborates with local universities, medical schools, and schools of public health.

(a) Each HSR&D CoE consist of 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. Awarded and renewed based on competitive merit-review, each of HSR&D's CoE has unique strengths and research foci. CoE staff constitute 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.

(b) HSR&D Research Enhancement Award Program (REAP) centers provide infrastructure support to groups of investigators at a medical center, not affiliated with a CoE, who have a history of HSR&D research and career development funding and potential to further develop health services research at the site. REAPs may compete to become CoEs.

(2) **Career Development.** Career Development provides protected research time for talented VA clinicians and non-clinicians who are dedicated to health services research. There are four award levels in the Career Development Program: Career Development Award-1 (CDA-1); Career Development Award-2 (CDA-2); Career Development Transition Award (CDTA); and Career Development Enhancement Award (CDEA). Each award corresponds to different research and academic levels in a scientist's career. Candidates need not be a VA employee to be considered for CDA-1 or CDA-2 awards, but must be nominated by the VA medical center (see VHA Handbook 1200.4).

c. **Research Infrastructure**

(1) **Resource Centers.** HSR&D's Resource Centers provide technical assistance and consultation services to VA researchers and others in Central Office and the field. Each of these Centers provides a specific expertise such as knowledge of organizational and management issues, the use of VA databases in research, and the conduct of economic analyses. HSR&D's extensive research dissemination program is also managed by a Resource Center.

(2) **Conferences.** In order to enhance opportunities for intellectual exchange, HSR&D provides support of VA sponsored conferences, including a national research conference and occasional conferences that address current priorities or specific topics of interest to VA, ORD, and HSR&D. These conferences facilitate communication, collaboration, strategic planning, and rapid dissemination of research findings and help define the research agenda.

(a) HSR&D's national scientific meeting is an important forum for exchange of health services research information, and is attended by VA managers and policymakers as well as VA and non-VA researchers. In conjunction with this conference, HSR&D sponsors a meeting for its Career Development and Research Career Scientist awardees.

(b) In select cases, consideration is given to requests from field-based researchers or administrators for limited HSR&D support of VA conferences on topics of importance to VA, ORD, and HSR&D. The proposed conference is expected to have wide applicability and import throughout the VA system or the health services community and have a significant product or result. Requests for conference support must be submitted to the Director, HSR&D (124). The organizers of the conference must acknowledge that VHA and HSR&D is the sponsor (or co-sponsor), include VA researchers on the planning committee, and provide in-kind or financial co-sponsorship.

d. **Quality Enhancement Research Initiative (QUERI).** QUERI is a systematic, national effort to translate research findings into improved patient outcomes and system improvements. QUERI promotes a systematic approach for identifying best practices, systematizing their implementation, and providing feedback to promote ongoing improvement and sustain positive change. Led and managed by HSR&D, QUERI relies on the collaboration of various divisions within VHA Central Office and between Central Office and field operations. HSR&D's key

QUERI partners include the Offices of Quality and Performance and Patient Care Services. QUERI Coordinating Centers are responsible for the implementation, program coordination, and the day-to-day management of all phases of QUERI work.

e. **Nursing Research Initiative (NRI)**. Designed to support the development of independent nurse investigators within VA, NRI is an ORD program implemented in collaboration with VA's Office of Nursing Service. The NRI allows VA nurse investigators who are in the early stages of their research careers to conduct a mentored research project. The NRI is managed by HSR&D for all the services within ORD and supports research pertinent to the mission of each of four services within ORD: (HSR&D, Biomedical Laboratory Research and Development (BLR&D), Clinical Science Research and Development (CSR&D), and Rehabilitation Research & Development (RR&D).