

March 13, 2011

**RESEARCH STANDARD OPERATING PROCEDURES (SOP)  
Strategic Improvement / Quality Assurance / Quality Improvement for the  
Human Research Protection Program**

**1. PURPOSE:** To outline the South Texas Veterans Health Care System (STVHCS) Research and Development Strategic Improvement / Quality Assurance / Quality Improvement (SI/QA/QI) for the Human Research Protection Program that includes the strategic planning, monitoring and auditing, education and training, and quality improvement activities involved in the protection of human research subjects. These quality improvement activities are integral components of the STVHCS Human Research Protection Program (HRPP).

**2. POLICY:**

- a. The SI/QA/QI program will provide an ongoing, continuous and proactive strategic planning, monitoring and auditing, education and training, and quality improvement program to strengthen and reinforce various elements of the HRPP. The STVHCS human subject research program is subject to periodic assessment to ensure compliance with policies, regulations, and laws which pertain to human research protections through compliance activities. The SI/QA/QI Program is responsible for ensuring that research using human subjects is conducted in a manner that protects the safety, rights, welfare, and other interests of the human subjects enrolled in research under the applicable statutes and policies.
- b. This program will maintain strategic planning, continuous quality improvement, integrated compliance, and quality assurance processes to assure that all aspects of the HRPP program are functioning appropriately. Modifications to the plan may be made as service and/or program needs warrant.

**3. RESPONSIBILITIES:**

- a. **Hospital Director**. The Hospital Director is responsible for the overall assurance of protections for human participants within the SVHCS. As the designated Institutional Official, the Hospital Director can exercise the authority to suspend or terminate research as deemed necessary, including for the protection of human participants.
- b. **Research and Development Committee**. The R&D Committee as part of its oversight function is responsible for reviewing research audit reports and ensuring that opportunities for improvement are identified and addressed and noncompliance issues are resolved.
- c. **Associate Chief of Staff for Research and Development (ACOS for R&D)**. The ACOS for R&D is delegated the responsibility for the implementation, conceptual oversight, and administrative leadership for administering the STVHCS R&D Program by the Hospital Director. As a function of these activities, the ACOS for R&D is responsible for administering the development, implementation, and maintenance of a program ensuring compliance and quality improvement for the HRPP.
- d. **STVHCS Research Compliance Officer**. The Compliance Officer or designee is responsible for the periodic monitoring of the HRPP, including the ongoing SI/QA/QI activities and the follow-up of corrective actions. The Research Compliance Officer or designee submits summaries of their findings to the R&D Committee.

## POLICY MEMORANDUM 11-41

- e. **Deputy ACOS for R&D.** The Deputy ACOS for R&D is responsible for assisting the ACOS for R&D in the development, implementation, and maintenance of all aspects of the HRPP, including SI/QA/QI activities.
- f. **Principal Investigator (PI).** Each PI is responsible for providing their designated research staff with an opportunity to attend training and education provided as part of the SI/QA/QI Program and for establishing an environment conducive to implementation of the requirements of the HRPP, including SI/QA/QI initiatives. Each PI is responsible for informing the R&D Office of any concern or allegation of non-compliance or research misconduct. Each PI is responsible for providing any records and/or documents requested for auditing activities, responding to any questions that arise as a result of an audit, and providing a corrective action plan as needed to assure ongoing compliance.

### 4. ACTION:

- a. **Strategic Improvement Planning:** The SI/QA/QI program includes a process of strategic planning, which is performed on an annual basis. In general, the strategic planning process includes the following components:
  - (1) **Assessing the Current Situation.** An understanding of the current situation of the STVHCS HRPP aids in identifying the barriers that stand in the way of further progress.
  - (2) **Defining the Vision.** The STVHCS aspires to discover knowledge, develop VA researchers and health care leaders, and create innovations that advance health care for our veterans and the nation. With this overall vision in mind, the annual strategic planning will identify short- and long-term goals to improve the HRPP.
  - (3) **Identifying the Barriers.** Potential and real barriers to effective function of the HRPP are assessed at the system level, research service level, and at the investigator microsystem level.
  - (4) **Planning the Strategy.** Major goals for improvement of the HRPP will be formulated based on the understanding of the current situation and identification of barriers. These goals must be met as a demonstration of progress toward achieving the vision.
  - (5) **Strategic Plan.** The strategic plan is the action plan that will be implemented to achieve the goals. Agreement to the strategic plan will be sought from all stakeholders in the research program up front. The R&D Committee will be integrally involved in the development of the annual strategic plan. The formulated strategic plan for the STVHCS Research Service will be linked to the fiscal year business plan submitted to STVHCS administration.
- b. **Educational Activities:**
  - (1) **On-line Standardized Training.** All individuals involved in human subjects' research at the STVHCS are required to annually complete the Collaborative Institutional Training Initiative (CITI) Course on Good Clinical Practice and ethical principles of human subject research protection.
    - (a) The R&D Office tracks CITI training for all investigators and study staff involved in human subjects' research.

## POLICY MEMORANDUM 11-41

- (b) Training must be completed before any investigator or study staff can commence any human subjects' research and must be completed annually to continue working on active research protocols.
- (2) **Investigator Handbook.** An Investigator Handbook has been developed, and is updated as needed, to provide important guideposts to policies and procedures that are critical for investigators and study staff to understand and follow in order to ensure human subjects are afforded maximum protection as participants in research. The Investigator Handbook is available in print form and on the STVHCS Research website. The handbook provides information regarding where investigators can go to find more information or to have questions addressed.
- (3) **On-site Assessment and Training for Investigators and Research Staff.** The R&D Office staff, the ACOS for R&D, and the Deputy ACOS for R&D are available to conduct on-site assessment and training when requested by a STVHCS Investigator, their study personnel, or the R&D Committee.
- (4) **Electronic Communication Network for Research Study Team Members.** The SI/QA/QI program has a Research Study Members email group of all active human subjects' investigators, study coordinators, and other key study personnel. This establishes an ongoing method for regular feedback and dialogue between the R&D Office, principal investigators, and key research coordinators involved in the day-to-day implementation and operational functions of human research projects.
- (5) **Education and Training Sessions for Research Study Team Members.** The Deputy ACOS for R&D routinely conduct needs assessments and review of newly drafted documents and/or procedures for investigator and study staff training opportunities. Interactive training sessions are conducted to disseminate new information. Handouts for each training session are provided to all Research Study Team Members, and are posted on the Research Service website for future reference.
- (6) **Clinical Research Training Course.** The STVHCS participates with the UTHSCSA in providing an 8-hour training course on "Conducting Clinical Research". All personnel involved in human subjects' research at the STVHCS are strongly encouraged to participate in this course, which is offered 3 times per year.
- (7) **IRB Training Sessions.** IRB forums which review policies and procedures for IRB submissions are held on a regular basis. Dates and times for the sessions are posted on the UTHSCSA IRB website and attendance by STVHCS investigators and study staff is encouraged.
- c. **Research Service Performance Measures.** The R&D Office has established a performance dashboard for monitoring the effectiveness of administrative processes and procedures related to the research program, including those that are applicable to the HRPP.
- (1) **Timeliness of Processes.** The R&D Office monitors time from a request or initial receipt to the date of completion or approval for a number of processes involved with human subjects research (e.g. research privileges, WOC applications, educational verification, protocol administrative pre-review, protocol review by R&D, protocol data security review, safety committee review, privacy review, protocol continuing reviews).

## POLICY MEMORANDUM 11-41

- (2) **Access to Research Resources.** The R&D Office provides a number of resources for investigators and study staff. Access to these resources are monitored on an ongoing basis (e.g. space utilization, common use equipment, statistical support, computer support)
  - (3) **Research Productivity.** In an effort to continually expand research activities available to STVHCS patients, and the number and types of new proposal submissions are monitored on a regular basis (e.g. investigator initiated, new investigator, industry sponsored, VA and NIH funded projects).
  - (4) **Training.** Training initiatives are monitored on a regular basis to assure targets for training are met or exceeded.
  - (5) **IRB Communication.** IRB minutes, protocol consent forms, and UPIRSOs from the IRB are monitored for prompt review and reporting.
  - (6) **Investigator Satisfaction.** Feedback from investigators regarding the level of service and satisfaction with the R&D Office will be solicited on a regular basis to continually identify areas for improvement.
- d. **Certain elements of the SI/OA/QI program are detailed in separate Research Standard Operating Procedures to include the following:**
- (1) **Procedures for Responding to Questions, Concerns, Complaints, and Allegations or Reports of Non-compliance with HRPP Requirements**
  - (2) **Monitoring and Reporting UPIRSOs**
  - (3) **Oversight of External Monitors**
  - (4) **Procedures for Compliance Audits**
  - (5) **Procedures for Reporting to Regulatory Agencies**
- e. **Assurance of Appropriate Oversight of IRB:** A key procedure for ensuring compliance and quality improvement for the HRPP is effective two-way communication and careful oversight of UTHSCSA IRB activities. Specific oversight is accomplished as follows:
- (1) The R&D Office maintains electronic access to UTHSCSA IRB data pertaining to VA-related projects. If at any time electronic access is unavailable, paper copies of IRB records pertaining to VA research will be provided by the IRB as needed.
  - (2) A VA representative (e.g., Research Compliance) attends, as an observer, a minimum of 75% of UTHSCSA IRB meetings in order to monitor appropriate review and oversight of VA-related projects.
  - (3) The minutes of all UTHSCSA IRB meetings are presented for review at R&D Committee meetings.
  - (4) The R&D Committee monitors the qualifications and experience of new IRB chairpersons through a survey tool provided to each VA member of the IRB. Results of the surveys are summarized and presented annually to the R&D Committee for review and recommendations.

## POLICY MEMORANDUM 11-41

- (5) The Compliance Officer or designee monitors specific IRB activities from a compliance standpoint as outlined in the Research Compliance Policy.
  - (6) Regularly scheduled meetings are held between VA (ACOS for R&D, Deputy ACOS for R&D, R&D Office Staff) and UTHSCSA IRB officials (IRB Director, IRB Assistant Director, IRB Office Staff) in order to maximize communication, facilitate collaboration, and ensure compliance with all HRPP requirements.
  - (7) Following R&D Committee review, any requirements for approval, which are in addition to those required by the IRB, are communicated to the PI and the IRB.
- f. **Compliance with Changes in HRPP Policies and Regulations:** Institutional officials responsible for the HRPP will closely monitor all policies and regulations which pertain to HRPP compliance requirements. Strategies for effective monitoring will be as follows:
- (1) Selected officials, as appropriate, will participate in recurring training in order to remain cognizant of all changes in HRPP policies and regulations. When changes are identified, they will be promptly reflected in local policies and procedures at the STVHCS and quickly disseminated to institutional officials, members of research review committees, and human research personnel via the STVHCS Investigator Handbook, R&D website and through ongoing educational activities.
  - (2) Communications from the VA Office of Research and Development, the VA Office of Research Oversight (ORO), and the VA Center on Advice and Compliance Help (COACH) will be closely monitored in order to maintain a keen awareness of changes in HRPP policies and regulations so that compliance can be maintained.
6. **REFERENCES:** VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research"
  7. **RESPONSIBILITY:** ACOS for Research and Development (151)
  8. **RECISSION:** Research Service Policy Memorandum/SOP 08-41, dated April 1, 2008
  9. **RECERTIFICATION:** March 2016

  
KIMBERLY K. SUMMERS, PHARM.D.  
Acting ACOS for Research and Development