

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78284

RESEARCH SERVICE
MEMORANDUM 05-19

February 17, 2005

HUMAN RESEARCH PROTECTION PROGRAM
Standard Operational Procedures

Research Quality Assurance

1. PURPOSE: To outline the Research and Development quality assurance program that will address the compliance and quality assurance activities involved in the protection of human research subjects. These quality assurance activities are integral components of the Human Research Protection Program (HRPP).

2. POLICY:

a. The day-to-day operations of the various elements of the Human Research Protection Program are subject to periodic assessment for purposes of assuring the protection of human research subjects through compliance and quality improvement activities. This may include such activities as investigator protocol compliance, study documentation, investigational pharmacy operations, IRB documentation. Such assessments will determine the extent to which the HRPP complies with VA and Federal regulations and local standard operating procedures. The Research Service Quality Assurance 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 integrated compliance, quality assurance, and continuous quality improvement processes to assure that all aspects of the HRRP program are functioning appropriately. Modifications to the plan may be made as service and/or program needs warrant.

3. RESPONSIBILITIES:

a. The STVHCS Research and Development 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.

b. The Associate Chief of Staff for Research and Development has been delegated the responsibility for administering the South Texas Veterans Health Care System's Research and Development Program by the STVHCS Director. As a function of these activities, the ACOS for R&D is responsible for administering the development, implementation, and maintenance of a program to insure research quality.

c. The facility Compliance Office, responsible for conducting periodic assessments, submits its findings to the Research and Development Committee's Quality Assurance Subcommittee.

c. Principal Investigators are responsible for providing any records and documents requested for auditing activities, responding to any questions that arise as a result of the audit, and providing a corrective action plan as needed to assure ongoing compliance.

4. PROCEDURES:

a. As in its oversight of human studies, animal studies, and safety, the Research and Development Committee will utilize a subcommittee of the R&D Committee to conduct the evaluations of quality review audits/findings. This subcommittee will review audit reports submitted to the R&D Committee from the Compliance Office and other STVHCS audit activities, as well as non-STVHCS audit activities such as the NIH-funded GCRC self-assessments or other outside entities. The Subcommittee's review and any recommendations for action will be documented in the subcommittee minutes and forwarded to the R&D Committee for appropriate action. If the R&D Committee determines specific actions should be taken, the minutes will document this action and the ACOS for R&D will be directed to develop and implement the required remedy/action. The ACOS for R&D will report to the R&D Committee on status of the actions.

b. QA Subcommittee Composition and Meeting Frequency. The R&D subcommittee membership will include one or more R&D Committee research investigator members; Chief of Staff, ACOS for R&D, and AO for R&D, ex-officio R&D Committee members; one or more STVHCS Compliance Office designees who will present results of Compliance Office reviews; and the GCRC Subject Advocate who will present results of GCRC self-assessments. The Subcommittee will meet on a quarterly basis to review all QA reports received during the previous quarter unless the nature of the findings requires immediate review and action.

c. Audits. Areas to be monitored may include, but are not limited to, the IRB function and adherence to applicable guidelines, regulations, and standards that govern human research; investigators' compliance with guidelines, e.g., consent forms, documentation, protocol criteria (exclusions, procedures used); compliance with training requirements; and Investigational Drug Pharmacy's function and adherence to applicable federal guidelines. Standardized audit forms/procedures will be used for each audit activity to insure consistency of reviews. This does not preclude the use of an improved evaluation instrument if there are program/policy changes or the findings dictate the need.

5. RESCISSION: Research Service Policy Memorandum 03-19, dated December 15, 2003.

6.. REVIEW DATE: February 2008.



PETER MELBY, M.D.
ACOS for Research and Development