

May 19, 2008

RESEARCH QUALITY ASSURANCE/QUALITY IMPROVEMENT SUBCOMMITTEE

1. **PURPOSE:** To outline the role and responsibilities of the Research and Development (R&D) Quality Assurance/Quality Improvement (QA/QI) Subcommittee that will oversee the compliance and quality assurance activities related to the South Texas Veterans Health Care System (STVHCS) research program, and report these findings and the subcommittee's recommendations to the R&D Committee. These quality assurance activities are integral components of the Human Research Protection Program (HRPP), and the animal and laboratory research programs.

2. **POLICY:** The day-to-day operations of the various elements of the STVHCS Research Program are subject to periodic assessment for purposes of assuring the protection of human and animal research subjects through compliance and quality improvement activities. This may include such activities as investigator protocol compliance, study documentation, investigational pharmacy operations, R&D Committee documentation, and IRB documentation. Such assessments will determine the extent to which the STVHCS Research Program complies with VA and Federal regulations and local standard operating procedures. The Research QA/QI Subcommittee is responsible for overseeing the compliance and QA activities involved in the protection of human research subjects, animal subjects, and research personnel, and reporting these findings and the subcommittee's recommendations to the R&D Committee.

3. **ACTIONS:**

a. **Accountability:**

(1) The STVHCS Research QA/QI Subcommittee, as a subcommittee of the R&D Committee, is responsible for reviewing research protocol audit reports, Institutional Review Boards (IRB) Audit reports, reports of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO), reports of research non-compliance or research impropriety, reports of animal welfare issues from the VMU Report, and reports of QA activities. The subcommittee is responsible to ensure that opportunities for improvement are identified and addressed and noncompliance issues are resolved.

(2) The Associate Chief of Staff for R & D has been delegated the responsibility for administering the STVHCS R&D 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. The ACOS for R&D will report any issues that impact the quality and compliance of the STVHCS research program to the Research QA/QI Subcommittee.

(3) The STVHCS Compliance Office, responsible for conducting periodic assessments and audits, submits its findings to the Research Quality Assurance / Quality Improvement Subcommittee

(4) Principal Investigators are responsible for:

(a) Providing any records and documents requested for auditing activities;

(b) Responding to any questions that arise as a result of the audit; and

(c) Providing a corrective action plan as needed to assure ongoing compliance.

(5) The R&D Committee is responsible to:

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(a) Review the findings and recommendations of the QA/QI Subcommittee and generate appropriate plans of action, and

(b) Inform the STVHCS Director, as appropriate, of any significant QA/QI issue, the plan for any corrective action, and the need for any additional resources to accomplish the plan of action.

(6) The STVHCS Director is:

(a) The institutional official ultimately responsible for the STVHCS research program;

(b) Advised and assisted by the R&D Committee; and

(c) Responsible to ensure that QA/QI issues reported by the subcommittee are satisfactorily resolved.

b. Procedures:

(1) As in its oversight of human studies, animal studies, and safety, the R&D Committee will utilize a subcommittee of the R&D Committee to conduct the evaluations of QA/QI activities and findings. This subcommittee will review audit reports submitted to the R&D Committee from the Compliance Office and other STVHCS audit activities, assessments from the R&D Office concerning the quality of the research program, as well as non-STVHCS audit activities such as the NIH-funded GCRC self-assessments or other outside entities.

(2) The subcommittee's review will include research-related audit reports, reports of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) from the IRB, reports of research non-compliance or research impropriety, reports of animal welfare issues from the VMU Report, and reports of Quality Improvement activities.

(3) Audit reports—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.

(4) 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, or his/her designee, 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.

(5) QA Subcommittee Composition and Meeting Frequency:

(a) The R&D subcommittee voting membership will include one or more R&D Committee research investigator members; the Chief of Staff, a STVHCS Compliance Office designee who will present results of Compliance Office reviews; and the STVHCS Privacy Officer or Alternative Privacy Officer.

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(b) Non-voting ex-officio members include the ACOS for R&D, and AO for R&D, the Assistant Chief for Clinical Research.

(c) The Subcommittee will meet at least 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.

4. **REFERENCES**: None

5. **RESPONSIBILITY**: Associate Chief of Staff for Research and Development (151)

6. **RESCISSION**: Research Service Policy Memorandum 05-19, dated February 17, 2005

7. **RECERTIFICATION**: May 2011

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RICHARD J. BALTZ, FACHE
Director

DISTRIBUTION: As appropriate