

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP #17

May 7, 2007

COMPLIANCE AND QUALITY IMPROVEMENT

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to protecting the safety and welfare of veterans participating in VA research. When veterans take part in VA research, they rely on us to keep them safe and they entrust us to safeguard the quality, safety and integrity of our research program.

It is the policy of the TVAMC to ensure the safety and welfare of veterans involved in VA research through a Continuous Quality Improvement (CQI) program that performs quality improvement activities to monitor and maximize compliance and to improve the safety, quality and effectiveness of the TVAMC HRPP. The over-arching goal of R&D CGI activities is to measure and improve HRPP effectiveness, quality and compliance with HRPP SOPs and applicable federal, state, and local laws with the primary aim of improving patient safety and outcomes.

This standard operating procedure (SOP) establishes procedures that ensure research at the TVAMC is conducted in accordance with the requirements of the HRPP, as well as state and federal regulations.

2. BACKGROUND

Since 1997, the TVAMC HRPP has had ongoing CQI activities that have become more detailed and structured over time. CQI is an integral part of the TVAMC's mission. These activities help identify opportunities for improvement in systems and processes in response to emerging needs and available resources. Our HRPP CQI activities follow the Medical Center's plan and structure outlined in Center Memorandum 00-3, which employs the Malcolm Baldrige Health Care Criteria as the performance improvement system and organizational framework.

The TVAMC Leadership has identified KEY FUNCTIONS that drive the performance of the organization, one of which is research function. Each Key Function is organized into a Continuous Readiness Assessment Team (C-RAT) that is charged to continuously plan, measure, assess, improve, and communicate the management of these key organizational

processes within their functional areas of responsibility. The HRPP CQI activities are coordinated by the R&D C-RAT.

To date, the TVAMC HRPP CQI program has internally assessed 1) patient satisfaction, 2) patient (or surrogate) consent process for those who do and do not participate in research, 3) investigator compliance, 4) IRB performance, 5) medical record documentation of informed consent, 6) IRB record keeping, 7) IRB resources, and 8) pharmacy compliance. In summary, the CQI program of the HRPP is established and active within the TVAMC. The CQI program of the HRPP goes hand-in-hand with the continuing education efforts on the protection of human subjects in research to ensure that research is conducted in the most ethical and safe manner possible, with the ultimate goal of improving the health and quality of life for our veterans.

3. RESPONSIBILITIES

The TVAMC Director has ultimate responsibility for ensuring that the CQI Program promotes the protection of the welfare of veterans through CQI activities to improve the quality, safety and effectiveness of the TVAMC HRPP, and compliance with the medical center Patient Safety Improvement Program. Working with management, clinical, and administrative staff, the Director is responsible for providing the framework for planning, providing and improving healthcare services based on the facility's mission.

R&D Administrative Officer (R&D AO) serves as the **TVMAC HRPP Research Compliance Officer (RCO)** and is responsible for coordinating CQI monitors, preparing documents and reports for review by the Coordinator of Research and Development (C/R&D), IRB and R&D Committee. The R&D AO/RCO ensures that the HRPP SOPs governing research are readily available to investigators, research staff, and anyone affiliated with the TVAMC in order to ensure that these individuals are informed about their responsibilities when conducting human research. The R&D AO/RCO is responsible for disseminating new information that may affect the HRPP, including laws, regulations, policies, procedures, and emerging ethical and scientific issues.

R&D Continuous Readiness Assessment Team (C-RAT) is chaired by the **Coordinator of R&D (C/R&D)** and is responsible for the oversight of existing CQI activities, for reviewing and revising existing HRPP policies and procedures, and for actively designing or facilitating the development of new CQI activities. The R&D C-RAT is responsible for ensuring the continuous readiness of the TVAMC HRPP for site visits conducted by numerous outside agencies, including the Joint Commission on Accreditation of Health Care Organizations, Association for the Accreditation of Human Research Protection Programs, Inc. (AHRPP), and Veterans Health Administration.

TVAMC Research and Development (R&D) Committee must assure that administratively approved CQI reports are reviewed and evaluated, make recommendations for appropriate corrective action related to findings of CQI reports related to research, and vote on any recommendations for actions proposed by the IRB on all CQI reports.

TVAMC Institutional Review Board (IRB) is responsible for participating in HRPP CQI reviews, when needed. The IRB reviews all CQI reports pertaining to the IRB, makes appropriate recommendations for quality improvement actions/measures to improve performance and votes on all recommendations for action forwarded to the R&D Committee.

Principal Investigators are responsible for cooperating in CQI processes, ensuring study related documents are available for review and following recommendations made by the AO/RCO, IRB, and R&D Committee regarding CQI findings.

Anyone involved in VA research must comply with the state and federal statutes, VA and TVAMC HRPP SOPs, including cooperating with CQI monitors and procedures.

4. PROCEDURES

a. CQI Monitoring Activities

Based on the needs of the TVAMC HRPP, the CQI activities may include, but is not limited to, a measurement of 1) patient satisfaction, 2) patient (or surrogate) consent process for those who do and do not participate in research, 3) investigator compliance, 4) IRB performance, 5) medical record documentation of informed consent, 6) IRB record keeping, 7) IRB resources, 8) pharmacy compliance, or 9) other processes as deemed necessary.

Any research protocol or research team of investigators is subject to CQI monitoring. At a minimum the CQI activities will monitor the compliance for reporting requirements (i.e. adverse events, protocol deviations), informed consent process, inclusion and exclusion criteria for protocols and any research that differs from an established protocol (i.e. to determine if research procedures or proposed changes did not commence until IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant). The following are principles for selecting a research protocol or research team for CQI:

- Any IRB approved research protocol involving currently enrolled human research participants may be reviewed.
- High risk research protocols will be prioritized for review first; otherwise a random selection will be made in selecting research protocols to be reviewed.
- A “for cause” review may be conducted at any time at the request of the R&D AO/RCO, IRB, R&D Committee or the C/R&D at any time potential or in event of serious deficiencies or complaints, close calls or unusual adverse events, or safety concerns identified in a research project.

Other CQI activities that will be monitored include oversight of the IRB, timely submissions of Continuing Reviews, compliance with HRPP annual training, compliance with the Research Data Security and Privacy policy, and compliance with

investigational drug policies. Other CQI reviews may be initiated as deemed necessary by the TVAMC HRPP, for example, a CQI evaluation of IRB processes and process time in order to improve the efficiency of the IRB.

In addition, investigators, IRB members, or R&D Committee members may bring forward concerns or suggestions regarding the HRPP, including the IRB review process and convey these suggestions to the C/R&D, R&D AO/RCO, or C-RAT. These suggestions are discussed between the parties concerned and possible improvements or changes are integrated into subsequent CQI activities.

b. CQI Review Procedures

Coordinated by the R&D AO/RCO, the C-RAT evaluates the effectiveness of a HRPP process, designs an improvement plan, implements the improvement plan, re-evaluates its effectiveness, judges whether further improvements are needed, and repeats the cycle as needed. Collectively this process is called CQI and the full cycle may take place over several months or several years.

Using audit or monitoring tools or surveys, the R&D AO/RCO, individuals in the HRPP designated by the R&D AO and/or the IRB members will conduct CQI reviews. Reviewers will be knowledgeable and familiar with the protocol being reviewed, CQI monitoring procedures, state and federal regulations and policy regarding human research participants and may NOT be personally involved with the protocol being reviewed. If a CQI monitor involves an investigational drug, the R&D AO/RCO will notify the Pharmacy Director to assist in the review the pharmacy drug logs. Findings are summarized in descriptive and frequency format as a report and recommendations that are forwarded to the C/R&D and subsequently to the C-RAT and IRB where it is evaluated. Corrective actions may be taken immediately if needed by the service, investigator, or program being evaluated. In addition, the IRB will vote on any recommendations for actions and forward the findings and recommendations for corrective action to the R&D Committee. The R&D Committee will review the findings and vote on any recommendations for action to improve compliance, quality and performance. The C-RAT makes additional plans for improvements and further monitors and measures, based on previous CQI reports. Trends over time may also be reviewed for measures of effectiveness of improvements.

c. Findings of Noncompliance

See the TVAMC HRPP SOP#18 Allegations of Non-Compliance for details on how findings of noncompliance is addressed by the TVAMC HRPP.

5. REFERENCES

- VHA Handbook 1200.1 and 1200.5
- VA Directive VA M-3 Part 1 Chapter 9

- TVAMC Center Memorandum 11-58 Patient Safety Improvement

6. ATTACHMENTS

CQI Audit Tools

7. RESCISSIONS

None.

8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

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