

LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service
SOP Cover Page

Effective Date: August 1, 2007

SOP Title: Quality Improvement Program (QIP)
SOP Number: ADM-001
SOP Version: .01

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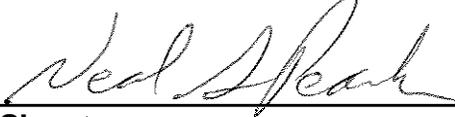


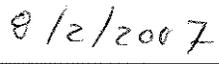
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Date

Approved By:

Associate Chief of Staff for Research



Signature 

Date

LOUIS STOKES CLEVELAND DVA MEDICAL CENTER
Medical Research Service
Standard Operating Procedure (SOP)

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1. **PURPOSE:** To establish a quality improvement program (QIP) for proactively assessing and improving the quality of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center's (LSCDVAMC) human research protection program (HRPP), animal care and use program (ACUP), and safety program.

2. **POLICY:** It is the policy of the LSCDVAMC to strive for excellence in research and education by identifying opportunities for improvement by focusing on programs that educate research personnel about their ethical and regulatory responsibilities in the conduct of research and on opportunities to improve processes. The primary focus of QIP is on research involving human subjects and protecting research participants, but may also address concerns related to the ACUP and/or to studies that do not use human or animal subjects.

3. **RESPONSIBILITIES:**
 - a. **Medical Center Director** is responsible for the overall implementation and effectiveness of the QIP.

 - b. **Associate Chief of Staff for Research and Development (ACOS/R)** is responsible for ensuring that the respective Service Chiefs and investigators participate in the QIP. The ACOS/R also ensures that necessary information is communicated when there are opportunities to improve research and education in Medical Center Services.

 - c. **Research and Development (R&D) Committee** is responsible for providing support, guidance and enforcement of quality improvement initiatives.

 - d. **Medical Executive Committee (MEC)** is responsible for reviewing and evaluating the scope, quality, and productivity of the LSCDVAMC Research Programs on an annual basis. The MEC reviews the final R&D Committee minutes from each monthly meeting. The ACOS/R reports regularly and updates the MEC on research-related activities and the HRPP.

 - e. **Performance Improvement Council (PIC)** directs and oversees the implementation of the LSCDVAMC's Performance Improvement Program. PIC reviews MEC activities via MEC minutes.

f. **Research Compliance Officer (RCO)** is responsible for facilitating the QIP which includes, but is not limited to, quality improvement, audits and monitoring, subject safety, data validation, quality control, compliance indicators and education. The RCO serves as chairperson of the QIP Oversight Committee, which is a subcommittee of the R&D Committee.

g. **Institutional Review Board (IRB) Office, Institutional Animal Care and Use Committee (IACUC) Office and Subcommittee on Research Safety (SRS) Office** are responsible for providing support, guidance and enforcement of quality improvement initiatives. They may also conduct audits and send reports of any findings to the QIP Committee through the RCO.

h. **Researchers and Study Staff:** Every individual directing or engaged in research has the responsibility to cooperate with and participate in quality improvement.

4. PROCEDURES/COMPONENTS:

Components of QIP include, but are not limited to:

- a. QIP Oversight Committee
- b. Quality Improvement
- c. Data Validation
- d. Participant Feedback
- e. Audits and monitoring
- f. Education and Training

a. QIP Oversight Committee

The QIP Oversight Committee advises the R&D Committee and its subcommittees on the compliance and assurance activities of the research program. It strives to maintain the high standards of the LSCDVAMC research program with emphasis on the HRPP. It is comprised of the Chief of Staff – Wade Park, ACOS/R, R&D Chairperson, Administrative Officer for R&D, a representative from Quality Management, and the RCO, who serves as committee chair. Ad hoc members include the subcommittee chairs (IRB Chairperson, IACUC Chairperson, and SRS Chairperson), IRB Administrator, IRB Coordinator, Research Safety Officer, IACUC Coordinator/Animal Research Facility Manager and/or Executive Director of VA Medical Research and Education Foundation. The Committee meets at least 4 times a year.

The Committee identifies areas for review for proactively assessing and improving the quality of the LSCDVAMC HRPP, ACUP, and safety program.

b. Quality Improvement

The QIP Oversight Committee follows a quality management process such as PDCA (Plan-Do-Check-Act) to evaluate the research program in order to determine whether it is effective in achieving its intended outcomes. Evaluation results are used to design and implement improvement plans.

c. Data Validation/Methodology:

- 1) The design of the activity is based on a specific statement of issues being evaluated.
- 2) The sample choice is unbiased and adequate to reflect the population of studies involved.
- 3) Data collection is conducted using a tool which will capture information required to address the issue in question and will ensure reproducible treatment of each sample.
- 4) Reporting is made to the R&D Committee and its appropriate subcommittees.

d. Participant Feedback / Research Participant Complaints

The RCO is the responsible representative to assist research subjects in exercising their rights. The RCO will provide a specific channel through which subjects can seek solutions to problems, concerns, and unmet needs. The RCO will investigate, document and respond to any research participant complaints and the QIP Oversight Committee will regularly review research participant complaint data. If the RCO identifies a potential problem, he/she will immediately bring it to the attention of the Committee. As needed, the Committee will initiate performance improvement activities to enhance customer service.

e. Audits and Monitoring

Quality improvement activities are prioritized and monitored with consideration of those projects that are high risk, high volume, and/or prone to problems. Priorities are adjusted in response to significant changes in the internal or external environment such as unusual or urgent events, e.g. those identified through data collection and assessment, unanticipated adverse occurrences affecting research participants, changing regulatory requirements, significant participant and staff needs, changes in the environment of care, or changes in the community.

Potential areas of audit and monitoring include, but are not limited to:

- 1) Performing investigator audits (regulatory documentation, IRB documentation, subject recruitment procedures, informed consent process, subject selection criteria, adverse event reporting, drug/device dispensing accountability, case report form/source documents, record keeping, allocation of responsibilities);
- 2) Monitoring informed consent process;
- 3) Monitoring subcommittees responsiveness to questions, concerns and complaints from participants, researchers, and/or subcommittees;
- 4) Evaluating the adequacy and effectiveness of the IRB, IACUC and/or SRS processes;
- 5) Evaluating subcommittee, i.e. IRB, IACUC and/or SRS, compliance with VA and federal regulations, and LSCDVAMC's policies.
- 6) Evaluating investigator knowledge and compliance with "FDA regulatory requirements for sponsors" for investigators that hold an Investigational New Drug Application (IND) or Investigational Drug Exemption (IDE).

f. Education and Training

The Clinical Research Orientation program is designed to provide an understanding of the critical elements to successfully initiate, administer and complete a clinical research study at the LSCDVAMC. This program is offered at least three times a year. The QIP Oversight Committee and/or Research Service continually evaluates and modifies this program based on changes in information, regulatory requirements, and participant and presenter feedback.

Research forums, which provide training and disseminate information on an ongoing basis, are presented at least four times a year. A general question and answer session is held at the end of each forum to provide a venue for open discussion of any suggestions, concerns, and/or questions our research community may have. Research forum topics are chosen by the QIP Oversight Committee and/or the Research Service based on policy and regulatory requirements, audience feedback, QIP activities/findings, etc.

Other educational training programs are provided as necessary.

5. **REFERENCE:** VHA Handbook 1200.1, 1200.5, MCP 000-005 "Performance Improvement (PI) Plan", LSCDVAMC Standard Operating Procedures Human Research Protection Program

6. **RESCISSION:** Medical Research Service ADM-001.00 "Quality Assurance and Improvement Program for Human Subjects Research" dated September 1, 2004 was rescinded. The review date for this SOP is August 1, 2010.

7. **FOLLOW-UP REponsibility:** Research Compliance Officer