SAINT LOUIS UNIVERSITY
INSTITUTIONAL REVIEW BOARD

QUALITY ASSURANCE REVIEW PROGRAM
(QAR)

INSTITUTIONAL REVIEW BOARD
OFFICE OF RESEARCH INTEGRITY
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INTRODUCTION

There are many benefits to quality assurance in research to both the University and the individual researcher. Demonstration of high quality research practices makes the University community more competitive in the global marketplace both for faculty and staff competing for research dollars, as well as for students seeking employment after their academic and research training at Saint Louis University. With increased competition for funding opportunities, the ability to demonstrate high quality research practices will provide the researcher with a competitive advantage over those who are unable to cite the ability to comply with University policy and federal regulations. In today’s climate of increased federal scrutiny, it is imperative that research programs can assure adherence to federal research compliance mandates in order to protect the reputation of the University, the researcher, and of academic research in general.

PURPOSE

The purpose of the QAR Program is to promote high ethical and quality standards in human subjects research and to support University compliance with federal regulations by providing monitoring and educational opportunities for researchers.

MISSION

The QAR Program is committed to: 1) work with researchers, staff, and students to assure compliance with all applicable federal, state, and institutional requirements and policies and 2) assist in fostering a culture of compliance at Saint Louis University.

GOALS

The QAR Program is committed to the overall goal of ensuring high quality research that is well-documented and has the highest level of integrity. The specific goals of Saint Louis University’s QAR Program are to:

1) Develop quality improvement initiatives, such as research compliance continuous education programs and corrective action plans;
2) Promote better communication among researchers, staff, compliance offices, and the IRB;
3) Assist in fostering a culture of compliance at Saint Louis University.
4) Assess research compliance activities to ensure high ethical standards in research;
5) Ensure compliance with University policies/procedures and federal regulations for human subjects research;
6) Identify and remediate any regulatory and University noncompliance;
7) Meet requirements for obtaining and maintaining accreditation for the Institutional Review Board (IRB).

**QAR ACTIVITIES**

The QAR program will consist of three major QA activities: 1) Routine Monitoring, 2) For-cause Investigations and 3) Compliance Education Programs.

**Routine Monitoring**

The QAR program will perform routine monitoring on a quarterly basis. Research departments are divided among the IRB coordinators (Coordinator Assignments). The QAR program will generally consist of one audit per coordinator per quarter. Investigators will not have routine QAR visits more than annually.

Routine Monitoring is the routine selection and review of an investigator, research study, or activities. For the most part, protocols to be audited will be chosen randomly, but the QAR personnel may use certain criteria for protocol selection, including but not limited to the involvement of:

- Vulnerable Populations (Children, Prisoners, Pregnant Women, etc.)
- Investigator Initiated clinical studies
- Large enrollment
- Multiple study sites
- Studies with identified conflicts of interest
- IRB termination of the protocol due to failure by the investigator to submit a study for continuation of IRB approval, or
- Follow-up monitoring.

Routine Monitoring is initiated by the random selection of investigator, research studies or activities. Once selected, the studies or activities will be reviewed according to standard operating procedures, and reports will be generated and sent to appropriate parties (e.g., division heads, institutional officials, the IRB).

*It is important to note that the intent of quality assurance review is not to be punitive; rather, it is designed to assist the researcher in assuring high quality research.*

Possible routine QAR visits could include, but are not limited to:

- Site visit
- Full study review
- Consent document review
- Observation of consent process
- Study organization and records review
- Research SOPs review (including security and storage of research records)
For-Cause Investigations
For-Cause Investigations are conducted in response to specific concerns or complaints. These investigations take place when there is credible evidence of a significant violation or misconduct of the conditions of the protocol or there are credible questions concerning the safety and welfare of research participants enrolled in the study. For-cause investigations are frequently initiated internally in response to whistleblower claims or concerns brought forth by an IRB committee or staff member, or externally in response to claims from an external agency (e.g. FDA, CRO, or study sponsor).

Education Programs
Education programs already exist at the Saint Louis University IRB. The QAR Program will offer supplementary Quality Assurance Self-Monitoring Programs as well as supplementary seminars and one-on-one assistance to improve areas found to be of issue during the monitoring or investigative visit.

QAR Self-Monitoring Education Programs (Under Development)
Principal investigators and other key research personnel have the opportunity to participate in the QAR Self-Monitoring Program, in which they can monitor their own research programs for compliance quality assurance. QAR Self-Monitoring working documents, such as tips sheets, guidance and forms, can be requested by the researcher or key research personnel. The QAR Self-Monitoring Programs may also be recommended as part of a corrective action plan for findings of non-compliance by the IRB or by the office of the Vice President for Research.

Once self-monitoring documents have been completed, the researcher or research personnel may request consultation. Written documentation need not be provided to QAR staff unless mandated or the researcher chooses to self-report.

QAR OFFICE AND NON-COMPLIANCE

Reporting Non-Compliance
QAR staff is responsible for the immediate reporting of non-compliance identified during monitoring or investigations. Such reports shall be made to the IRB administrative management who will work closely with the Administrative chairperson in accordance with IRB policies and procedures.

If reporting to federal agencies is required, such reporting will take place per the IRB Reportable Events SOP.

Corrective Action Plans
QAR staff will coordinate with the IRB if corrective action plans include QAR programs or initiatives.

**KEY PERSONNEL**

The QAR Program is located within the IRB Office.

The QAR staff will work closely with the following University committees, boards and offices to monitor human subjects research compliance:

- Institutional Review Board
- Radiation Safety Committee
- Institutional Biosafety Committee
- Conflict of Interest Committee
- Office of Sponsor Programs
- Office of Research Services
- Clinical Trials Office
- University Compliance Office

QAR staff, in collaboration with the IRB Executive staff, is responsible for the development of standard operating procedures, forms, and reports related to the above mentioned activities of the QAR Program.

The QAR staff will prepare and submit initial monitoring and investigative reports to appropriate parties. For routine monitoring or for-cause investigations in which non-compliance has been indicated during the investigative process, the QAR staff will provide IRB administrative management and Administrative Chair with information immediately. The final report is to be disseminated to applicable parties (e.g., division heads, institutional officials, federal agencies, sponsors). The final report will reflect IRB decisions and recommended actions from the convened IRB meeting.

**Sub-Committee**

If needed (in for-cause investigations), the Executive IRB Committee and QAR staff will work together to form a QAR Sub-Committee to serve as consultants to QAR staff during the course of the investigation. The Sub-Committee typically consists of the IRB Chair, QAR staff, and individuals with the expertise to serve as consultants for the focus of the investigation such as IRB members, members of General Counsel, and/or staff of other related research compliance areas.

**Monitoring and Investigative Teams**
The Assistant IRB Coordinator – Quality Assurance will coordinate each QAR team dependent on the volume of review or the need of additional expertise from other research compliance areas to perform the monitoring or investigative procedures. In cases of for-cause investigation, QAR staff may form a team including additional IRB staff to assist in the review of the IRB files, investigator regulatory files, and review of research participants' records. QAR staff will work with the other research compliance areas on forming a monitoring team when necessary.

**KEY ROLES**

Key roles to be accomplished by the QAR Team include the following:

- Development of Auditing Team
- Identification of sites for random audits
- Notification to researchers
- Arrangement of Monitoring Visits
- Performance of Monitoring Visits
- Selection of documentation for QAR monitoring/review
- Selection of protocols/documentation for follow-up QAR monitoring
- Creation of QAR Monitoring Reports
- Conduct QAR Continuous Education
- Notification to appropriate internal and external parties

**END OF DOCUMENT**