SAINT LOUIS UNIVERSITY
INSTITUTIONAL REVIEW BOARD

QUALITY ASSURANCE REVIEW PROGRAM (QAR)

INSTITUTIONAL REVIEW BOARD
RESEARCH INTEGRITY AND SAFETY GROUP
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
3556 CAROLINE STREET
ROOM C110
ST. LOUIS, MO 63104

INTRODUCTION

A quality assurance program provides many benefits to the University and its research program. It is imperative that research programs can assure adherence to federal research compliance mandates in order to protect the operation and reputation of the University, its human research program and researchers. Demonstration of high quality research practices also makes the University more competitive in the global marketplace. 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 federal regulations. Finally, the University and its researchers have an obligation to conduct high quality research to protect the safety and welfare of research volunteers; quality assurance can help to ensure high standards in conduct and identify areas for improvement.

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 and the Institutional Review Board (IRB).

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 IRB's QAR Program are to:

1) Monitor human research study conduct to assess compliance with University policies and applicable regulations;
2) Monitor IRB activities to assess compliance with University policies and applicable regulations;
3) Identify and remediate any regulatory and policy noncompliance;
4) Promote quality improvement initiatives, such as continuing education and self-assessment programs;
5) Promote better communication among researchers and the IRB Office;
6) Assist in fostering a culture of compliance at Saint Louis University.

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 - Investigator
The QAR program will perform routine investigator monitoring on a routine basis. Research departments are divided among the IRB Analyst (Department Assignments). Investigators will not have routine QAR visits more than every two years.

Routine Monitoring is the routine selection and review of an investigator, research study, or activities. For the most part, protocols to be reviewed 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 studies
- Large enrollment
- Multiple study sites
- Studies with identified conflicts of interest
- Safety or reportable events

Once selected, the studies or activities will be assessed for compliance with IRB-approved protocols, regulatory and policy requirements and potentially unit SOPs or sponsor requirements. Summary reports from the review will be generated and sent to appropriate parties (e.g., division heads, institutional officials, the IRB).

Routine QAR visits include, but are not limited to:

- Consent Documentation Review
- Observation of Consent Process
- Study Organization and Records Review
- Study Procedure Adherence Review
- Inclusion/Exclusion Criteria Review

Routine Monitoring - IRB
The QAR program will also perform routine reviews of IRB activities to assess compliance with regulations, policies and internal standard operating procedures. Internal QAR (iQAR) reviews include, but are not limited to:

- Consent Element Review
- Exempt Determinations
- Expedited Determinations
- Medical Device Determinations
- Meeting Minute Review
- Membership Roster Review

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 noncompliance with 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 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. CRO or study sponsor).

While the QAR program doesn't initiate for-cause audits, if QAR audit assistance is requested, QAR staff will conduct audits independently or in cooperation with the IRB or other university offices such as the Office of University Compliance.

QAR Self-Assessment and Education Programs

Principal investigators and other key research personnel have the opportunity to conduct self-assessment, in which they can monitor their own research programs for compliance and quality assurance. QAR Self-Assessment forms are made available to research personnel on the QAR website. Self-Assessment may also be recommended as part of a corrective action plan for findings of non-compliance by the IRB or other University offices. Written documentation of self-assessment need not be provided to QAR staff unless mandated or reportable violations are found.

If a need exists for external quality assurance, the QAR program will visit investigators on a voluntary basis. Information on how to request these services is maintained on the IRB QAR website.

The QAR Program will periodically offer seminars on commonly found errors and will offer one-on-one assistance to investigators during/after reviews to improve areas of improvement found during investigator reviews.

QAR PROGRAM AND FINDINGS OF NON-COMPLIANCE

Reporting Non-Compliance

QAR program staff are responsible for promptly notifying IRB management of potentially significant non-compliance identified during performance of routine reviews or for cause audits; requests are also made to the PI/research team to submit reportable events to the IRB directly.

Notifications of non-compliance shall be made to the IRB administrative management who will work closely with the IRB to address the events in accordance with IRB policies and procedures, including in reporting to institutional officials and/or federal agencies as applicable.

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

KEY PERSONNEL AND RESPONSIBILITIES

The QAR Program is located within the IRB.

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

- Identification of routine investigator reviews
- Notification to researchers
- Arrangement of Reviews
- Performance of Reviews
- Selection of materials for QAR review
- Creation and distribution of QAR Reports
- Conduct QAR Continuous Education
- Creation and maintenance of QAR SOPs
- Maintain documentation of QAR activities

QAR program staff may form a team that includes additional IRB staff or partners from the following committees or offices to assist in conducting reviews:

- Institutional Review Board
- Office of General Counsel/Compliance Office
- Radiation Safety Committee
- Institutional Biosafety Committee
- Conflict of Interest in Research Committee
- Office of the Vice President for Research
- Clinical Trials Office

END OF DOCUMENT