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.

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.