Saint Louis University
Office of Research Integrity
Quality Assurance Review (QAR) Program FAQ

- **What is the QAR Program?**
  - The QAR Program is part of the Research Division’s Office of Research Integrity (IRB Office specifically). 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. A full program description can be found here: [http://www.slu.edu/Documents/research/IRB/Quality%20Assurance%20Review%20Program_Final.pdf](http://www.slu.edu/Documents/research/IRB/Quality%20Assurance%20Review%20Program_Final.pdf).

- **How often are QAR visits conducted?**
  - We currently conduct 16 visits per year. Each quarter, 4 researchers with active IRB-approved research studies are chosen at random.

- **Are routine QAR visits an audit?**
  - Absolutely not. We are here to provide Quality Assurance. While we work closely with the IRB in the event there are any reportable findings, the purpose of our team is to ensure researchers are meeting all of the University’s and regulatory requirements so you are confident in the quality of your research program and will be prepared in case of an external audit.

- **Why was I chosen for a routine QAR visit?**
  - You were randomly selected during our routine quarterly investigator selection process. Your selection was in no way prompted by a complaint or other problem that would provide cause for concern. Investigators who conduct research with higher risk or sensitivity could be selected more often than others, but no investigator is randomly selected more than once every two years.

- **Who will be involved in the QAR visit?**
  - Hayley Graf, QAR Coordinator
  - The IRB Coordinator who oversees your department

- **Where will the review take place?**
  - The QAR team is dedicated to making this review as convenient as possible for you. In order to facilitate on-site review activities, we do request that the visit occur in or near your research space. Some visits also require the availability of a conference room or a quiet area with access to a photo copier for record reviews.

- **What can I do to prepare for the visit?**
  - Researchers are encouraged to review their research materials in advance of the visit. The QAR team is working on the development of self-assessment materials that can be used to prepare; those will be made available to the research community once available.
• **Will I need to be present during the review?**
  o As the Principal Investigator, you are ultimately responsible for the research. Because of this, your presence at the visit is mandatory. Other key research team members are welcome to attend and we may request to meet with other members of your research team to discuss findings and/or recommendations that may derive from the review once it is completed.

• **How long will this take?**
  o We generally give the investigator and research team about two weeks to prepare for the review, and the QAR team visit itself should not take more than a few hours depending on the review type. A summary report will be provided to the PI in the weeks following the visit.

• **What are the types of QAR visits? What typically takes place during these types of reviews?**
  There are currently 6 types of Quality Assurance Reviews:
  
  o **Research SOPs Review** - This is a general review of the investigator’s and study team’s standard operating procedures, including security and storage of research records.
  o **Study Organization and Records Review** – This type of review takes place on site and looks at study organization and record keeping.
  o **Site visit** – This is a more broad review of research documentation which may include touring the research facilities. Discussions with research personnel will take place to get a better feel for operating procedures.
  o **Observation of Consent Process** – At least one member of the QAR team will observe the consent process of one or more research study participants (with the permission from the research participant, of course!)
  o **Consent Documentation Review** – This review is focused on review of participant consent, assent, and HIPAA Authorization documents.
  o **Full Study Review** – This is a combination of most other reviews that may include (but is not limited to) general study information, general subject information, individual participant information, record keeping, and research SOP’s. The QAR team may tour the research facilities as well as conduct interviews with research personnel.