

**Saint Louis University  
Institutional Review Board  
Quality Assurance Review (QAR) Program**

**Frequently Asked Questions**

❖ **What is the QAR Program?**

The QAR Program is part of the OVPR's Research Integrity and Safety Group (IRB, 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. See the [QAR Program](#) for more information.

❖ **Are routine QAR visits an audit?**

We are here to provide Quality Assurance in order to proactively avoid non-compliance. 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 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.

❖ **Will I need to be present during the review?**

The Principal Investigator is ultimately responsible for the research, and as such, should attend. 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.

❖ **What will be looked at during the review?**

Unless requested, we do not currently review all elements of your research. Rather, our visits review a subset, such as adherence to an IRB protocol's study procedures, consent or data documentation and storage of research records. Please see our [Review Types](#) document for more information on particular reviews.

❖ **How long will this take?**

Depending on the review type, the QAR team visit itself should not take more than a few hours.

❖ **Who will be involved in the QAR visit?**

Typically the IRB Analyst who oversees your department. Other individuals may attend for training, support, or expertise purposes.

❖ **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?**

While there is nothing required of you to prepare for the visit, researchers are encouraged to review their research materials in advance of the visit. The [QAR Investigator Self-Assessment](#), available on the QAR Website, provides a good example of the types of things the QAR team assesses at reviews.

❖ **Who will be notified about the results of the QAR review?**

The PI and research team members present at the visit will get the detailed summary (if applicable) and final report from the QAR visit. Department Chairs, the SSM Health Representative (if research is conducted at an SSM Health site) and the IRB will be copied on the final report.

❖ **How often are QAR visits conducted?**

We currently conduct approximately 10 visits per year.