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

Types of QAR Reviews

If you were to be randomly selected for a QAR review, the review type will be stated in the notification email you receive. Review types include:

- Consent Documentation
- Consent Observation
- Inclusion/Exclusion Criteria
- Retrospective Data Collection
- Study Documentation & Records
- Study Procedure Adherence

Consent Documentation Review

Objective - to ensure that participant informed consent, assent, and HIPAA Authorization is being obtained and documented in accordance with federal regulations (45 CFR 46.116/21 CFR 50) and SLU requirements.

Elements of Review - The QAR team considers the following key elements when reviewing the consent documentation for a protocol:

1. The informed consent process has been appropriately completed and documented, including all applicable consents, assents and HIPAA authorization forms;
2. All relevant informed consent documentation has been appropriately stored in accordance with the privacy and confidentiality procedures stated in the approved protocol;
3. The informed consent documentation appropriately records the authorization of the subject's legally authorized representative, if applicable.

Consent Observation Review

Objective - to ensure that participant informed consent, assent, and HIPAA Authorization is being obtained in accordance with federal regulations (45 CFR 46.116/21 CFR 50) and SLU requirements.

Elements of Review - The QAR team considers the following key elements when observing the consent process:

1. The informed consent process has been appropriately completed and documented;
2. The participant has had sufficient time to consider study participation;
3. No coercion or undue influence has been used by the consenting staff;
4. The information presented to the participant reflects the content of the consent form and is conveyed in understandable language.

Inclusion/Exclusion Criteria Review

Objective - to assess verification documentation for inclusion and exclusion of subject eligibility.

Elements of Review - The QAR team considers the following key elements when reviewing inclusion/exclusion documentation:

1. The inclusion and exclusion criteria for subject eligibility was documented in accordance with the IRB-approved protocol and good clinical practice if applicable (i.e., source documentation is adequate)

Retrospective Data Collection Review

Objective - to ensure that research is being conducted in accordance with federal regulations for exempt/expedited categories of review, institutional requirements and IRB approval.

Elements of Review - The QAR team considers the following key elements when reviewing the data collection for a protocol:

1. The data collection was done in accordance with the IRB protocol;
2. The data are being stored appropriately according to the IRB protocol;
3. IRB-approved procedures to maintain confidentiality are in place, including the removal of any identifiers that may have been used during the data collection process

Study Documentation & Records Review

Objective - to ensure that research is being documented in accordance with federal regulations, institutional requirements and the IRB-approved procedures for maintaining confidentiality.

Elements of Review - The QAR team considers the following key elements when reviewing study documentation and research records:

1. The data collection was done in accordance with the IRB protocol;
2. That the data are being stored appropriately according to the IRB protocol;
3. IRB-approved procedures to maintain confidentiality are in place, including the removal of any identifiers that may have been used during the data collection process.

Study Procedure Adherence Review

Objective - to ensure the research is being conducted in accordance with the procedures approved in the IRB protocol.

Elements of Review - The QAR team considers the following key elements when reviewing the adherence to the IRB research protocol:

1. The study procedures were done in accordance with the IRB-approved protocol;
2. The study procedures were documented in accordance with the IRB-approved protocol and/or good clinical practice if applicable (i.e., source documentation is adequate);
3. Any adverse events were documented and assessed by the PI and reported to the appropriate parties.