Categories Reviewed by RCQA

Areas or documentation reviewed within these categories include, but are not limited to, the following

Subject Accountability

- Compliance with the Clinical Research Participant and Enrollment Tracking policy
- Documentation of subject withdrawals and screen failures

Informed Consent/Assent

- Informed consent/assent documentation
- Informed re-consent documentation
- Documentation of the consent process
- Elements of informed consent and ClinicalTrials.gov statement, ifapplicable, are included on informed consent form
- HIPAA Authorization Form B documentation

Training and Regulatory Administration

- Essential regulatory documentation
- Comparison of Grant document versus study protocol
- Documentation of training and in-services
- Licensure and certifications
- Delegation of Authority Log

Protocol Compliance

- Compliance with protocol requirements
- Study activity during periods of protocol suspension

Documentation Practices and Data Management

- Comparison of source data versus case report forms in electronic or paper form
- Documentation of changes made to research records
- Use of Good Documentation Practices

Subject Protection and Adverse Events

- Adverse event documentation, assessment and follow up
- Reporting of SAEs, AEs, UPs
- Compliance with HIPAA regulations
- Procedures to protect health, safety and rights of subjects
- PI oversight

Test Articles and Facilities

- Chain of custody of the investigational product
- Drug/medication transport, storage, dispensation, expiration, blinding, returns, and destruction
- Device storage, transport and labeling
- Documentation of test article management
- Current laboratory inspections/certifications
- Specimen handling and storage procedures
- Temperature logs

Sponsor

- Sponsor approvals
- Sponsor-investigator responsibilities
- Monitoring
- Submissions to the FDA