CONTINUOUS QUALITY IMPROVEMENT (CQI) ASSESSMENT PREPARATION

Most Common Deficiencies Identified

1. Deficiencies in Informed Consent documentation
2. Discrepancies between IRB application and practice
3. Lack of documentation (e.g., no documentation that subject met eligibility criteria)
4. Deficiencies in HIPAA form documentation
5. Deficiencies in communication with the IRB (e.g., adverse events incorrectly reported, expired study)

Sample Interview Questions

- Provide an overview of studies, procedures, organization, laboratory organizational chart, if available
- Describe overall investigator involvement in study; describe PI responsibilities delegated to study staff
- How is new staff trained? How is new information or changes to study or policies communicated to study team?
- Are regular meetings scheduled to discuss study progress? If so, who attends?
- Did the investigator encounter any problems in recruitment, subject retention or other areas? If so, what was the nature of the problem and how was it addressed?
- Has the investigator encountered any adverse events or unanticipated problems? How were they handled?
- Is there new information or updates regarding the study not yet communicated to the IRB, sponsor or other sites?
- Describe the subject population and demographics. Are they vulnerable? If yes, what extra protections are in place?
- How do you assess subject understanding of study/consent?