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?