

Quality Assurance Internship Program: a Model to Improve Compliance in an Academic Clinical Trials Office

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1. Background

One of the most challenging areas in clinical research is ensuring continued compliance with institutional standard operating procedures (SOPs) and regulatory requirements. Despite the delivery of consistent and comprehensive training, and existing quality assurance checks from both internal and external monitoring and auditing, errors are not consistently identified and corrected contemporaneously.

Our goal is to implement a proactive, process-driven Quality Assurance (QA) program within the Clinical Trials Office (CTO) at Huntsman Cancer Institute that focuses on evaluating and strengthening systems, supports adherence to institutional SOPs, enhances regulatory compliance, and emphasizes error prevention through targeted training rather than relying solely on Quality Control activities that identify issues after they occur.

2. Goals

- Support the development of the quality assurance program through the utilization of student interns who assist with QA projects under the oversight of the senior education and compliance manager, while also providing a pathway for potential future employment opportunities
- Support QA activities that help reinforce coordination staff competency in navigating SOPs and applicable regulations

3. Solutions and Methods

During creation of a formal QA program within the CTO, it was identified that student intern volunteers are an excellent resource. The interns are college student volunteers with interest in pursuing clinical research or other health care careers. They spend five to 10 hours per week working at the CTO. The focus of these interns is to receive rapid, structured training designed to support independent QA work. Following training, interns are assigned specific QA projects. These projects vary in scope and are adaptable based on the needs of the CTO.

QA projects are assigned to interns and overseen by the senior manager for clinical research education and compliance. Focused training and guidance are provided to interns for each project that they are assigned. Projects include subject chart review, monitoring to support complete and contemporaneous research notes, quality reviews of delegation logs, etc. QA interns are focused on a proactive process review to ensure compliance with established systems, and institutional procedures. Any findings are reviewed by the senior manager for education and compliance prior to disseminating them to the applicable coordination team.

4. Outcomes

1. Establishment of an expedited training program and onboarding of eight quality assurance interns
2. Completion of a variety of QA projects

5. Lessons Learned and Future Directions

An important aspect of the quality assurance internship program has been establishing streamlined training for the interns. This training enables them to function more independently and effectively within a quality assurance role. Another critical aspect has been to consistently identify appropriate and focused projects for the interns.

Throughout the upcoming year, our aim is to continue onboarding interns providing them with meaningful experiences and supporting the completion of QA projects for the CTO. Additionally, we aim to provide pathways to full-time entry-level roles within our laboratory or clinical research coordination teams for interns with experience in interventional adult oncology trials following graduation.

Figure

