Audit Committee Frequently Asked Questions (FAQs)

**What is the Audit Committee?**

The Audit Committee is responsible for overseeing the conduct of the auditing program, applicable to those studies monitored by the DMC. The Audit Committee meets semi-annually, following each comprehensive audit. Unless the Committee chair requests additional meetings, review following other audits is done via email. The Audit Committee is responsible for:

- Reviewing all audit findings and Corrective Action Plans (CAPs), assessing the audit’s outcome, and recommending measures for the next audit.
- Assisting with and advising on audit-related activities and questions, as needed.
- Attending key audits, as needed.
- Advising leadership on audit-related activities, outcomes, and policy issues.
- Assisting in the development of quality assurance tools and measures.
- Cause-specific review of all “problem” audits with particular attention to the following:
  - Decisions regarding recommendations to suspend an individual site’s accrual;
  - Recommendations to the DMC co-chairs of membership termination for a site due to substandard performance; and
  - Formulating recommendations to the DMC co-chairs of necessary changes to policy, protocols, or procedures based on cumulative audit findings.

**How are audits conducted?**

Audits are conducted quarterly with two comprehensive and two targeted audits performed each year. Audit assessments are primarily made following the “Clinical Trials Monitoring Branch (CTMB) Guidelines for Monitoring of Clinical Trials for Cooperative Groups, CCOP Research Bases and the Clinical Trials Support Unit (CTSU),” A biostatistician is responsible for randomly selecting cases for each audit, following the audit strategy guidelines. During the comprehensive audit, cases are selected by randomly choosing at least 10% of the subjects enrolled since the last comprehensive audit (6 months previous), with a minimum of 10 cases selected. Only those studies open or suspended to accrual at the time of the audit are at risk. At least one case is selected from any newly opened NU IIT within the past 6 months. The targeted audits focus on studies for which major deficiencies were found during the comprehensive audits and include an expanded audit of these trials.

While the Audit Committee oversees the audit process, the committee itself does not conduct the audits. Instead, the Quality Assurance Monitors (QAMs) assemble audit teams including faculty members, fellows, nursing staff and CRO staff to perform each audit. To avoid Conflict of Interest (COI), the faculty and staff who work on any of the studies included in each audit cannot be chosen to participate in that audit. Each audit team is responsible for a complete audit including:

- Case review, including a review of protocol compliance (subject consent, eligibility, treatment administration, monitoring for adverse events and outcomes). This review includes source document verification. The goal of source document verification is to not only ensure the protocol was followed and that this is well documented in the medical record, but also that the data reported on the case report forms is accurate.
- Review for appropriate adverse event reporting, focusing on identification of serious adverse events.
- Regulatory compliance review.
• Drug accountability and pharmacy review.
• Data quality review.

What happens after the audit?

The Audit Committee reviews and finalizes the Audit Report and determines if a CAP is required of any study team.

If required for an assessed deficiency, the study team must submit a CAP using the NU CAP template that identifies the root cause of the identified problem, creates a measurable solution that addresses the root cause, and has identifies personnel accountable for the solution.

Lastly, the Audit Report and all required CAPs are presented to the DMC for final review and approval. The DMC is responsible for reporting any findings that affect the scientific integrity of the trial to the SRC.