**POLICY**

The NCI audit guidelines note “FDA regulations require the Division of Cancer Treatment and Diagnosis (DCTD) to maintain a monitoring program. The Clinical Trials Monitoring Branch (CTMB) of the Cancer Therapy Evaluation Program (CTEP) in the DCTD, provides direct oversight of each Network Group’s monitoring program which includes auditing as one component. The purpose of an audit is to document the accuracy of data submitted to the Network Groups and to verify investigator compliance with protocol and regulatory requirements. In addition, the monitoring program provides an opportunity for the audit team to share with the institution staff, information concerning data quality, data management, and other aspects of quality assurance. The major objective of the audit program used by the Network Groups is to verify study data that could affect the interpretation of primary study endpoints. This is done through independent verification of study data with source documents.”

Cooperation with Research Bases data monitoring and onsite auditing programs with appropriate compliance is essential for the consortium success (NCI NCORP Programs Guidelines May 2018).

The NCI requires each research base to audit sites a minimum of every 36 months. This policy defines the process the Upstate Carolina NCORP will utilize when these audits are scheduled and performed by the research bases with or at any of the UC NCORP sites.

**RESPONSIBILITY**

*Community Responsible Investigator, QA Coordinator, all research staff*

**GUIDELINES**

**These guidelines are directly from the CTMB audit website**

* The institution will be supplied with a list of protocols and patient cases selected for review at least two but no more than four weeks prior to the audit according the CTMB audit guidelines. This allows the institution staff sufficient time to collect, prepare, assemble and label the required materials.
* A minimum of 10% of patient cases accrued since the last audit will be reviewed
* While most cases will be selected from patients accrued since the previous audit, any patient case may be at risk for selection for audit.
* In addition, the Network Group/NCORP Research Base must select at least one or more unannounced cases to be reviewed, if the total accrual warrants selection of unannounced cases. The audited institution(s) may learn of the unannounced case(s) the day before or the day of the audit.
* The institution is responsible for ensuring that all relevant materials are available for review at the time of the audit. If an institution is audited off-site at the Network Main Member, NCORP, or LAPS main member, the following records must be available the day of the audit: IRB documents, copies of the locally utilized informed consent forms, other regulatory documentation, if applicable
* NCI Drug Accountability Record Forms (DARFs) for control and satellite pharmacies, shipping receipts, etc. and/or log for imaging/radiopharmaceutical agents
* Complete medical records (or copies)
* Dictated report of all imaging studies (X-rays, scans, MRIs, PET, etc.)
* For imaging studies: source documents/worksheets used for imaging acquisition, processing, quality assurance documentation, reader’s interpretation, record of imaging administration, patient/study participant monitoring (vital signs, monitoring of contrast reactions, etc.), and log of staff signatures and imaging responsibilities

• Other relevant source documents or information

These above-mentioned documents must be made available the day of the audit or sooner, if requested by the Network Group/NCORP Research Base. The location of the audit may be at the institution being audited, the linked-parent (per the CTMB-AIS) or at the Network Group/NCORP Research Base conducting the audit. It is also recommended that a representative from each of the audited institutions be present at the audit (if applicable) to address questions during the audit.

**PROCEDURES**

**UC NCORP QA responsibilities:**

1. The audits will usually take place at the Consortium Office.
2. The UC NCORP QA coordinator will work with each site in obtaining an appropriate date requested by the research base. Notification of the chosen final approved date will be communicated with each site.
3. Each site will be notified of the audit participant case list, within one working day of receipt of the list with instructions from the research base indicating all items required for the audit. Specific items noted in the audit letter that are required PRIOR to the audit date are to be sent, by each site, according to audit letter instructions.
4. The UC QA Coordinator will coordinate/communicate the auditors request for information with each site prior to and after the audit.
5. The UC QA Coordinator will coordinate and integrate the final integrated audit response and CAPA’s from each site.
6. The audit reports and responses will be sent to the PI for review, approval of responses and signature. The reports will also be reviewed at the NC NCORP monthly leadership council meetings.
7. A copy of the reports should be sent to the local IRB if / when applicable or required per each sites policies.
8. The acceptance letter from the research base for the CAPA’s when required, will be filed electronically in the Consortium Office and each site will be provided with documentation of the acceptance of their CAPA.

**Site Responsibilities:**

1. Submission of any items requested by the research base, PRIOR to the audit, are to be sent as indicated in the audit letter.
2. Sites are expected to have all data up to date, in order and tagged appropriately prior to research base audits.
3. All charts should be tagged consistently identifying the following key items:

* Signed Informed Consent(s)
* Demographics
* Eligibility and Screening source documents and Form
* Treatment and/or Interventions by cycle or timeframe
* Adverse Event Logs
* Concomitant Medications
* Response documentation
* Specimen collection and shipments

1. Sites are responsible to bring to the audit, pharmacy documents: DARS, receipt packing slips, notes to file, prescriptions, agent return and or destruction documentation and temperature monitoring documentation.
2. At least one representative from each site, along with their records, is required to attend the audit at the UC NCORP office on the scheduled date for their charts to be reviewed.
3. Each site will submit any additional information not available during audit and any corrections requested while at the audit, within 24 hours of the audit when possible.
4. A completed CAPA is required by each site addressing those items indicated in their audit report. Each site’s completed CAPA will be submitted to NC NCORP office for review and integration into the final audit response.
5. *As noted in the section above, all items should flow thru the UC office for consistent communication unless otherwise noted.* If an affiliate site is contacted directly by a research base/sponsor regarding scheduling an audit for a Specific Federal Trial (those that requires an onsite individual audit), the site should notify the UC NCORP office of the communication. Please include name of lead auditor, Protocol #, the date of the audit and list of patients to be audited.

**REFERENCE:**

* <https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf>
* CTSU website-resources-education education available on auditing:
* NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program including NCORP and NCORP Research Bases: https://ctep.cancer.gov/branches/ctmb/clinicaltrials/monitoring\_coop\_ccop\_ctsu.htm

**ASSOCIATED FORMS: N/A**

**COMMITTEE APPROVAL:**

UC Policy and Procedure Committee