NCI National Clinical Trials Network
a National Cancer Institute program

NCI/DCTD/CTEP/CTMB

Summary of Changes to the CTMB Audit Guidelines

Effective: 10 April 2023

NOTE: Few revisions were made throughout the audit guidelines that are not reflected in this table if it did not change the meaning.

Summary of Changes to the CTMB Audit Guidelines (10 April 2023)

Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
1.	3.3	**[Auditable and Non-Auditable Institutions]** An 'Auditable' institution refers to an institution when an audit is scheduled and conducted as a single institution audit and the audit report will consist of findings only for that specific institution being audited (one final audit report by CTEP Site Code). A Preliminary Report of Audit Findings form is uploaded in the CTMB-AIS by the Group/NCORP Research Base for each audited site(s). Characteristics of an Auditable Institution: • The audit flag for the institution (by Group) is 'Yes' in the CTMB-AIS • Usually these types of audits are conducted on-site. On occasion, an audit can be conducted off-site if, for instance, the Network Group/NCORP Research Base is conducting a re-audit of only the regulatory documentation. In this scenario, the audited institution will be required to provide the appropriate documentation to the Group/NCORP Research Base location for review. This scenario would also apply to audits being conducted entirely off-site/remotely. • Auditable institutions may include NCORPs, Main Members, Affiliates, LAPS Main Members and LAPS Affiliates. A 'Non-Auditable' institution refers to an institution when an audit is comprised of more than one institution and a single final audit report consists of findings for all the institutions audited (one final audit report for multiple CTEP Site Codes). One Preliminary Report of Audit Findings form is submitted for the institutions audited 'as a whole' (combined). Characteristics of a Non-Auditable Institution: • The audit flag for the institution (by Group) is 'No' in the CTMB-AIS • Usually these types of audits are scheduled and conducted at the parent site (see Figure 1 on page 10) and corresponding Tier 2 (and Tier 3) sites being conducted offsite. The scheduling and auditing of multiple sites at a single visit is	**[Revised Paragraphs]** An 'auditable' institution (auditable flag set to 'yes' in the CTMB-AIS) is an institution that is designated to be audited as stand-alone audit with its own preliminary report and final audit report. This 'auditable' designation is required for all enrolling LAPS and rostered sites categorized as Tier 1 and Tier 2 sites (see Figure 1). See exception for a LAPS Integrated Component sites under Section 3.9. A 'non-auditable' institution (auditable flag set to 'no' in the CTMB-AIS) is an institution that is audited but in combination with other site(s). These types of audits are referred to auditing 'as a whole'. It is an audit comprised of more than one institution being reviewed and all information and audit findings incorporated into one preliminary report and one final audit report under the parent institution (consisting of multiple CTEP site codes). For NCORP sites, the designation of the auditable flag may vary and is at the discretion of the Group/Research Base. For instance, the auditable flag can be set to 'no' for all NCORP components (Tier 2) but the NCORP (Tier 1) must then be set to yes. Note that the auditable flag for a Tier 1 and Tier 2 institutions within the same NCORP cannot be both set to 'No' for an audit to be scheduled correctly. See Section 3.7 for alternative methods for setting the auditable flag for NCORP sites. Tier 3 sites (sub affiliate and NCORP sub affiliates) are routinely 'non-auditable' (auditable flag set to 'no' in the CTMB-AIS). The audits for these sites are scheduled to be in combination with the parent site. CTMB in consultation with the Group/NCORP Research Base may request to schedule a stand-alone audit of a Tier 3 site if there are reasons for concern. In this scenario, the auditable flag would need to temporarily change from 'No' to 'Yes' for the audit to be scheduled appropriately in CTMB-AIS. For audits that include non-auditable institutions, when there

Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
		considered an audit 'as a whole' (or combined). This scenario would not apply to audits being conducted entirely off-site/remotely. • The final audit report is generated for the parent site and includes all audited sites under the parent. All audited sites are listed by CTEP Site Code and institution name. <u>Other Items Related to the Audit Flag</u>: • The Network Group/NCORP Research Base is responsible for designating and/or changing the audit flag for Tier 1 and Tier 2 sites, where applicable. • The audit flag for a Tier 1 and Tier 2 institution within the same NCORP cannot be both set to 'No' for an audit to be scheduled correctly. This rule applies to NCORPs and NCORP Affiliates. • The audit flag for Tier 3 institutions must be set to 'No' in the CTMB-AIS. The CTMB (in consultation with the Group/NCORP Research Base) may request an on-site audit (and separate final audit report) of a Tier 3 site if there are reasons for concern. In this scenario, the audit flag would need to temporarily change from 'No' to 'Yes' for the audit to be scheduled appropriately. This scenario would not apply to audits being conducted entirely off-site/remotely. • For audits that include non-auditable institutions, when there are separate IRBs or pharmacies (i.e., receives drug directly from PMB or other sponsors), each IRB and pharmacy must be identified in the final audit report by CTEP site code, IRB name, and pharmacy location(s). Protocols and patient cases must be selected for review from the parent and each non-auditable institution being audited.	are separate pharmacies (i.e., receives drug directly from PMB or other sponsors), the pharmacy must be identified in the final audit report by CTEP site code and pharmacy location(s). Protocols and patient cases must be selected for review from the parent and each non-auditable institution being audited.
2.	4.3	**[Audit Location]** The use of the above approaches for off-site review is primarily intended for review of the Patient Case Review component. It is at the discretion of the Network Group/Research Base on how the review of the Regulatory Documentation and Pharmacy	**[Revised Paragraph]** The use of the above approaches is at the discretion of the Network Group/Research Base. The address to enter in the AIS database when scheduling an Off-site or Hybrid review is as follows:

Summary of Changes to the CTMB Audit Guidelines (10 April 2023)

Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
		components are conducted. Sites should not request the auditors to disclose any Personally Identifiable Information (PII) other than the auditor's name. Examples of what should not be provided are birthdate, copy of auditor's driver's license, social security number, etc. Their IAM account number may be used in lieu of these identifiers. Furthermore, auditors are not Business Associates as defined in the HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule.	• Off-site/Remote Review – enter address of Network Group/Research Base *or* Parent Institution • Hybrid Review – enter address of the where the component(s) being reviewed off-site is taking place. For example, if regulatory documents are reviewed at the Network Group and patient cases are review on-site at the institution, enter the 'off-site' address for the review of the regulatory documents. **Note:** Location of review by component must be identified under the Audit Procedures section of the audit report. For on-site visits, institutions may require all entrants (including auditors) to display a government issued ID. For off-site/remote visits, institutions may require the auditor to display a government issued ID. However, Personally Identifiable Information (PII) should not be requested of the auditor. Examples of what should not be provided are birthdate, copy of auditor's driver's license, social security number, etc. Their IAM account number may be used in lieu of these identifiers. Furthermore, auditors are not Business Associates as defined in the HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule.
3.	5.2	**[Review of the Regulatory Documentation]**	**[Added Text]** Protocols with no patient enrollment are not required to be selected for audit.
4.	5.2.4	**[Review of Informed Consent Content (ICC)]** The content of the local informed consent documents for at least four protocols (if there are four or more protocols) must be reviewed regardless of patient registration/enrollment to ensure the informed consent documents contain the elements required by federal regulations.	**[Deleted Text]** "regardless of patient registration/enrollment"

Summary of Changes to the CTMB Audit Guidelines (10 April 2023)

Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
5.	5.2.5	**[Review of the Delegation of Tasks Log (DTL)]**	**[Added Bullet]** Under: Major DTL Deficiencies • Performing study-related activities without an approved DTL
6.	5.2.6 5.3.5 5.4.2	**[Assessment of the Regulatory Documentation Review]** Acceptable • No deficiencies identified and no follow-up being requested • Few lesser deficiencies identified **[Assessment of the Pharmacy Review]** Acceptable • Compliance in all categories and no follow-up being requested **[Assessment of the Patient Case Review]** Acceptable • No deficiencies identified and no follow-up being requested • Few lesser deficiencies identified and no follow-up being requested	**[Revised Text]** Acceptable • No deficiencies identified, and no follow-up required • Few lesser deficiencies identified, and no follow-up required Acceptable • Compliance in all categories and no follow-up required Acceptable • No deficiencies identified, and no follow-up required • Few lesser deficiencies identified, and no follow-up required
7.	5.4.1	**[Deficiency Type by Category]** Under: General Data Management Quality – Major Deficiencies • Frequent data inaccuracies • Delinquent data submission* ***NOTE:** A major or lesser deficiency must be based on the following: extent of the delay, phase of the study, patient on active treatment versus follow-up, etc. The Groups and NCORP Research Bases have established guidelines and acceptability of the timeliness, completeness, and accuracy of submitted data. A disregard of or untimely data reporting per Group or NCORP Research Base guidelines may be rated as a major deficiency.	**[Added and Deleted Text]** Under: General Data Management Quality – Major Deficiencies • Frequent data inaccuracies; un-redacted data[a] • Delinquent data submission[b] [a] Assigning a major or lesser deficiency is dependent on the number of instances and type of un-redacted data (e.g., security number, patient name, etc.). [b] Assigning a major or lesser deficiency is based on the following: extent of the delay, percentage or number of delinquent forms, type of form (baseline, treatment, follow-up, etc), phase of the trial, patient on active treatment versus follow-up, etc.