



NCI/DCTD/CTEP/CTMB

# Summary of Changes to the CTMB Audit Guidelines

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Revised: January 2021

[Effective: 15 February 2021]

'Summary of Changes' does not include the items listed below:

- Editorial revisions throughout the document that did not change the meaning.
- The term 'days' was replaced with 'calendar days', where applicable.
- The term 'Component' when referring to a membership type was replaced with 'Affiliate' throughout the document.

## Summary of Changes to the CTMB Audit Guidelines (15 February 2021)

Item #	Section	Previous Text	New/Current Text (Added/Revised)
1	List of Appendices	<p>[List of Appendices]</p> <p>Appendix 1 – Audit Tool for Regulatory Documentation Review</p> <p>Appendix 2 – Audit Tool for Pharmacy Review</p> <p>Appendix 3 – Audit Tool for Patient Case Review</p>	<p><b>[Revised]</b></p> <p>Appendix 1 – Audit Worksheet for Regulatory Documentation Review</p> <p>Appendix 2 – Audit Worksheet for Pharmacy Review</p> <p>Appendix 3 – Audit Worksheet for Patient Case Review</p>
2	List of Acronyms		<p><b>[Added]</b></p> <p>List of Acronyms</p>
3	Section 1.2	<p>[Section Header] Background</p> <p>Coordinating activities of multi-Group audits for the Single Site Audit initiative</p>	<p><b>[Revised]</b></p> <p>[3<sup>rd</sup> Bullet Removed]</p>
4	Section 2.0	<p>[Section Header] Roles and Responsibilities for the Conduct of Quality Assurance Programs</p> <p>...implementation of RAVE (a common data capture system) and RAVE audit templates, launching the Single Site Audit pilot initiative, and the ongoing modifications...</p>	<p><b>[Revised]</b></p> <p>[Deleted Text]</p> <p>“launching the Single Site Audit pilot initiative”</p>
5	Section 2.2.2.4	<p>[Section Header] CTMB – Audit Information System (AIS)</p> <p>The CTMB-AIS can be accessed after providing a username and password...</p>	<p><b>[Revised]</b></p> <p>[Sentence Revised]</p> <p>The CTMB-AIS can be accessed after obtaining: An Identity and Access Management (IAM) account, appropriate documented training, and providing a username and password...</p>
6	Section 2.4.2	<p>[Section Header] Single-Site Audit Initiative (Multi-Group Audits)</p> <p>As part of an initiative between the CTMB and the CTSU, certain sites/ organizations are subject to audit by more than one Network Group at the same time, i.e., on the same date(s). These multi-Group audits are intended to promote more efficient auditing practices and are conducted in the manner described within these audit guidelines. Sites selected for a multi-Group audit can be Main Member sites, Lead Academic Participating Sites (LAPS), or NCI Community Oncology Research Program (NCORPs) sites, to include affiliates or components as appropriate. The CTSU, CTMB, and the Network</p>	<p><b>[Revised]</b></p> <p>[Revised Section Header]</p> <p>Auditing Patient Cases Utilizing the Source Document Portal (SDP)</p> <p>[Revised Text]</p> <p>This approach is an alternative to auditing patient cases when access to the EMRs cannot be obtained, or in some circumstances may also be used in combination with other approaches. The process of auditing utilizing this approach is currently only applicable to review of the Patient Cases. Review of the Regulatory Documentation and Pharmacy is conducted separately.</p> <p>The following instructions are available when conducting Remote Audits utilizing the Source Document Portal.</p>

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		Groups/NCORP Research Bases select these sites based on parameters related to accrual, Network Group audit schedules, expected audit duration, and other attributes of the site(s) or organization being audited. The CTSU facilitator for this initiative is responsible for orchestrating the logistics for a multi-group audit before, during and/or after the audit. A CTSU auditor may also assist a Group(s) with the audit or may take on the role of auditor in place of a Group auditor, per the Group's request. See link below for more information related to Multi-Group Audits: <a href="https://www.ctsu.org/readfile.aspx?fname=Public/Multi-Group-Audit-Overview.pdf">https://www.ctsu.org/readfile.aspx?fname=Public/Multi-Group-Audit-Overview.pdf</a>	Remote Auditing Instructions for Auditors (Note: Links below require log-in to the CTSU website) <a href="https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-REMOTE-AUDITING-AUDITORS#Introduction">https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-REMOTE-AUDITING-AUDITORS#Introduction</a>  Remote Auditing Instructions for Site Staff: <a href="https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-REMOTE-AUDITING-SITES#Introduction">https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-REMOTE-AUDITING-SITES#Introduction</a>
7	Section 3.3	[Section Header] Auditable and Non-Auditable Institutions [Sub-Header] Characteristics of an Auditable Institution	<b>[Added]</b> [Added Text to End of 2 <sup>nd</sup> Bullet] This scenario would also apply to audits being conducted entirely off-site/remotely.
8	Section 3.3	[Section Header] Auditable and Non-Auditable Institutions [Sub-Header] Characteristics of a Non-Auditable Institution	<b>[Added]</b> [Added Text to End of 2 <sup>nd</sup> Bullet] This scenario would not apply to audits being conducted entirely off-site/remotely.
9	Section 3.3	[Section Header] Auditable and Non-Auditable Institutions [Sub-Header] Characteristics of a Non-Auditable Institution  The final audit report is generated for the parent site, and all audited sites audited are listed CTEP site codes and institution name.	<b>[Revised]</b> [Revised 3 <sup>rd</sup> Bullet] 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.
10	Section 3.3	[Section Header] Auditable and Non-Auditable Institutions [Sub-Header] Other Items Related to the Audit Flag	<b>[Added]</b> [Added Text to End of 3 <sup>rd</sup> Bullet] This scenario would not apply to audits being conducted entirely off-site/remotely.
11	Section 3.5	[Section Header] Network Group Main Member Institutions  The 18 month rule does not apply to an institution that has been previously audited by the same Group or legacy Group. This rule also applies if a main member institution moves to a new location...	<b>[Revised]</b>  The 18-month rule does not apply to an institution that has been previously audited by the same Group. This rule also does not apply if a Main Member institution moves to a new location...

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12	Section 3.6	[Section Header] Network Affiliate, LAPS Affiliate and LAPS Aligned Affiliates Institutions	<b>[Added]</b> [Added Text to End of Paragraph] This scenario would not apply to audits being conducted entirely off-site/remotely.
13	3.11	[Section Header] Auditing of Withdrawn or No Longer Funded (NLF) Institutions  If the NCORP is “defunded” by DCP or the LAPS by CTEP, their status will be set to ‘NLF in the CTMB-AIS...	<b>[Revised]</b> [Sentence Revised] If the NCORP is “defunded” by DCP, or the LAPS is no longer funded by CTEP, their membership status will be set to ‘NLF’ in the CTMB-AIS...
14	3.11	[Section Header] Auditing of Withdrawn or No Longer Funded (NLF) Institutions  The decision whether to audit should be based on the number of total patient cases and protocols with emphasis on important or pivotal trials, have a high number of patients/study participants in follow-up, or are not meeting acceptable quality standards for audit and/or follow-up data. If the institution has never been audited, it must have a close out audit. A decision not to audit these institutions must first be discussed with CTMB.	<b>[Revised]</b> [Last Paragraph Revised] [Added Text] The decision whether to conduct an audit is based on the following: <ul style="list-style-type: none"> <li>• The number of patient cases enrolled since the previous audit.</li> <li>• The number of active protocols with emphasis on registration or pivotal trials.</li> <li>• If there is a high number of patients/study participants in follow-up.</li> <li>• Site performance is not meeting acceptable quality standards for audit and/or submitting follow-up data.</li> </ul> If there is accrual and the institution has never been audited, it must have a close out audit conducted. A decision not to audit these institutions must first be discussed with CTMB.
15	4.3		<b>[Added]</b> [New Section Header] Off-site/Remote Audit  [Added Text] For continued oversight of patient safety, there may be circumstances when remote auditing (i.e., off-site) is necessary. To the extent possible, this approach should include remote access to the site’s Electronic Medical Records (EMRs) system. Due to logistical issues and unfamiliarity with the site’s EMR system related to conducting remote audits, it may require extending the audit duration (i.e., # of days). Use of the Source Document Portal (SDP) as described under Section 2.4.2 is an alternative and may also be used in combination with other approaches.

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			<p>The use of the above approaches is primarily intended for review of Patient Cases. It is at the discretion of the Network Group/ Research Base on how the review of the Regulatory and Pharmacy documentation are provided and reviewed.</p> <p>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.</p>
16	4.4 <i>(Previously Section 4.3)</i>	[Section Header] Selection of Protocols and Patient Cases	<p><b>[Revised]</b></p> <p>[Section Header Revised] Selection of Protocols and Patient Cases for On-site or Off-site Audits</p>
17	4.4 <i>(Previously Section 4.3)</i>	<p>[Section Header] Selection of Protocols and Patient Cases</p> <p>In addition to the above criteria, a patient case from every registration trial must be selected for audit. This includes patients enrolled onto a registration trial for every site being audited. Depending on the volume of patients enrolled onto a registration trial, auditing additional patient cases may be required. A listing of clinical trials designated as registration trials can be found at: <a href="http://www.ctsu.org/RAVE/SiteAudit.aspx?nodeKey=11385">www.ctsu.org/RAVE/SiteAudit.aspx?nodeKey=11385</a></p>	<p><b>[Revised]</b></p> <p>[Deleted Text] A listing of clinical trials designated as registration trials can be found at: <a href="http://www.ctsu.org/RAVE/SiteAudit.aspx?nodeKey=11385">www.ctsu.org/RAVE/SiteAudit.aspx?nodeKey=11385</a></p>
18	4.4 <i>(Previously Section 4.3)</i>	<p>[Section Header] Selection of Protocols and Patient Cases</p> <p>While most cases will be selected from patients accrued since the previous audit, any patient case may be at risk for selection for audit.</p>	<p><b>[Revised]</b></p> <p>[Sentence Revised] While most cases will be selected from patients accrued since the previous audit, any patient case may be audited at any time.</p>
19	4.4 <i>(Previously Section 4.3)</i>	<p>[Section Header] Selection of Protocols and Patient Cases</p> <p>These cases may have a limited review consisting of minimally reviewing the patient informed consent document and patient eligibility. Note: If unannounced cases receive a limited review, these patient cases do not count towards the required minimum of 10% to be reviewed.</p>	<p><b>[Revised] [Added]</b></p> <p>[Sentence Revised/Sentence Added] These cases may have a limited review consisting of minimally reviewing the patient informed consent document and patient eligibility to be counted as part of the selection process noted above. Note: If unannounced cases receive a limited review, these</p>

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			patient cases do not count towards the required minimum of 10% to be reviewed. Selection of unannounced cases for review does not apply when conducting an off-site/remote audit.
20	4.4 <i>(Previously Section 4.3)</i>	[Section Header] Selection of Protocols and Patient Cases  In the event of a patient case transfer to another institution (another CTEP site code), it is the 'date of transfer' that the responsibility shifts to the new Clinical Investigator/ institution where the patient case resides.	<b>[Revised]</b>  [Paragraph Revised] In the event of a patient case transfer, the receiving/accepting institution should ensure that complete documentation is provided as part of the transfer process. Any audit taking place after the date of transfer will occur in its entirety at the receiving/accepting institution. This is because only the accepting institution will have access to the subject's information after the transfer takes place.
21	4.6 <i>(Previously Section 4.5)</i>	[Section Header] Institution Responsibilities  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: <ul style="list-style-type: none"> <li>• IRB documents, copies of the locally utilized informed consent forms, other regulatory documentation, if applicable</li> </ul>	<b>[Revised]</b>  [Sentences Revised] If an institution is audited off-site at the Network Main Member, NCORP, LAPS Main Member or if the entire audit is conducted remotely, the following requested records must be available during of the audit: <ul style="list-style-type: none"> <li>• IRB documents, copies of the locally utilized informed consent documents, Delegation of Tasks Logs (DTLs) and other regulatory documentation, if applicable</li> </ul>
22	4.6 <i>(Previously Section 4.5)</i>	[Section Header] Institution Responsibilities	<b>[Added]</b>  [Added Text] For audits conducted off-site/remotely, the circumstances vary depending on the approach used to review the documentation. Regardless, the above bulleted items must be made available as requested. A designated site staff member must also be available to contact and assist with navigating through the site's EMR system, when necessary.
23	5.2	[Section Header] Review of the NCI CIRB – IRB of Record  Unanticipated problems, serious non-compliance and/or continuing noncompliance problems as defined by OHRP not reported (see <a href="https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html</a> )	<b>[Revised]</b>  [Revised Text] Unanticipated problems, serious non-compliance and/or continuing noncompliance problems as defined by OHRP are reported (see <a href="https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr46/index.html</a> )

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24	5.2.5	[Section Header] Review of the Delegation of Tasks Log [Sub-Header] Major DTL Deficiencies  Individual not listed on DTL	<b>[Revised]</b>  [Revised Text] Individual performing study-related activities not listed on DTL
25	5.3.1	[Section Header] Control Dispensing Area/Pharmacy  Timely final disposition of non-dispensed study-supplied agents	<b>[Revised]</b>  [5 <sup>th</sup> Bullet Revised] Timely return of final disposition of non-dispensed study-supplied agents
26	5.3.5	[Section Header] Assessing the Accountability of Investigational Agents and Pharmacy Operations [Sub-Header] Limited Review Needs Follow-up (applies to 'on-site' pharmacy audits only)	<b>[Revised]</b>  [Sub-Header Revised] Limited Review Needs Follow-up (On-site or Virtual Pharmacy Visits Only)
27	5.3.5	[Section Header] Assessing the Accountability of Investigational Agents and Pharmacy Operations  For other routine pharmacy audits, the Groups/NCORP Research Base can use their own discretion to determine if/when an on-site audit of the pharmacy should be conducted.	<b>[Revised]</b>  [Revised Text] For other routine pharmacy audits, the Groups/NCORP Research Base can use their own discretion to determine if/when an on-site or virtual visit of the pharmacy should be conducted.
28	5.4	[Section Header] Review of Patient Case Records  Reporting of adverse events related to treatment	<b>[Revised]</b>  [5 <sup>th</sup> Bullet Revised] Assessment and reporting of adverse events related to treatment
29	5.4.1	[Section Header] Deficiency Type by Category [Sub-Header] General Data Management Quality – Major Deficiencies  Protocol-specified laboratory tests not done, not reported, or not documented	<b>[Revised]</b>  [2 <sup>nd</sup> Bullet Revised] Protocol-specified laboratory tests or other parameters (Quality of Life forms, collection of research samples, etc.) not done, not reported, or not documented
30	6.2.1	[Section Header] Submission (Preliminary Report)  A revised preliminary report may be uploaded into the CTMB-AIS if it is within ten business days of the audit.	<b>[Revised]</b>  [Revised Text] A revised preliminary report may be uploaded into the CTMB-AIS if it is within ten business days of Day 1 of the audit.

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31	6.3.2.5	<p>[Section Header] Audit Procedures</p> <p>This section indicates audit procedures such as how the audit was conducted, if any items were reviewed 'off-site', and other pertinent information.</p>	<p><b>[Revised]</b></p> <p>[Revised Text]</p> <p>This section indicates audit procedures such as how the audit was conducted, if any items were reviewed off-site or if entire audit was conducted remotely, and other pertinent information.</p>
32	6.5	<p>[Section Header] Re-audits</p> <p>For tracking purposes, off-site re-audits must also be scheduled and reported in the CTMB-AIS.</p>	<p><b>[Revised]</b></p> <p>[Revised Text]</p> <p>For tracking purposes, any off-site/remote audit or re-audit must also be scheduled and reported in the CTMB-AIS.</p>