



**DATE:** August 23, 2019

**SUBJECT:** Addendum to 2017 NCTN Audit Guidelines

**TO:** NCTN Group Administrators, QA Audit Coordinators, NCORP Research Bases and Other CTMB-AIS users

**FROM:** Gary Smith, M.G.A., Chief of the Clinical Trials Monitoring Branch 

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The following changes to the 'NCI Guidelines for Auditing Clinical Trials for the NCI National Cancer Trials Network (NCTN) Program including NCI Community Oncology Research Program (NCORP) and NCORP Research Bases' commonly referred to as the CTMB Audit Guidelines are effective the date of this memo.

1. **Section 4.2.** Arranging the Audit

Sentence reads as: "The institution must 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. "

Sentence change to: "The institution must be supplied with a list of protocols and patient cases selected for review at least four but no more than six weeks prior to the audit."

2. **Section 5.1** Assessing Audit Findings – Definition of a Lesser Deficiency

Lesser Deficiency definition reads as: "Finding does not have significance impact on the outcome or interpretation of the study...An unacceptable frequency/quantity of lesser deficiencies should be **treated** as a major deficiency when determining the final assessment of a component."

Lesser Deficiency definition changed to: "Finding does not have significance impact on the outcome or interpretation of the study...An unacceptable frequency/quantity of lesser deficiencies should be **assigned** as a major deficiency when determining the final assessment of a component."

3. **Section 5.2.4** Review of Informed Consent Content (ICC)

Consistent with changes made when implementing the 2017 Audit Guidelines with requiring a minimum of four protocols representing studies conducted at the institution to be selected for audit (per Section 4.3), change should also apply to the number of informed consent documents reviewed.

Reads as: "The content of the local informed consent documents for at least **three** protocols (if there are **three** or more protocols) must be reviewed for content..."

Changed to: "The content of the local informed consent documents for at least **four** protocols (if there are **four** or more protocols) must be reviewed for content..."

4. **Section 5.3.5** Assessing the Accountability of Investigational Agents and Pharmacy Operations

Header reads as: No Assessment Required (*applies to 'on-site' pharmacy audits only*)

Header changed to: No Assessment Required

5. **Section 5.4.1** Deficiency Type by Category (General Data Management Quality – Major Deficiencies)

Deficiency type reads as: Errors in submitted data

Deficiency type changed to: Errors in submitted data; data cannot be verified

6. Throughout entire document (changes in the CTMB-AS database related to this change are due to occur in the very near future):

All references to NCORP Component changed to “NCORP Affiliate”

All references to NCORP Sub Component changed to “NCORP Sub Affiliate”