ETCTN

Experimental Therapeutics Clinical Trials Network

Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

NCI/DCTD/CTEP/CTMB

Summary of Changes to the ETCTN Monitoring Guidelines

Effective: 10 April 2023

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

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

Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
1.	3.1.2	**[Routine Monitoring (CTMS-Monitored)]** For protocols assigned for CTMS Routine Monitoring, data is to be submitted to CTMS at least once every two weeks via Medidata Rave (or other modality if approved by CTEP). Monitoring visits will be conducted on an 18-36 month basis as part of routine cancer center site visits.	**[Deleted Text]** "as part of routine cancer center site visits"
2.	4.2	**[Location of Monitoring Visit]** 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 CTMS with consultation with CTMB on how the review of the Regulatory Documentation and Pharmacy components are conducted. Sites should not request the monitors to disclose any Personally Identifiable Information (PII) other than the monitor's name. Examples of what should not be provided are birthdate, copy of monitor's driver's license, social security number, etc. Their IAM account number may be used in lieu of these identifiers. Furthermore, monitors are not Business Associates as defined in the HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule.	**[Revised Paragraphs]** The use of the above approaches is at the discretion of the CTMS with consultation with CTMB. The address to enter in the AIS database when scheduling an Off-site or Hybrid review is as follows: • Off-site/Remote Review – enter address of CTMS 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 CTMS and patient cases are reviewed 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 Review Procedures section of the monitoring report. For on-site visits, institutions may require all entrants (including monitors) to display a government issued ID. For off-site/remote visits, institutions may require the monitor to display a government issued ID. However, Personally Identifiable Information (PII) should not be requested of the monitor. Examples of what should not be provided are birthdate, copy of monitor's driver's license, social security number, etc. Their IAM account number may be used in lieu of these identifiers. Furthermore, monitors are not Business Associates as defined in the HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule.

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Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
3.	5.2	**[Review of the Regulatory Documentation]**	**[Added Text]** Protocols with no patient enrollment are not required to be selected for review.
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"
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

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Item #	Section	[Section Header Name] Previous Text	[Added, Revised or Deleted] New/Current Text
7.	5.4.1	**[Deficiency Type by Category]** Under: <u>General Data Management Quality – Major Deficiencies</u> • 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: <u>General Data Management Quality – Major Deficiencies</u> • 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.