Clinical Trial Monitoring Services for College of Medicine Investigator-Initiated Trials	CR-405
Clinical Research Standard Practices	**Effective Date:** August 2023

SCOPE AND PURPOSE The document is applicable to the following people and processes of Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:

Roles:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
X	Data Specialists	X	Central Research Office Personnel

This policy describes the Clinical Trial Monitoring (CTM) services provided by the Department of Public Health Sciences (PHS) to Penn State College of Medicine (COM) investigator-initiated trials (IITs). Since 2015, the Penn State College of Medicine (COM) has supported CTM.

POLICY AND PROCEDURE STATEMENTS

1. CTM services are required by the COM for IITs that involve an investigational new drug (IND), investigational device exemption (IDE), or multi-site. IITs that are classified high-risk by the Penn State University HRPP/Institutional Review Board (IRB) and/or Research Quality Assurance (RQA) offices.

2. In addition to structured CTM throughout the study, the Human Research Protection Program (HRPP)/IRB may direct the PHS to provide 'for cause' monitoring services to IIT outside these criteria.

3. The CTM services provided by the PHS support all COM investigators serving as the Sponsor Investigator for clinical research, including investigators with a dual appointment to another institute or college. The Penn State Sponsor Investigator will review, approve, and facilitate the implementation of the PHS clinical trial monitoring plan in collaboration with the PHS clinical trial monitor(s) responsible for implementing the CTM services.

4. The PHS receives institutional support from the COM to provide CTM services at no-charge to COM IITs meeting the above criteria when no discreet funding for monitoring is included in the funding agreement for the IIT.
    a. Investigators are encouraged budget for the cost of CTM when submit grant proposals. The Clinical Trials Office can assist with budgeting this service

5. RQA will meet with the PHS clinical trial monitors routinely to review study monitoring activities, and the RQA Director will be copied on all Penn State site monitoring reports. The RQA Director will be copied on any external site monitoring reports if corrective actions are noted by the Penn State Sponsor Investigator or delegate. This communication serves as a reporting line to the COM as the sponsor of IIT monitoring services.

RELATED POLICIES AND REFERENCES

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

International Conference on Harmonization Good Clinical Practice E6(R2)

Clinical Research Definitions (CR-104)

Sponsor/CRO Monitoring Visits (CR-212)

APPROVALS

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DATE OF ORIGIN AND REVIES

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Review Date(s):

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