Criteria for the Required Submission of Studies in Institution's Clinical Research Management System	CR-111
Clinical Research Standard Practices	**Effective Date:** March 2025

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

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

This policy describes the criteria for determining which clinical research studies require submission in the Institution's Clinical Research Management System (CRMS). A CRMS serves as a centralized platform for research sites to efficiently manage all aspects of a clinical trial, including study timelines, enrollment tracking, regulatory documentation, financials, and reporting. STAR ensures regulatory compliance with federal regulations as well as Good Clinical Practice and institutional policies.

A CRMS enhances billing compliance and financial tracking by managing budgets, invoicing, and reimbursements while ensuring adherence to Medicare Coverage Analysis (MCA) and other financial regulations. Participant management is also streamlined, allowing research teams to track enrollment, visit schedules, and study milestones while minimizing protocol deviations. Furthermore, a CRMS optimizes site productivity by reducing administrative burdens and improving workflows for study coordinators, investigators, and other staff engaged in clinical research administration and operations.

The key benefits of using a CRMS include improved study oversight through real-time dashboards and reporting, allowing teams to monitor progress and enrollment goals. Automated scheduling and reminders help manage visit schedules and ensure compliance with study timelines. A CRMS also facilitates better communication and collaboration between study teams and other institutional staff by providing remote access and centralized coordination. Optimized budgeting and financial management allow for accurate tracking of payments, invoicing, and contract milestones, ensuring financial transparency. Finally, a CRMS enhances compliance and audit readiness by maintaining comprehensive audit trails, making regulatory inspections more seamless. Overall, a CRMS significantly improves trial efficiency, financial oversight, and communication, making it an essential tool for research sites.

This policy may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. The official CRMS of Penn State College of Medicine and Penn State Health is Study Tracking and Analysis for Research (STAR) system.

2. A CRMS submission is mandatory for any clinical research study that meets any of the following criteria:
    a. **Hospital Billing Capture**: Studies where items and services may be captured in the hospital billing system, including services from Clinical Research Core (CRC), Clinical Specimen Processing Core (CSPC), and Investigational Drug Service (IDS), and potentially billable to a study sponsor, a third-party payer, and/or the participant. This includes, but is not limited to:
        i. Externally sponsored research studies
        ii. Investigator-Initiated Trials funded by departmental monies, the federal government, non-profit, or for-profit entities.
    b. **Invoicing**: Studies in which invoices will be generated to a sponsor/funding agency for services provided.
    c. **NIH definition of a Clinical Trial**: a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
        i. Applies to new studies opening effective April 1, 2023.
    d. **Clinical Trial Office Involvement**: Studies that are budgeted and/or negotiated by the CTO.

3. A CRMS submission is optional for non-billable/non-invoiceable clinical studies that do not meet the NIH definition of clinical trials. Research teams may choose to use the STAR system for study participant and financial tracking functionality. Optional studies may include:
    - Chart reviews
    - Survey studies
    - Educational/training studies
    - Biospecimen collection/analysis
    - Interview procedures or focus groups
    - Data collection/data analysis
    - Patient registries
    - Long-term follow-up
    - Observational studies

    a. Investigators and/or study teams considering the use of the Institution's CRMS for an optional study should contact the Clinical Trials Office.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Protection of Human Subjects (45 CFR 46, "Common Rule")

National Institutes of Health website: NIH Definition of a Clinical Trial (https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition)

Clinical Trials Office website (https://research.med.psu.edu/research-support/clinical-trials-office/)

STAR website (https://research.med.psu.edu/research-support/star/)

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

APPROVALS

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