Audits and Inspections	CR-403
Clinical Research Standard Practices	**Effective Date:** August 2022

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

Entities:

[ ]	Penn State Health Shared Services
[X]	Milton S. Hershey Medical Center
[X]	St. Joseph Medical Center
[X]	Holy Spirit Medical Center
[X]	Hampden Medical Center
[X]	Penn State College of Medicine
[X]	Medical Group – Academic Practice Division
[X]	Medical Group - Community Practice Division
[X]	Penn State Health Life Lion, LLC

Roles:

[X]	Principal Investigator
[X]	Sub-Investigator
[X]	Study Coordinators/Associate
[X]	Data Specialist
[X]	Financial Analyst
[X]	Key Study Ancillary Personnel

This standard operating procedure (SOP) describes the operations followed at this investigative site when an audit (internal, Sponsor/CRO and FDA) occurs to assess this site's extent of compliance with regulatory requirements/guidelines and SOPs for conducting clinical research.

This SOP applies to the procedures to prepare for an audit at any of the clinical studies conducted at this site. It describes the steps followed by the site from the time the audit is scheduled until all follow-up activities associated with the audit have been completed.

POLICY AND PROCEDURE STATEMENTS

1. Preparing for the audit

    a. If notified of an audit, notify the sponsor (if applicable), PSU Human Research Protection Program, Research Quality Assurance (RQA) Director, Clinical Trials Office (CTO) Director, and all other parties involved with the study as soon as possible (e.g. Investigational Drug Services).
    b. Ensure that all documentation, including informed consent forms, source documents, case report forms, and the regulatory binder for the study identified as the focus of the audit are accurate, complete and available for review by the auditor.
    c. For guidance in preparing for an internal audit refer to the IRB Policies and Operating Procedures maintained in CATS-IRB and contact the Research Quality Assurance office.

d. For drug studies:
    i. Ensure that the study drug dispensing records are accurate, complete and available for review. If there were any instances in which emergency breaking of the blind was required, have that documentation available.
    ii. Ensure that drug accountability records are accurate, complete and available for review.
e. Ensure that records of staff qualifications and training are available for review by the auditor.

2. During the audit
    a. Meet with the auditor or inspector. Request to see identification, and if this is an FDA audit, request Form FDA 482. A representative from Research Quality Assurance (RQA) may be in attendance in cases of for cause inspections or at the request of the investigator.
    b. Provide orientation and access to the study records and files.
    c. Provide copies of requested study-related documents. Maintain a list of or copies of all documents provided.
    d. Ensure that questions posed by the auditor or inspector are answered by appropriate study personnel.

3. Following up after the audit
    a. Participate in the exit interview with the auditor or inspector. If this was an FDA audit, request Form FDA 483, if appropriate. If appropriate, others (Research Quality Assurance Director, CTO Director, IRB representative etc.) may be invited.
    b. If appropriate prepare a draft response to the audit report as soon as possible after its receipt. Reply to each item in the report, providing clarification or steps that will be taken to institute corrective action. See Attachment B, Key Steps to Writing a Response Letter.
    c. Send draft response to Associate Dean for Research, Associate Dean for Clinical, RQA Director, and CTO Director for review.
        i. Sponsors may have language in the Clinical Trial Agreement (CTA) that they must be provided with the Investigative site's draft response to the FDA. Contact the Office of Research Affairs (ORA) Director to review the CTA for such language. While Sponsor may review the draft response, it is the position of Penn State that any comments that Sponsor may provide are not required to be included in the formal response to the FDA.
    d. Send a copy of response letter and Form FDA 483 to the IRB for inclusion in study files.
    e. Upon receipt of final report from FDA provide a copy to Associate Dean for Research, applicable Clinical Trials Office Director, and Research Quality Assurance Director. Send a copy to the IRB for inclusion in study files .

RELATED POLICIES AND REFERENCES

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

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.60,62,64,66)

Compliance Program Manual, Bioresearch Monitoring Program, Clinical Investigators and Sponsor-Investigators (Program# 7348.811); U. S. Food and Drug Administration; 22 July 2020

Guidance for Industry Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring; U. S. Food and Drug Administration; August 2013

Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators; U. S. Food and Drug Administration; June 2010

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APPROVALS

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