Site Initiation of Externally-Sponsored Research	CR-204
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 Investigators
[X]	Sub-Investigators
[X]	Study Coordinators/Associates
[X]	Data Specialists
[X]	Regulatory Specialists
[X]	Key Study Ancillary Personnel
[X]	Financial Analyst/Research Accountants
[X]	Central Research Office Personnel

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor of a potential study conducts a study initiation visit (SIV) to prepare site personnel to implement the protocol according to Good Clinical Practice (GCP) requirements, review intervention administration and accountability, and provide instruction in any specialized procedures.

SIVs may be undertaken via an onsite visit by the Sponsor/Contract Research Organization (CRO), face-to-face via the internet, by teleconference or some combination thereof. The steps in the processes below may need to be tailored to fit the specific SIV method.

POLICY AND PROCEDURE STATEMENTS

1. Prior to scheduling and preparing for the Site Initiation Visit (SIV)
    a. Ensure that the study has received IRB approval.
        i. Study teams agreeing to conduct an SIV prior to receiving IRB approval are solely responsible for ensuring no participants are consented/enrolled prior to receiving IRB approval or is not approved.
    b. Ensure that the study is awarded by ORA ***before*** conducting the SIV.
        i. Inquires on the status of the progress of the contract and budget should be sent by email to the CTO (cto@pennstatehealth.psu.edu) and ORA with the IRB and OSP numbers included in the subject line
            1. For grants: e-grants@pennstatehealth.psu.edu

2. For contract: e-contracts@pennstatehealth.psu.edu
3. For subawards: subawards@pennstatehealth.psu.edu

ii. If congruence has not been completed by the CTO and ORA, then the SIV cannot take place, unless study team contacts CTO and ORA for an exception.
iii. If congruence has been completed and ORA are awaiting signature-ready documents from the Sponsor/CRO, then department conducts the SIV at their own risk should something derail the execution agreement.
iv. If completed documents are circulating for signatures, the study team is to email ORA for status, and based on discussion with ORA, may schedule SIV with the Sponsor/CRO.
v. It is up to the study team to clarify if the Sponsor/CRO will conduct the SIV without a fully executed agreement
vi. Study teams agreeing to conduct an SIV prior to CTA execution are solely responsible if the agreement is not executed.

c. Check that the site has received all current versions of the study documents (e.g. protocol, investigator brochure or package insert, informed consent form(s), manuals (e.g. Laboratory, Pharmacy, Radiology, etc.).

2. Preparing for the SIV
   a. Identify key clinical research personnel likely to be involved in conducting the study under consideration.
   b. If using Investigational Drug Services, contact IDS regarding availability for an SIV on the dates under consideration.
   c. At a minimum, the PI and primary study coordinator should be present. Back study coordinator(s), sub-investigators, and other study team members should attend the SIV to reduce the number of study team members needing to be trained after the SIV.
   d. Confirm the SIV date and time with the Sponsor/CRO.
   e. Notify the study team of the date, time and location of the scheduled SIV. Depending on the number of study team members, a room may need to be booked for the SIV.
   f. Once the SIV is confirmed, send a map of the campus (mark on the map where the Sponsor/CRO will start the day), agenda of timings (e.g. protocol meeting, IDS training, etc.), and contact details for the study coordinator(s) in case of issues on the day of the SIV.
   g. Check and confirm the status of any study team training/access (e.g. randomization, EDC, safety report, or other systems), receipt of study kits/supplies, and any other study-specific items.
   h. Ensure that all documentation and materials associated with the study are provided to the study team and will be available at the SIV.

3. Participating in the SIV
   a. Be prepared to provide sponsor with an update on any study-related issues including detailed review of protocol.
   b. Confirm CRF completion guidelines and source documents.
   c. Ensure proper storage of all study equipment and that all study personnel are familiar with the use of the equipment.
   d. Provide the Sponsor/CRO with a copy of the departmental or institutional

monitoring SOP.

e. Describe the process by which the monitor(s) are granted access to the Electronic Medical Record (EMR) and develop a plan to have the monitor provide the necessary information to obtain access prior to the first monitoring visit.
    i. See CTO website for additional information regarding EMR access for monitors.
f. Complete and obtain signatures for the study's Delegation Log, if not already completed.
g. Document SIV attendance by ensuring the training log is completed.

4. Following up after the SIV
    a. Ensure that the Sponsor/CRO sends written documentation summarizing the SIV and providing a study "activation" letter.
    b. File all applicable documents in the study regulatory file (paper or electronic) as they are part of the regulatory documentation.
        i. See Clinical Research Guidebook for further guidance
    c. If applicable, conduct and document in-service training for referring and support staff (e.g., physicians, nurses, and all personnel having a role in execution of the study) who were not able to attend the SIV.
    d. Create appropriate study files (i.e. patient files).
    e. For drug studies:
        i. Ensure that study drug has been received and is available for dispensing
            1. If utilizing IDS, please note that all IDS staff must be trained on the protocol before they can train the in-house pharmacists (if needed) before they are open for enrollment of patients.
        ii. Create infusion room or other research-related orders, and obtain any necessary approvals.
    f. For device studies, ensure that study devices have been received and are available for use, or understand sponsor's plan to ship devices prior to procedure
    g. Inventory supplies of central lab kits, any paper case report forms, and any other study-related items.
    h. Begin recruitment and screening activities. Utilize any appropriate IRB approved materials.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 52, 60, 66, 68)

International Conference on Harmonization Good Clinical Practice E6(R2)

Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, Guidance for Industry. August 2013 (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/oversight-clinical-investigations-risk-based-approach-monitoring)

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

December 2022	
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."