Pre-Study Site Selection Activities	CR-202
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	Penn State College of Medicine
X	Milton S. Hershey Medical Center	X	Medical Group – Academic Practice Division
X	St. Joseph Medical Center	X	Medical Group - Community Practice Division
X	Holy Spirit Medical Center	X	Penn State Health Life Lion, LLC
X	Hampden Medical Center		

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 standard operating procedure (SOP) describes the processes and procedures for conducting any pre-study site selection activity for all clinical studies involving human subjects in research during all investigational phases of development. Pre-study site selection activity may include completion of questionnaires and/or conduction of pre-site selection visit (PSSV), site selection visit (SSV), or study qualification visit (SQV) with the Sponsor/Contract Research Organization (CRO). These pre-study visits may occur onsite, face-to-face via the internet, by teleconference, or some combination thereof. The goal of a pre-study visit is to meet with study personnel and review their qualifications for the study, assess the facilities of the research site for implementing the study, and evaluate the possibility of collaborating on the study.

POLICY AND PROCEDURE STATEMENTS

1. Preparing for the pre-study site selection activity
    a. Identify key clinical research personnel likely to be involved in conducting the study under consideration.
    b. Ensure that the sponsor's Confidentiality Agreement (CDA) or Non-Disclosure Agreement (NDA) has been submitted to Office of Research Affairs through the appropriate process.
    c. Review the protocol and other study-related materials to assess the feasibility of conducting the study at this site.
    d. Determine if the sponsor has any areas of special interest that require advance scheduling, such as:

i. Visiting the treatment site (clinic or hospital), Investigational Drugs Services (IDS), laboratory, medical records department, infusion room, inpatient areas, equipment, monitoring room, etc.
ii. Seeing any specialized equipment needed to implement the study.
iii. Visiting auxiliary facilities such as the Clinical Research Center, Clinical Specimen Processing Core, device storage, etc.
iv. Meeting briefly with ancillary personnel involved in any specialized data collection.
v. Please contact College of Medicine Clinical Trials Office if any non-College of Medicine or non-Penn State Health facility is to be visited.

2. Conducting the pre-study site selection activity
    a. Meet with Sponsor/CRO representatives to review protocol.
    b. Study Coordinator will tour the areas of the research facility with Sponsor/CRO representatives (e.g., areas where the clinical trial will be conducted, IDS, laboratory, any other areas of special interest the Sponsor/CRO has requested to visit, etc.).
    c. Assess the feasibility of the site during discussions with or comments from the Sponsor/CRO representative.

3. Following up after the pre-study site selection activity
    a. Document the pre-study site selection activity as per departmental practice. It is recommended to have a sign-in sheet to record attendance
    b. Ensure that the pre-selection activity letter and the post-selection activity letters from the Sponsor/CRO are filed in the regulatory binder (paper or electronic).
    c. Confirm continuing feasibility of study.
    d. If Sponsor/CRO confirms site selection, please see CR-203, Study start-up activities.
        i. Do not provide Sponsor with specific timelines as to initiation and completion of contract and budget negotiations and IRB approval as there are many variables which impact these timelines.
        ii. Do not provide Sponsor with specific names of ORA and CTO staff who will be conducting negotiations. They will be provided at a later time.
    e. If Sponsor/CRO does not select as a study site, ask for feedback to improve future suitability for other Sponsor/CRO studies.

Related Policies and References

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 52,53, 60, 66, 68)

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

Authorized:	Kevin Gardner, Jr., MS, BSN, RN, CCRC Director, College of Medicine Clinical Trials Office Adam McDowell, BA, JD, CRA Director, Office of Research Affairs, Contracts Thomas Brydebell Director, Office of Research Affairs, Grants Elizabeth Galgocy, MEd, RN, CIP Director, Research Quality Assurance, Human Research Trials
Approved:	Neal Thomas, MD, MSc Associate Dean of Clinical Research Sheila Vrana, PhD Associate Dean of Research

DATE OF ORIGIN AND REVIEWS
Date of origin: February 2010

Review Date(s): October 2021, April 2022, December 2022

CONTENT REVIEWERS AND CONTRIBUTORS
Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

Director, Research Quality Assurance, Clinical Trials

History of Reviews and Revisions

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