Assessing Protocol Feasibility	CR-201
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 steps for assessing the feasibility of protocols for clinical research conducted at the investigative site during all investigational phases of development. The feasibility of implementing a protocol at the investigative site is necessary to fulfill the regulatory, medical, and ethical requirements by determining the scientific, ethical, and financial merits of conducting the study.

POLICY AND PROCEDURE STATEMENTS

1. Evaluate the protocol and the intervention, assess the potential impact upon the well-being of the subjects, and review of the budget.
    a. Determine size of potential pool of patients based upon historical data and the inclusion/exclusion criteria.
        i. Historical data can be obtained from, but not limited to, available tools (such as TriNetX), enrollment/screening logs from similar previous studies, and PI clinic lists
    b. Distribute the protocol and assessment tools to key research team members for their assessment.
        i. A protocol feasibility form is available on the Clinical Trials Office (CTO) website under *Study Management Tools and Forms*, if needed.
    c. Consider personnel resources, patient availability, potential benefits to patients, and ease of implementing the study. Review staff time and effort, discuss any research-related issues identified by other key personnel/facilities.
    d. Based upon the established review process, determine the scientific and ethical merits as well as the financial impact of conducting the study at this investigational site.

i. Should the outcome of the review be a negative result, the PI or other member of research team will notify the Sponsor of his/her decision.
ii. If the Departmental evaluation leads to a positive result, the PI or other member of the research team will enter the study into Centralized Application Tracking System Institutional Review Board (CATS-IRB) and the Study Tracking and Analysis for Research (STAR) system to begin.
    1. Financial feasibility will be evaluated 1) after budget development and 2) during budget negotiations as described in **CR-203 Study Start-Up**

2. For industry sponsored clinical trials a nondisclosure/confidentiality agreement (NDA/CDA) may be required by the Sponsor or Clinical Research Organization (CRO_ prior to providing the protocol and feasibility questionnaire.
    a. Please note that research team members, including the investigator, lack signature authority to bind the university to legal agreements including NDA/CDAs.
    b. The research team must obtain an editable version (in Microsoft Word format) of the NDA/CDA and submit a request to the Office of Research Affairs (ORA) using the University's online NDA submission request from located here: https://apps.sims.psu.edu/NDA/Assurance.aspx.
    c. ORA will review and negotiate the NDA/CDA to align with the Institution's approved standards.
    d. Upon full execution of the NDA/CDA, the research team will receive the protocol and feasibility information from the CRO or Sponsor.

RELATED POLICIES AND REFERENCES

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

Code of Federal Regulations: Institutional Review Boards (21 CFR 56.109 & 111)

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.21 & 23)

International Conference on Harmonization Good Clinical Practice E6(R2)

Responsibilities of the Research Team (CR-102)

Site-Sponsor/CRP Communications (CR-301)

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.”