Responsibilities of the Research Team	CR-103
Clinical Research Standard Practices	**Effective Date:** August 2024

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

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

This standard operating procedure (SOP) defines the responsibilities of the research team for conducting clinical studies at this investigative site. It identifies administrative accountability as well as general responsibilities of the research team and of individual team members for fulfilling regulatory and clinical requirements.

Additionally, this defines what activities can be delegated to personnel employed or contracted by Penn State College of Medicine and Penn State Health (collectively, the Institution) who would not be listed with the Penn State University (PSU) Institutional Review Board (IRB). Lastly, activities that do not need to be delegated, or are assumed to be delegated, shall be defined.

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

POLICY AND PROCEDURE STATEMENTS

Administrative Responsibilities

1. Participate as appropriate in the hiring and training of individuals recruited as members of the research team, including optional clinical research personnel training by the Clinical Trials Office.
2. Assign trained Research Nurse/Coordinator/Associate to manage each clinical study planned or ongoing at this site.
3. Assist in managing the business aspects of studies, including developing and negotiating study budgets and contracts.
4. Design appropriate recruitment strategies and track study enrollment.
5. Communicate with the IRB as appropriate.

General responsibilities of the research team

1. Conduct clinical studies according to all applicable state, federal, and local regulations and guidelines and SOPs of this clinical site in accordance with institutional policies and procedures.
2. Ensure appropriate disclosure by all study team members of potential Conflicts of Interest
3. Ensure that the PI is informed in a timely manner of all study-related activities through appropriate means of communication.
4. Ensure the safety and welfare of study subjects by being knowledgeable about ongoing

study protocols and investigational articles.

Principal Investigator (PI) responsibilities

1. The PI has the authority to delegate responsibility to individual members of the research team while maintaining ultimate responsibility for the overall conduct of the study.
2. For drug studies, sign Form FDA 1572 to acknowledge responsibilities as defined by the regulations.
    a. The PI is the individual of record who assumes the authority and responsibility for the conduct of a clinical study. By signing Form FDA 1572, the PI agrees to comply with the conditions required by FDA for use of investigational articles.
    b. The decision about whether to list individuals on the 1572 in Section 6 ***Names of the Sub-Investigators Who Will Be Assisting the Investigator in the Conduct of the Investigation(s)*** is a matter of judgment of the PI, dependent upon that the individual making direct and significant contribution to the data of the study.
3. Ensure trial registration and updating at ClinicalTrials.gov, if Penn State College of Medicine or a Penn State Health entity is the sponsor of the study.
4. While retaining knowledge of and overall authority for the conduct of all studies, supervise members of the research team qualified by their education and training (and state and local laws) to accept these responsibilities for study-related activities not directly performed by the PI.
5. Document the delegation of responsibilities.
6. Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.
7. Participate as appropriate in the hiring and training of individuals recruited as members of the research team.
8. Assign trained study personnel to manage each clinical study planned or ongoing at this site.
9. Ensure that specific sponsor requirements of the PI are fulfilled as requested.
10. Meet with sponsors' representatives as appropriate to discuss planned and ongoing studies.
11. Meet with auditors (internal, sponsor, and FDA) at the conclusion of their audits to review findings.

Study team responsibilities (inclusive of Research Coordinators/Associates, Data Specialists, Regulatory Specialists, and Key Study Ancillary Personnel)

1. Develop organizational aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data.
2. Enroll subjects in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements.
3. Maintain the regulatory and study files for each research project.
4. Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits).
5. Train other study team members on study management specific information with PI oversight. Such training would include, but not be limited to, protocol review, applicable manuals (operations, imaging, labs), source document completion, data entry, order set implementation (such as ordering labs, imaging, medications, IDS, etc.) and sharing other sponsor-provided training and materials.
6. Fulfill those job responsibilities specific to that job title according to federal regulations and guidelines including institutional HR policies and performance evaluation plan.

Delegation of activities to non-study team members

1. Employees of the Institution who are performing activities within their scope of practice and role description are not required to be listed with the PSU IRB as study team members and thus are not listed on a study's delegation of authority log. These employees would be also be considered Key Study Ancillary Personnel, and their roles include, but are not limited to:
    a. Cardiac technicians
    b. Clinical Specimen Processing Core staff
    c. Device Clinic staff
    d. Investigational Drug Service staff
    e. Nurses administering study medication(s) and obtaining biospecimens. Registered Nurses and Licenses Practical Nurses will function within their respective scope of practice for their licensure.
    f. Phlebotomists
    g. Physicians, Nurse Practitioners, and Physician Assistants performing routine care assessments and procedures function within their respective scope of practice for their licensure.
    h. Radiology technicians
    i. Respiratory Therapist administering Pulmonary Function Testing and study medication(s), within their scope of their practice.
    j. Sonographers
2. To list someone on the study's delegation of authority log, the individual must be listed with the IRB of record as a study team member. In compliance with the PSU IRB's training requirements, the study team member would need to complete biomedical research training, biosafety (when involved in handling potentially biohazardous materials), and Good Clinical Practice training as well as protocol training.
3. In the event a sponsor would require individuals whose roles would not otherwise qualify them as study team members to be delegated responsibilities, the individual will be required to complete necessary Institutional training to be listed with the PSU IRB. The study sponsor will be responsible for remuneration of the associated training to the Institution as the individual would not otherwise be required to complete Institutional training. Such remuneration would be inclusive of any retraining needed during the course of the study.
4. Though not required to be listed with the PSU IRB, individuals performing such activities for the study will be trained with applicable manuals and/or study training materials. Training will be documented on the study's training log or as per departmental standards.

Activities that do not need to be delegated or are assumed to be delegated

1. Study team members who are listed with the IRB of record are not required to be delegated activities that are within their scope of practice and/or role description. Such as activities include, but are not limited to:
    a. Application of sponsor- or vendor-provide devices, wearables, etc.
    b. Collection of vital signs
    c. IRB submission
    d. Processing of safety reports sent by sponsor or their representative.
    e. Quality assurance or quality control audits or preparatory reviews for an audit or inspection

f. Regulatory file maintenance
g. Screening of patients' medical records for potential recruitment into an IRB-approved study. These activities do NOT include contacting or otherwise interacting with patients.
h. Transmission of study imaging.
i. Transmission of adverse event
j. Venipuncture

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.53, 60, 61, 62, 64, 66, 68, 69)

FDA Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572) - June 2010

Penn State University IRB Investigator Manual (HRP-103)

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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."
June 2023	
Scope and Purpose	Add "Lancaster Medical Center" as an applicable entity Added statement to address that some study team members may be delegated responsibilities without being listed with the IRB of record and certain duties can be delegated without being expressly delegated on the delegation log
Policy and Procedure Statements	Section 1 renamed to "Administrative Responsibilities" Section 3 divided into separate sections, now 3 and 4. These sections are named to "PI responsibilities" and "Study team responsibilities." Added training as a responsibility of study team members. Added sections 5 and 6.
August 2024	
Scope and Purpose	Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine is Updated "Financial Analyst/**Contract Management Accountants**". Notation made that this SOP may be shared with Sponsors and/or CROs upon request.
Policy and Procedure Statements	Bulleting adjusted. PI responsibilities updated to include a statement that those persons to be listed in Section 6 of FDA 1572 is at the PI's discretion based on FDA guidance.