Site-Sponsor/CRO Communications	CR-210
Clinical Research Standard Practices	**Effective Date:** September 2023

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	[X]	Lancaster 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 various ways of communicating including telephone and written interactions with the Sponsor/CRO to ensure that all regulatory, medical and ethical requirements are fulfilled. This SOP applies to communications between this site and sponsors/CROs with regard to any clinical studies involving human subjects in research during all investigational phases of development. These communications serve to protect the safety and well-being of participants by keeping sponsors/CROs fully appraised of study activities and to ensure that the studies are carried out appropriately.

POLICY AND PROCEDURE STATEMENTS

1. General communications principles
    a. When communicating by email, use your Penn State Health or Penn State University email.
    b. Communicate regularly and appropriately with Sponsor
    c. Sponsor/CRO about all study-related issues
    d. Document relevant conversations.
        i. Send a follow-up email summarizing any in-person or phone/web-based conversations, including action items and responsible party/ies
    e. Keep originals or photocopies of all relevant documentation, including facsimile confirmations, and file in the study binder with appropriate documents.

f. When transmitting PHI:
    i. Follow the *minimum necessary* standard of HIPAA to use, disclose, and request only the minimum amount of protected health information need to accomplish the intended purpose
    ii. Documents should be encrypted and/or sent through institutionally approved method if disclosing more than Participant ID

2. Pre-study communications
    a. Send CDA provided by sponsor or request a CDA be sent to sponsor through the Office of Research Affairs for review, execution and approval.
    b. Notify Sponsor/CRO of decision to participate in the study by telephone, fax, letter, email.
    c. Send Sponsor/CRO signed protocol signature page (if appropriate).
    d. Submit all pre-study regulatory documents to applicable IT applications (e.g., CATS IRB, STAR).
    e. Send updated/revised documents as necessary.

3. Communications while the study is ongoing
    a. Inform Sponsor/CRO about SAE(s) immediately as per protocol and Institutional IRB guidelines.
    b. Inform Sponsor/CRO about the study progress through screening/enrollment forms by whatever means (fax, e-mail) requested
    c. Forward CRFs to Sponsor/CRO as requested.
    d. Respond promptly to data queries as requested (fax, e-mail, remote data entry query resolution procedures).
    e. Inform Sponsor/CRO regarding IRB communications such as SAEs, IND safety reports, IRB acknowledgment of reports received, amendment approvals, revised informed consent form, continuing approval for study.

4. Communications when the study is completed
    a. Inform Sponsor/CRO promptly if notified by FDA of impending inspection.
    b. Provide copies of all FDA documentation (Form FDA 483, letters) generated as a result of the inspection.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.32, 33,44)

Code of Federal Regulations: Protection of Human Subjects (21 CFR 50, 56)

Code of Federal Regulations: Protection of Human Subjects (21 CFR50,56)

FDA Information Sheets 1998 Sponsor-Investigator-IRB Interrelationship (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sponsor-investigator-irb-interrelationship#:~:text=The%20regulations%20do%20not%20prohibit%20direct%20sponsor-IRB%20contacts%2C,communication%20link%20between%20the%20IRB%20and%20the%20sponsor)

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html)

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APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

May 2023	
Header	SOP identifier corrected to CR-210
Scope and Purpose, Entities	Added Lancaster Medical Center.
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."
Policy and Procedure Statements	Subsection "Collecting, filing and storing study-related documents and records" renamed to "General standards" Subsection "Electronic" renamed to include "maintenance of files" Subsection "Sponsor/CRO-provided electronic Trial Management File (eTMF)" added.
History of Reviews and Revisions	Section added.