Study-Specific Communications

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-RE-360.3	Status: Final	Version Date: 02/11/2025 Effective Date: 03/14/2025

1. PURPOSE

This Standard Operating Procedure defines the standards related to communications and documentation of communications associated with the conduct of clinical research at VCU/VCU Health, affiliate, participating, and partner sites.

2. GUIDANCE

Ongoing communications between VCU/VCU Health key research personnel, affiliated investigative site(s), regulatory authorities, and/or contracted vendors are crucial to ensure the quality of clinical research studies.

3. DEFINITIONS N/A

4. PROCESS

A. All communications between investigators, the sponsor (and/or the CRO), VCU, VCU Health, key research personnel (or appropriate designees), affiliated sites, regulatory authorities, and other authorized parties should be thoroughly documented.

B. All communications pertinent to the conduct of the study and/or the management of study records should be summarized and documented on the appropriate forms (or other records), distributed, and filed as required by policy and/or regulations.

C. The frequency of communications depends on the subject matter and context but should be regular enough that all parties are thoroughly apprised of the current status of the study.

D. The principal investigator (PI), or designee, is responsible for ensuring that all participating investigators and other key study personnel understand the required communications and documentation of those communications. The study team should discuss what makes a record pertinent to the regulatory record for the study.

E. The PI, or designee, is responsible for establishing and maintaining an effective communications network among all affected parties involved in the clinical research program.

F. The PI, or designee, is responsible for maintaining all pertinent, study-specific original documentation or, where appropriate, copies of documentation of communications among all affected parties.

G. All participating investigators and key research personnel should be trained on communication requirements during the initiation visit.

H. All key research personnel at VCU, VCU Health, and/or affiliated sites should be advised of significant upcoming events (e.g., scheduled monitoring visits, investigational product shipments, etc.), as appropriate.

I. All pertinent communication with the IRB should be maintained in fulfillment of the responsibilities outlined within the IRB of record's policies and procedures.

J. All originals or photocopies of relevant communications records (including fax confirmations and printed copies of email) should be maintained in the study regulatory file.

K. All FDA documentation (e.g., form FDA 483 and warning letters) and any return correspondence generated as a result of the inspection of the sponsor, IRB, and investigators should be maintained in the study regulatory file.

L. Modes of communication include, but are not limited to, email, fax, IRB notifications, and summaries of telephone or in-person discussions.

5. REFERENCES

A. Code of Federal Regulations
- 21 CFR 312.60 – General Responsibilities of Investigators (Drugs/Biologics)
- 21 CFR 812.100 – General Responsibilities of Investigators (Devices)

B. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
    - Section 2 – Investigator
        - Section 2.4 – Communication with the IRB/IEC
        - Section 2.13 – Progress Reports
    - Section 3 –Sponsor
        - Section 3.16 – Data and Records
        - Section 3.17 – Clinical Trial/Study Reports

C. IRBs

- HRPP Policies and Guidance; HRPP Toolkit
  - HRP-103; Investigator Manual
- National Cancer Institute CIRB Policies
- WCG IRB Guide for Researchers
- Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsors' Representatives (see Reference Materials on CIRBI's platform)
- Other external IRB Policies

Review/Revision History CR-RE-360

Version No.	Effective Date	Description
CR-RE-360.3	03-14-2025	● Updated to ICH E6(R3) ● Updated to align with HRPP toolkit ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-RE-360.2a	07-01-2020	● Links updated
CR-RE-360.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-RE-360.1	02-04-2018	● Original