West Virginia Clinical and Translational Science Institute Center of Excellence

STANDARD OPERATING PROCEDURE

Title:	COE-117.00	
Sponsor/CRO Communication	Page 1 of 3	
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Prepared by:	Reviewed by:	Approved by:
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Shelley Welch, RN, MSHS	Tanya Moran, MS	Sally L. Hodder, MD

Purpose:
This standard operating procedure (SOP) describes the operational guidelines followed by the Morgantown, West Virginia University (WVU) Health Science Center (HSC) and affiliated health systems regarding external communications with the sponsor or Clinical Research Organization (CRO).

Scope:
This SOP describes the suggested mechanisms used for communication to and from sponsor/CROs to ensure full awareness of study activities, while protecting subjects' rights and confidentiality, ensure subject safety and that the studies are carried out according to the protocol and sponsor/CRO requirements.

Materials:
NA

Responsibility:
This SOP applies to study team members from HSC Institutions and associated clinical departments actively engaged in clinical research involving human subjects.

Procedure:

All communications should be in compliance with clinical trial agreements with the Sponsor/CRO and institutional policies.

A. Effective external communication is extremely important in maintaining respectful relationships with the sponsors/CROs.

1. Communication may occur prior to study conduct for reasons such as but not limited to:
    - Confidentiality Agreements
    - Feasibility
    - Site Selection
    - Site Initiation

2. Establish a clear communication plan with the sponsor. This shall enable appropriate and prompt response from the responsible team member. This can be discussed and/or provided during the site initiation meeting.

3. Communicate regularly and appropriately with the sponsor/CRO about study-related issues.

4. Three primary mechanisms for communicating externally with regards to operational and clinical related information.
    - In person/Videoconference: Meetings scheduled on a regular basis or as needed. Action items/minutes shall be documented as possible.
    - Electronic mail (email)/Internet (portal): Has been accepted as one of the main working tools. Most staff regularly use email to send and receive messages, documents, appointments and tasks.
    - Telephone: Shall be recorded on a phone log or documented as per internal process. It would be recommended to follow up with email to document pertinent study information that was discussed.

5. Communication during study conduct may include but not limited to:
    - Recruitment or enrollment status
    - IRB communications such as approvals and safety reports
    - Scheduled monitoring visits
    - Data submission
    - Query response – deviation notification
    - Prompt notification of Serious Adverse Event (SAE)

6. Communication following study conduct may include but not limited to:
    - Reports as required per protocol
    - Scheduled site close-out visit
    - Prompt notification of regulatory agency (e.g. FDA) impending inspection

7. All communication sent to and received from the sponsor in relation to the clinical research project shall be documented and maintained in the regulatory files.

8. The rule of communication is "If it was not documented/written, it never happened."

History of Revisions to SOP

Effective Date	Nature of Revision
17 May 2021	New SOP