University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Date Created: **November 1, 2010**

Title: **General Correspondence**

Version Date: **January 1, 2023**

SOP Number: **SM35**

PURPOSE: The purpose of this standard operating procedure (SOP) is to describe what study specific correspondence is relevant for capture and maintaining in the study regulatory binder.

SCOPE: This SOP applies to all sponsored clinical trials in which the Clinical Research Center (CRC) has been contracted to provide study coordination Nebraska Medicine (NM) or University of Nebraska Medical Center (UNMC).

PERSONNEL RESPONSIBLE: Principal Investigator and all study staff that generate any correspondence pertinent to the conduct of the study.

DEFINITIONS:

- **Email**-A system for sending and receiving messages electronically over a computer network, as between personal computers.
- **Contract Research Organization (CRO)**-A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's research-related duties and functions.
- **Institutional Review Board (IRB)-** An independent group made up of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent forms, and the methods and materials used in the trial.
- **Sponsor-**An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

- Correspondence pertinent to the conduct of the research, such as communication between the site, sponsor and the IRB, will be maintained in the study regulatory binder at the clinical site.
- The site will prepare and maintain records of all general correspondence to and from the investigative site. All records will be maintained in an area accessible to regulatory authorities if requested during an inspection.
- Relevant communications/correspondence will include:
    - Log of telephone calls pertinent to the conduct of the research
    - Newsletter and fax communications
    - Emails or letters to and from sponsor/CRO representatives
    - Emails or letters to and from study subjects (subjects specific correspondence will be filed in the subject's research records, not in the general study binder)

- Letters to and from colleagues regarding the research
- Other pertinent communications documenting any significant discussion, such as meeting notes

RESOURCES:

- 21 CFR 54.185- Reporting of Results of a Clinical Investigation
- 21 CFR 312.64- Investigator Report
- 21 CFR 812.140- Records
- 21 CFR 812.150- Reports
- ICH GCP Consolidated Guideline—Part 8. Essential Documents for the Conduct of a Clinical Trial

Department Approval

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