University of New Mexico Comprehensive Cancer Center / New Mexico Cancer Care Alliance

STANDARD OPERATING PROCDURE

Clinical Research Office

Title: ELECTRONIC CORRESPONDENCE WITH THE HEALTH SCIENCES CENTER HUMAN RESEARCH PROTECTIONS OFFICE (HRPO) AND GENERAL CLINICAL RESEARCH CENTER (GCRC)

SOP No.: 3.7	Version No.: 4	Effective Date: 02-01-2006

Owner: NMCCA Clinical Research Supervisor

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Signature 12/21/17 Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature 12/22/2017 Date

INTRODUCTION AND PURPOSE

This SOP is designed to provide direction regarding the flow of electronic correspondence from the University of New Mexico (UNM) Health Sciences Center (HSC) Human Research Protections Office (HRPO) to investigators and regulatory staff in the UNM Comprehensive Cancer Center Clinical Research Office (CRO), and the New Mexico Cancer Care Alliance (NMCCA). It describes procedures which enable the HRPO to forward communications to one central electronic location in addition to the Principal Investigator of individual adult oncology clinical trials. The nature of these communications is related to oversight by the Human Research Review Committee (HRRC) of clinical oncology trials for which the HRRC is the IRB of record.

For those trials involving participant activities conducted in the General Clinical Research Center (GCRC), communications regarding studies will be sent to the CPDM Coordinator email box. These include GCRC approvals of new studies, requests for modifications, updates to Data Safety Monitoring Plans (DSMPs) and other notifications.

The information included in the electronic correspondence pertains to adult clinical oncology studies sponsored by the National Cancer Institute, pharmaceutical companies, through local (UNM School of Medicine/ UNM Comprehensive Cancer Center) and external institutional support (Investigator-Initiated Trials). Correspondence includes but is not limited to: pre-HRRC review modification requests, new study approval announcements, study suspensions, study closures, amendment approvals, scanned National Cancer Institute (NCI) Clinical Trials Support Unit (CTSU) documents, external adverse event reporting and reminders regarding study renewal deadlines, modification requests, and study continuation approvals.

SCOPE

This standard operating procedure defines the responsibilities of the UNM CCC CRO and NMCCA, for retrieving and managing correspondence between Principal Investigators and the HRPO. The Pediatrics Department maintains separate communications with the HRPO. It identifies administrative accountability as well as the flow of documentation between departments and team members for fulfilling regulatory and clinical requirements. It also identifies systems for backup of information and data analysis tools. Procedures and timelines for generation of notifications by the HRPO office are outside of the scope of this CPDM SOP.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
21 CRF 56.109	IRB Functions and Operations

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to the regulatory staff involved in the submission of new oncology clinical study applications, updating and tracking of amendments/revisions, and annual review of and closure of clinical studies managed by the UNM CC and NMCCA. This includes the following:

Executive Director
Principal Investigator
Clinical Research Supervisor
Regulatory Coordinator
Administrative Assistant
HRPO Manager
HRPO Coordinators

PROCEDURES

Receiving and managing correspondence

Owner	Criteria / Steps
HRPO Staff or CLICK system;	Electronically notifies the Principal Investigator and the Primary Contact of the study of study number assignment, initial approvals, requests for modifications, continuing renewal deadlines, modification approvals, CTSU form approval, closure and other changes to a clinical protocol by sending email and attachments to CPDMCoordinator@salud.unm.edu or the appropriate regulatory coordinator.
Clinical Research Supervisor	Forwards along documentation to appropriate parties, if applicable.
Regulatory Coordinator and Clinical Research Supervisor	Checks email account and Click IRB account. Responds to the correspondence and communicates as needed with each other, the study PI and/or the HRPO Manager and staff. Prints required documents and files in the protocol regulatory binder according to sponsor and protocol number. Saves required documents to the appropriate CRO electronic folder located at R:TRIALS

Monitoring electronic correspondence

Owner	Criteria / Steps
UNM Admin Assistant	Updates the CPDMCoordinator@salud.unm.edu distribution list.

Maintaining Correspondence

Owner	Criteria / Steps
HRPO Staff, GCRC Staff	In the event of a power outage or other natural acts for more than 24 hrs or computer down time more than 24 hours, provides correspondence by paper and notifies the Clinical Research Supervisor and the Principal Investigator.