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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: MAKING A HAND WRITTEN ERROR CORRECTION

SOP No.: 6.6	Version No.: 4	Effective Date: 8/9/2009

Owner: Assistant Director of Quality Assurance, Monitoring, and Training

Name: Christine M. Gan, PhD

Signature 03/19/2018 Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature 3/28/2018 Date

INTRODUCTION AND PURPOSE

The Food and Drug Administration (FDA) ensures the protection of the rights, safety, and welfare of human research subjects and the quality and integrity of data submitted to the agency. Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. This SOP addresses regulation regarding the Principal Investigators' responsibility to ensure the accuracy, completeness, legibility, and timeliness of the data. Specifically, this SOP addresses the correct procedure to follow when making hand written error corrections.

SCOPE

This SOP applies to all Group and Investigator Initiated research activities by faculty, staff, student and/or others who are involved in human subject research that falls under the jurisdiction of the UNMCCC CRO and NMCCA.

APPLICABLE REGULATIONS AND GUIDELINES

Current	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
June, 2010	Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in managing, recording, or maintaining data at this research site. This includes the following:

Principal Investigator (PI)

Sub-investigator (Sub-I)

Assistant Director of Quality Assurance, Monitoring, and Training (AD-QAMT)

Quality Assurance/Data and Safety Monitoring Committee (QA/DSMC) Coordinator

UNMCCC Clinical Research Operations Manager (CROM)

NMCCA Clinical Research Manager (CRM)

NMCCA Clinical Research Supervisor (CRS)

Clinical Research Nurse

Clinical Research Coordinator

Regulatory Coordinator

Data Coordinator

Laboratory Technician

Study Pharmacist/Technician

PROCEDURES

Implementing a correction to data

Owner	Criteria / Steps
PI Research Coordinator Regulatory Coordinator Data Coordinator Laboratory Technician NMCCA CRM NMCCA CRS UMCCC CROM Pharmacist/ Technician	Identify incorrect case report form (CRF) or source document entry. Make correction (using indelible blue or black ink): • Draw one clear horizontal line through the incorrect data which does not obscure that entry. • Write in the correct data next to the original. • Initial the correction. • Date the correction. • If necessary, a note of explanation may be completed and attached to the CRF or source document. • Erasure, scribbling out, using correction fluid (e.g. White Out), or using any other means that could obscure the original entry is not allowed.