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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: PREPARING FOR AN FDA AUDIT

SOP No.: 6.4	Version No.: 3	Effective Date: 9/15/2009

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

Name: Christine M. Gan, PhD

Signature 12/20/2017 Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature 12-15-2017 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. This SOP addresses FDA site visits to clinical investigators who conduct clinical investigations at the University of New Mexico Comprehensive Cancer Center (UNMCCC) that are regulated by FDA regulations and statutory requirements. Clinical investigators who conduct FDA regulated clinical investigations are required to permit FDA investigators to access, copy, and verify any records or reports made by the clinical investigator with regard to the disposition of a product and subject case histories. The FDA audit documents how the study was actually conducted at the clinical investigator's site. The FDA may conduct both announced and unannounced inspections. Inspections may be conducted:

- Routinely
- As a result of a complaint
- At the request of an FDA review division
- Related to certain classes of investigational products identified as products of special interest

SCOPE

This SOP applies to all research activities by faculty, staff, students, and/or others who are involved in human subjects research that falls under the jurisdiction of the UNMCCC and the NMCCA.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of IRB review
December 8, 2008	FDA Internal Compliance Program Guidance Manual, 7348.811 Clinical Investigators
June, 2010	Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators
Current	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
Current	UNMCCC Standard Operating Procedures 1.1 – 7.1

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging, managing, or participating in the audit at this research site. This includes the following:

UNMCCC CEO and Director

UNMCCC Medical Director

NMCCA Medical Director

Director UNMCCC Clinical Research Office (CRO) and NMCCA Executive Director

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

Notification of FDA audit

Owner	Criteria / Steps
PI All Research Staff	Upon receiving notification of an FDA audit, notify Director of CRO and AD-QAMT as soon as possible. Director of CRO will notify the sponsor of the study, UNM Health Science Center (HSC) Office of Research, NMCCA Board of Directors, and UNMCCC Senior Leadership.

Preparing for an FDA audit

Owner	Criteria / Steps
CRO Director	Convene and direct an internal team to include at a minimum the PI, Associate Director for Clinical Research, NMCCA CRS, Nurse Manager and AD-QAMT.
PI	Ensure that the study is conducted in accordance with the protocol and in compliance with regulatory agencies guidelines and UNMCCC Standard Operating Procedures.

	Ensure Delegation of Authority log is accurate, complete, and available for review.

Preparing for an FDA audit, continued

Owner	Criteria / Steps
NMCCA CRM NMCCA CRS UNMCCC CROM Regulatory Coordinator Research Nurse	Ensure that all documentation, including the CRO Research Subject Charts, informed consent forms, source documents, case report forms (CRFs), and the regulatory binder for the study identified as the focus of the audit are accurate, complete, organized, and available for review by the auditor.
Data Coordinator Pharmacist/ Technician	Ensure that the study drug dispensing records are accurate, complete, organized, and available for review. If there were any instances in which emergency breaking of the blinding was required, have that documentation available. Ensure that drug accountability records are accurate, complete, organized, and available for review.
AD-QAMT	Work with the auditor to develop a proposed schedule (estimated number of days, times) for the audit, and ensure that all key personnel will be available before confirming a time. Identify adequate space for the auditor to use to review documents and records. Ensure that FDA pre-site visit requests (if applicable) are completed. Ensure that records of staff qualifications and training are accurate, complete, and available for review by the auditor. Ensure that Standard Operating Procedures are available.

During the audit

Owner	Criteria / Steps
PI CRO Director UNMCCC CROM AD-QAMT NMCCA CRM NMCCA	Meet with the FDA inspector(s) and request to see identification. Request Form FDA 482 (Notice of Inspection) from the inspector(s). Provide orientation and access to the study records and files. Provide copies of requested study related documents. *Do not provide financial data* except the investigator disclosure. *Do not provide personnel records* except for job description and training records. Ensure questions posed by the inspector(s) are answered by appropriate study personnel.

CRS	

Closing the audit

Owner	Criteria / Steps
PI CRO Director UNMCCC CROM AD-QAMT NMCCA CRM NMCCA CRS	Attend exit interview with the inspector(s). Request Form FDA 483 (Inspectional Observations) for findings or deficiencies. Respond verbally in the exit interview, if applicable, to findings or deficiencies.

Follow up after the audit

Owner	Criteria / Steps
PI CRO Director	Distribute the final report letter from the FDA. Implement appropriate action: No response necessary: No significant deviations were found. (Note that a letter is not always sent when the FDA observes no significant deviations). Voluntary Response: Identified deviations from statutes and regulations for which voluntary corrective action is sufficient. Prepare and submit written response with corrective and preventative action plans (CAPAs): prompt correction taken and a plan to prevent such deviations in the future.
AD-QAMT	The Quality Assurance Office is to provide inspection notes, final report letter, and the CAPAs to the UNMCC CEO and Director, UNMCCC Medical Director, CRO/NMCCA Executive Director, NMCCA Medical Director, the Chairs of the PRMC and DSMC, and the UNM HSC Compliance Office.