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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: NATIONAL CLINICAL TRIALS NETWORK (NCTN) TRIENNIAL GROUP AUDITS

SOP No.: 6.3	Version No.: 8	Effective Date: 2/26/2004

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

Triennial audits are performed by the National Clinical Trials Network (NCTN) to enhance the delivery of accurate and reliable clinical trials data and results. These quality assurance audits are designed to 1) Verify the accuracy of data sent to the sponsor; 2) Verify that the institution is in compliance with protocol and regulatory requirements; and 3) Provide educational support to the clinical trials sites regarding issues related to data quality, data management, and other aspects of quality assurance. This standard operating procedure (SOP) describes the procedures to be followed when an NCTN group notifies the University of New Mexico Comprehensive Cancer Center (UNMCCC) Clinical Research Office (CRO) of a triennial audit. Once an onsite audit is completed and the final report is received, department managers are responsible for providing corrective action plans, assuring compliance to deficiencies, and responding to requests for off-site follow up or re audit. The CRO Leadership Team provides oversight for triennial audits.

SCOPE

This SOP applies to the procedures to prepare for an onsite or offsite audit of clinical studies conducted at the UNMCCC or the New Mexico Cancer Care Alliance (NMCCA). It describes the steps followed by the site from the time of notification until all follow-up activities have been completed.

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, 17348.811 Clinical Investigators
June, 2010	Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators
May 9, 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
Current	NCI Guidelines for Auditing Clinical Trials for the NCI National Clinical Trials Network (NCTN) Program, Community Clinical Oncology Program (CCOP) / NCI Community Oncology Research Program (NCORP) and Research Bases

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 a triennial audit. This may include the following team members:

Principal investigator (PI)

Sub-investigator

Director, UNMCCC Clinical Research Office and NMCCA Executive Director

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

UNMCCC Clinical Research Operations (CRO) Manager

Research Nurse

Research Coordinator

NMCCA Clinical Research Manager (CRM)

NMCCA Clinical Research Supervisor (CRS)

Regulatory Coordinator

Study Pharmacist

Quality Assurance (QA) Coordinator

PROCEDURES

Receiving notification of a group sponsor quality assurance audit

Owner	Criteria / Steps
PI Research Coordinator Regulatory Coordinator NMCCA CRM NMCCA CRS	Notify the Assistant Director of Quality Assurance, Monitoring, and Training (AD-QAMT) upon notification of an audit by the cooperative group.
AD-QAMT	Notify the Executive Director, NCTN Group PI and NCI Community Oncology Research Program (NCORP) PI.

Preparing for the group sponsor quality assurance audit

Owner	Criteria / Steps
AD-QAMT	Convene and coordinate an internal team to include at a minimum the NCTN Group PI, CRO Director, CRO Operations Manager, NMCCA CRM, NMCCA CRS, and Study Pharmacist (if applicable) to prepare for the audit.
PI Research Coordinator	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 and complete.

Research Nurse Regulatory Coordinator NMCCA CRS Pharmacist	Notify the AD-QAMT of any potential quality-related issues prior to the audit. Notify the AD-QAMT of any communication or information received from the sponsor related to the audit.
AD-QAMT QA Coordinator Research Nurse Research Coordinator	Prepare and coordinate all communication to on and off site contacts for the audit. Reserve adequate facility space for the audit. Review selected patient record(s) for compliance to protocol. Tab patient record(s) according to sponsor request. Provide pre-audit review findings to the PI and research team members. Dispute any finding by providing source documentation. Provide immediate correction for findings if appropriate.
AD-QAMT QA Coordinator Study Pharmacist	Review selected investigational drug dispensing records(s) for regulatory compliance. Dispute any finding by providing source documentation. Provide immediate correction for findings if appropriate.
AD-QAMT QA Coordinator NMCCA CRS	Review regulatory binders for the selected studies. Dispute any finding by providing source documentation. Provide immediate correction for findings if appropriate.
CRO Operations Manger NMCCA CRM NMCCA CRS	Ensure that records of staff qualifications and training are available for review by the auditor. Ensure UNMCCC Standard Operating Procedures (SOPs) are up to date and available for review by the auditor.

Conducting the audit

Owner	Criteria / Steps

AD-QAMT	Provide orientation and access to the study records and files to the audit team
PI	Provide copies of requested study-related documents.
	Ensure that questions posed by the auditor or inspector are answered by appropriate study personnel.
	Participate in the exit interview with the audit team

Following up after the audit

Owner	Criteria / Steps
PI	Respond to the audit report within required time frames after its receipt.
CRO Director	Reply to each item in the report, providing clarification or steps that will be taken to institute corrective action, if needed.
CRO Operations Manager	Submit a corrective and preventative action plan (CAPA) within the time requirements (usually within two weeks).
NMCCA CRMNMCCA CRS	Submit final findings and the approved CAPA to the CRO Quality Assurance Committee.
AD-QAMT	Review CAPA and assure completion of all items.
	All materials and information relative to the audit will be maintained in the Office of Quality Assurance.