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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: TRAINING AND EDUCATION

SOP No.: 1.3	Version No.: 7	Effective Date: 2-26-04

Owner: CRO/NMCCA Executive Director

Name: Teresa Stewart, MS

Teresa Stewart
Signature

12/20/2017
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature

12/22/2017
Date

INTRODUCTION AND PURPOSE

Research studies will be conducted according to ICH Guidelines and FDA and HHS regulations to protect the safety and welfare of study subjects that must be ensured by a research team knowledgeable about ongoing study protocols and investigational articles.

Investigators and all key members of the research team who are working in or overseeing programs that conduct research on humans will receive training regarding the responsible conduct of research.

SCOPE

This standard operating procedure (SOP) describes the process and documentation required by the New Mexico Cancer Care Alliance sites, including the University of New Mexico Comprehensive Cancer Center for training and education of the principal investigator and research staff in Good Clinical Practices (GCPs) and the ethical conduct of research conducted at this research site.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
45 CFR 46	46DHHS Part 46 Protection of Human Subjects
21 CFR 812	Subpart E Responsibilities of Investigators
ICH h Harmonized Guidelines	ICH E6 (R2), November 2016
September 1993	FDA Internal Compliance Program Guidance Manual for Clinical Investigators: 7348.811
June 5, 2000	NIH Notice OD-00-029: Required Education in the Protection of Human Research Participants
September 12, 2000	Clarification on June 5, 2000 Notice (OD-00-39)

REFERENCES TO OTHER APPLICABLE SOPs

All SOPs are applicable to this SOP.

RESPONSIBILITY

This SOP applies to the all employees and investigators who participate in research performed at NMCCA sites, including UNM CCC.

This includes all research staff and investigators conducting NMCCA research, including the following:

Principal investigator

Sub-investigators

Research managers

Research coordinator

Regulatory coordinator

Pharmacist

Information specialists

Research technicians

Data managers

Quality assurance auditors

PROCEDURES

Process for initial education and documentation by research staff –

Owner	Criteria / Steps
Director of CRO/Exec Director – NMCCA All Research Managers - Supervisors	When initially hired at NMCCA and NMCCA sites, including UNM CCC, each new research employee will complete the following training: CITI Training • Group I Biomedical research investigator (includes HIPAA) • Good Clinical Practice Financial Conflicts of Interest Training (FCOI) Standard Operation Procedures Other training as outlined on the position specific Training and Orientation checklist (Form A), as indicated by the employees supervisor.
All Research Directors, Managers and Supervisors	It is the responsibility of the director/supervisor to assure the completion of the above required training elements for their employees. Documentation may include evidence of completion of the Employee Orientation Checklist, a certificate and documentation of competencies. File evidence of completion in the employee's department human resource file.
Research Staff	Complete the Training and Orientation checklist and competencies with their Director, manager or Supervisor. Staff at NMCCA sites will spend time training at NMCCA and designated sites to shadow colleagues. Annually, NMCCA will conduct a training update for research staff working at NMCCA sites.

Process for ongoing education and documentation by research staff

Owner	Criteria / Steps
All Research Staff	Research staff, including investigators, research coordinators, data managers, clinical research pharmacy staff and regulatory coordinator will complete the following re-training: CITI Good Clinical Practice, every 2 years CITI Group 1 Biomedical Research Investigator, every 3 years Financial Conflict of Interest, every 4 years Training on SOPs, annually, as amended Other trainings as indicated by the Director, Manager or Supervisor
All Research Staff	Will provide copies of training or sign in sheets to their Director, Manager or Supervisor.