CTO – SOP 4.3

New Mexico Cancer Care Alliance

SUBJECT MANAGEMENT WHILE ON STUDY

INTRODUCTION AND PURPOSE

The safety and well-being of subjects is of paramount concern to the research team. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements to ensure adherence to study procedures for the evaluation of a subject's response to the investigational article. Through close monitoring and careful assessment of subjects, adverse events can be detected early and treated appropriately. By following these procedures, close attention is paid to subject well-being and to integrity of the data.

SCOPE

This SOP applies to the activities involved in managing subjects on clinical studies conducted at New Mexico Cancer Care Alliance (NMCCA) sites, including the University of New Mexico Cancer Center (UNM CC) subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all phases of development.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.20	General requirements for informed consent
21 CFR 56.109	HRRC review of research
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator record keeping and record retention
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in ensuring the appropriate clinical management of all clinical trial activity. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator
- Research technician
- Pharmacist
- Information specialists
- Regulatory coordinators
- Research technicians
- Data managers
- Patient services assistants
- Quality assurance auditors

PROCEDURES

Enrollment assessments and management

• PI	Determine that patient has consented (SOP 12)
• Research coordinator	Confirm Eligibility criteria and baseline requirements have been completed. Enter patient as a "Study Screening" status in Evelos.
	Elicit and document the subject's medical history
	Perform a complete or directed physical examination
	Establish the subject's baseline signs and symptoms.
	Review with the subject the use of any current medication
	Inform the subject about the required study procedures and visits.
	Order tests/procedures as directed by the protocol.
	Treat patient according to protocol
	Provide contact information to the subject.
	Schedule the follow-up visit.
	Complete enrollment process in Evelos database.

• Data Coordinator • Research coordinator	Register the subject. Enter the patient as "Enrolled" status into Evelos. Note; Enter in patient's study # at this time.
• PI	Randomize and dispense the test article.
• Study pharmacist • Research coordinator	Review with the subject the use of any study aids, such as a diary. Collect baseline specimens as directed by the protocol. Lab Technician to complete Specimen Shipping Tracking Form in Evelos once baseline/screening study labs and/or blood is drawn and shipped, if applicable.

Treatment Activation and Management

• Study pharmacist	Verify patient enrollment in Evelos.
• Research Coordinator/Nurse	Change patient to On-Treatment status in Evelos after medication is started (Cycle 1 Day 1)
• PI or Sub-Investigator	Assess and document the subject for signs and symptoms of any adverse events.
	Collect specimens as directed by protocol.
	Order diagnostic tests and procedures.
	Institute appropriate therapy if required by the subject's condition.
	Assess the use or discontinuation of concomitant medications.
	Review the subject's laboratory and other test results.
	Perform a complete or directed physical examination.
	Assess compliance with the study medication/s.
	Dispense study medication as appropriate.

Follow-up, completion and early termination from the study

• PI or sub-investigator • Research coordinator	Perform a complete or directed physical examination (if applicable)
• Data Manager	Assess the subject for ongoing adverse events appropriately

	Collect specimens as directed by the protocol.
	Order diagnostic tests and procedures.
	Review any use of concomitant medication.
	Schedule follow-up visits per protocol.
• PI or sub-investigator	Collect unused test article, if appropriate.
• Research coordinator	
• Study pharmacist	
• Research coordinator	
• PI	Document survival data as required
• Sub-investigator	

Communication with primary or referring medical providers

• Research nurse/coordinator • Data Manager	Place the original signed consent/s form in the patient's Research Chart (at UNM this is the paper Research Chart). A copy of the consent/s will be scanned into the appropriate Electronic Medical Record, at UNM this is Mosaic..
	The UNM-CC physician will dictate a copy of H&P to be sent to the subject's primary care or referring provider about the subject's progress while on study, as appropriate.

Management of ineligible subjects

• PI or sub-investigator • Data Coordinator	Document the reason for ineligibility in Evelos. Retain a copy of signed consent form.
• Research nurse/coordinator	Discuss treatment alternatives with the subject.

Approved: _____ Date: 2/17/12
CPDMI Medical Director

Approved: _____ Date: 2/28/12
NMCCA Medical Director