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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: NMCCA NEW STUDY PROCESS

SOP No.: 1.7	Version No.: 3	Effective Date: 2-2011

Owner: NMCCA Executive Director

Name: Teresa Stewart

Teresa R Stewart
Signature

3/19/2018
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature

3/28/2018
Date

INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the procedures whereby a new study (clinical trial) is opened through NMCCA

SCOPE

This SOP applies to the documents and training that are required once a study is submitted by a sponsor to NMCCA for consideration.

Owner of this SOP and Annual Reviewer: NMCCA Executive Director

APPLICABLE REGULATIONS AND GUIDELINES

N/A

REFERENCES TO OTHER APPLICABLE SOPs.

SOP1.2 Responsibilities of the Research Team
SOP2.0 Study Start-up Procedures

RESPONSIBILITY

All NMCCA Investigators

NMCCA Executive Director

NMCCA Clinical Research Manager (CRM)

NMCCA Clinical Research Supervisor (CRS)

NMCCA Regulatory Coordinators

NMCCA Protocol & Outreach Coordinator

PROCEDURES

Request from Sponsor to submit a clinical trial for approval -

. Owner	Criteria / Steps
Protocol & Outreach Coordinator	After receiving interest from a sponsor to submit a study to NMCCA for approval: Send email to sponsor to include but not limited to: Cover letter or appropriate sections of the cover letter (Form A) Process Flow Chart (Form B) Sponsor Contact/Questionnaire (Form C)
Executive Director	Upon receiving the Confidentiality Disclosure Agreement (CDA) the Executive Director of NMCCA will execute the agreement and return to the sponsor.

. Owner	Criteria / Steps
Protocol & Outreach Coordinator	Upon receiving the full final protocol the review process will begin. The protocol will be submitted to the Disease-site Clinical Working Group (CWG). Upon approval by the CWG, a pre-study site visit if required should be scheduled. Upon approval by the CWG, the protocol will be submitted to the Protocol Review and Monitoring Committee (PRMC). Upon approval by the PRMC, the protocol will be given to the e NMCCA CRS. Note: This is the process for most clinical trials. Please see attached table to determine specific steps for specific clinical research studies. (Attachment A)
NMCCA CRS	Refer to SOP 2.1 for Study Start – up Procedures.