



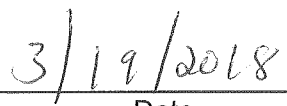
<p>University of New Mexico Comprehensive Cancer Center / New Mexico Cancer Care Alliance</p>  <p>STANDARD OPERATING PROCEDURE</p> <p>Clinical Research Office</p> 		
Title: NMCCA NEW STUDY PROCESS		
SOP No.: 1.7	Version No.: 3	Effective Date: 2-2011

Owner: NMCCA Executive Director

Name: Teresa Stewart



Signature

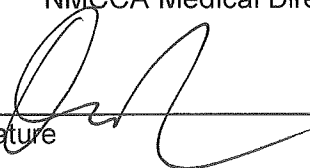


Date

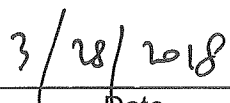
Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director



Signature



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