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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: INVESTIGATOR AND INVESTIGATIVE SITE REQUIREMENTS

SOP No.: 1.5	Version No.: 6	Effective Date: 12-2009

Owner: NMCCA Executive Director

Name: Teresa 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 required for an institution to become an Institutional Participant of the New Mexico Cancer Care Alliance (NMCCA) and the procedures required for a physician to become an NMCCA Class A Participant who can enroll and manage subjects on NMCCA clinical trials. These required procedures are mutually dependent, as a site cannot be activated without its physicians and research-required support staff being credentialed, and the physicians cannot take part in research without their site being activated.

SCOPE

This SOP applies to the documentation and training that is required once an institution is approved by the NMCCA Board of Directors to become an Institutional Participant, and to the documentation and training that is required once a physician is approved by the Board of Directors to become an NMCCA Class A Participant.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
September 1993	FDA Compliance Program Guidance Manual 7348.811: Clinical Investigators

REFERENCES TO OTHER APPLICABLE SOPs

SOP 1.2	Responsibilities of the Research Team
SOP 1.6	NCTN Group Participation

RESPONSIBILITY

NMCCA Board of Directors (BOD)
NMCCA Executive Director
All NMCCA Investigators
NMCCA Regulatory Coordinator
NMCCA Project Specialist
NMCCA Clinical Research Supervisor (CRS)

PROCEDURES

Activation of an NMCCA Institutional Participant (institutional or physician practice) -

Owner	Criteria/Steps
NMCCA BOD, NMCCA Executive Director	NMCCA Executive Director obtains a signed "Site Participation Agreement" and presents the potential participant site (institutional or physician practice) to the NMCCA BOD.
NMCCA Project Specialist	Once the potential site is approved by the NMCCA BOD: Send "Welcome" packet from the Executive Director which includes: • Welcome letter • Current Bylaws

- IRB Agreements for the Site
  - UNM HRRC
  - WIRB
- Research Service Agreement
- Site Evaluation Checklist

Facilitate obtaining required documents from site.

Obtain a CTEP Institution Code by contacting ecuhelpdesk@mail.nih.gov Provide all required documentation.

Once CTEP Institution Code is issued, it will be pulled into NCORP-SYS from the NCI's Enterprise Core Module (ECM). At that point, provide the following information via NCORP-SYS:

- Activation Letter (i.e., a document that lays out the terms under which the component/subcomponent will participate with the NCORP applicant organization) addressed to the NCORP's Program Director and is signed by the Principal Investigator, appropriate official from the site and appropriate official from the NCORP/MU NCORP grantee organization (identified on the Notice of Award).

- Tumor Registry Form (required for a component/subcomponent that is a hospital). Provide the number of newly diagnosed cancer patients per site for the previous and current calendar years. A template is located at: https://applications.prevention.cancer.gov/ncorp-portal/resources/ncorp-guidelines/component-guidelines-table5.pdf/view

- Federal Wide Assurance Number with expiration date. Please Note: The institution must be listed on the OHRP website with an FWA number that matches the number provided (http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc).

- Organization's participation type (i.e., hospital, group practice or other – definitions available in NCORP SYS). If it is a hospital whether it has a current ACOS accredited program. Also, the number of hospital beds used and select attributes (list available in NCORP SYS) regarding the hospital.

- Organization's website site address, if one is available.

- Type of clinical site (menu of types available in NCORP SYS).

[After execution of Agreements and Site Evaluation Checklist (Form E), the physicians at site will be sent instructions on credentialing as a part of the research team. The site will not be considered active until sufficient study personnel are credentialed as described in the procedures listed below.]

NMCCA CRS	Registration with the NCI Central IRB (NCI CIRB) Verify Federal Wide Assurance* for site has been updated to include the following IRB's: U New Mexico Hlth Sci Ctr IRB #1: IRB00000591 U New Mexico Hlth Sci Ctr IRB #2: IRB00000592 U New Mexico Hlth Sci Ctr IRB #3: IRB00001775 U New Mexico Hlth Sci Ctr IRB #4: IRB00001776 Natl Cancer Inst-NCI Central IRB (Adult): IRB00000781 NCI Central IRB (Pediatrics): IRB00004296 NCI Central IRB (early phase trials): IRB00009430 CCDR NCI CIRB : IRB00010018 Western IRB #: IRB0000053 Notifies Investigators what documentation is necessary before proceeding with clinical trial approval for that site or with the investigator. (*For solo-practitioners, an Unaffiliated Investigator Agreement is required rather than an FWA) NOTE: Some sites may participate in Investigator Initiated Trials that are not Class A Participants. These trials must have approval and these sites must be approved using the Site Evaluation Checklist (Form E)

NMCCA Activation of a new Class A Participant -

Owner	Criteria/Steps

NMCCA Project Specialist	To become an NMCCA Class A Participant who can enroll and manage subjects on NMCCA clinical trials the following must be completed/collected:
	
	• NMCCA BOD Approval
	• Application for Appointment as a Class A Participant which includes:
	  o NCTN Group Participation Form
	  o Authorization for Release of Information
	• Welcome letter from the Executive Director
	• Current Medical License
	• Request for Current, updated CV
	• Instructions for CITI training
	• Instructions for Financial Conflicts of Interest Training
	• Financial Conflict of Interest Disclosure Form (non-UNM participants only)
	• Handling investigational drugs: Mandatory video training
	
	Once CITI Training is complete, send instructions for obtaining a CTEP ID and setting up a CTEP-IAM account

	Once CTEP ID obtained, complete NCI Registration Packet in CTEP's Registration and Credential Repository (RCR) application. Forward prepared submission to investigator to review, sign and submit. Once the NCI Registration is approved, link and activate the investigator in the NCORP-SYS, then roster the investigator to all requested NCTN groups. [NOTE: The process of registering/activating/rostering the investigator with the NCI/NCTN Groups cannot occur until the participant's site has also been approved/activated as a CTEP Investigative site, as the investigator must link him/herself to the site within the CTEP applications.]

Class A Investigator Requirements for NMCCA Trial Participation -

Owner	Criteria/Steps
Class A Participants	Execute appropriate agreements (Participation Agreements, Release of Information, IRB Authorizations and Research Services Agreements). CITI Training (Good Clinical Practice and Biomedical Research Investigator courses) https://www.citiprogram.org/ NOTE: this training is required for Physician Participants, as well as their research staff (research and data coordinators). Print out the completion report and send to NMCCA Project Specialist. Handling Investigational Drugs: Mandatory video training https://swog.org/Members/Training/InvDrugHandling.asp Any staff member who handles any process to do with investigational drug. Financial Conflicts of Interest Training • UNM Participants: Course provided in *Learning Central* • Non-UNM Participants: NIH Course: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm Signed and Dated Curriculum Vitae from Investigator, updated annually. Complete National Clinical Trial Network Participation form identifying desire to participate in National Cancer Institute Trials and specify the research groups. (Form D) Obtain CTEP ID and submit NCI Registration Packet though the NCI Registration and Credentialing Repository (RCR). Return forms to NMCCA Project Specialist