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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: NCI NATIONAL CLINICAL TRIAL NETWORK (NCTN) PARTICIPATION

SOP No.: 1.6	Version No.: 5	Effective Date: 12-2009

Owner: NMCCA Executive Director

Name: Teresa Stewart, MS

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

The National Cancer Institute (NCI) National Clinical Trial Network (NCTN) group trials are some of the most important clinical trials available, and it is a priority of the UNM Comprehensive Cancer Center (UNMCCC) and the New Mexico Cancer Care Alliance (NMCCA) that these trials are available to every cancer patient in New Mexico. The NCTN groups with which the NMCCA and UNMCCC participate are SWOG, the Alliance for Clinical Trials in Oncology (Alliance), Children's Oncology Group (COG), ECOG-ACRIN, NRG Oncology and Wake Forest Research Base. The UNMCCC, an NMCCA Participant Site, is the holder of an NCI grant (Community Oncology Research Program, Minority/Underserved – NCORP) which funds participation in NCTN and Clinical Trials Support Unit (CTSU) trials. The funding specifically for community involvement in these trials is sub-awarded to NMCCA for the expressed purpose of reimbursing NMCCA participant sites for their NCTN participation. However, participation with these groups requires the formal recommendation of the Principal Investigator at the UNMCCC for that NCTN group, and requires a commitment on the part of interested physicians and NMCCA Sites to enroll patients on these trials.

If a PI is not a member of the specific NCTN sponsoring the trial, but the trial is open through the Clinical Trial Support Unit (CTSU) the PI may enroll patients on the trial, but credit will be given to the NCTN group of which the PI is a member.

SCOPE

This standard operating procedure describes the procedures for registering or credentialing an investigator and an investigative site with the available NCTN groups.

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 Research Team
SOP 1.5 Investigator and Investigative Site Requirements

RESPONSIBILITY

Principal Investigators
Sub Investigators
CRO/NMCCA Executive Director
NMCCA Clinical Research Manager (CRM)
NMCCA Clinical Research Specialist (CRS)
NMCCA Project Specialist

PROCEDURES

Registration of investigator with a cooperative group -

Owner	Criteria/Steps
PI/Co-PI/ Sub PI	Complete all requirements listed in SOP 1.5 for each investigator and well as the investigative site. Complete the NCTN Participation checklist Form A. The checklist should include a copy of the investigator's CV, NCI Investigator number (CTEP ID), human research protections training certificate, copy of Federal Wide Assurance or Unaffiliated Investigator Agreement. Return the checklist and documents to NMCCA.
NMCCA Project Specialist	Receive the checklist and documents from the new NMCCA investigator.
NMCCA Project Specialist	Facilitate the process of obtaining an NCI Investigator number (CTEP ID) for any investigator who does not have one by sending a link to the registration site with instructions. Once the CTEP ID is received, complete the NCI Registration Packet in the CTEP Registration and Credential Repository (RCR). Send notification to the investigator to review, sign and submit the registration. Once the registration is approved and active, add and activate the investigator in the NCORP-SYS system. Upload required documents including documentation of human research protections training for investigator (HRP). Once activated, roster the investigator to each of the NCTN groups, uploading any documentation required specifically for the NCTN group. SWOG requires a nomination letter signed by the PI of the NM-NCORP grant, an Affirmation of Integrity signed by the investigator and a New Investigator Pharmacy Information form for investigators who will be ordering investigational drugs.
NMCCA Project Specialist	Once verification of approval of the investigator's NCTN group rostering is received, inform the NMCCA CRS.
NMCCA CRS	Register investigator with the NCI CIRB

Registration of an investigative site with a cooperative group –

Owner	Criteria/Steps
CRO/NMCCA Executive Director	After approval by the NCORP PI or the NMCCA Board of Directors, inform the NMCCA Project Specialist that a new site/Participant is to be added as a component to the NM NCORP grant. A subcomponent of an existing Component requires approval by the NCORP PI.
NMCCA Project Specialist	Contact ecuhelpdesk@mail.nih.gov to begin the process of obtaining a CTEP Institution code. Follow steps/submit documentation required. Once CTEP Institution Code is received, add component or subcomponents to the NCORP/MU-NCORP roster via NCORP-SYS (https://applications.prevention.cancer.gov/ncorp-sys) Once a site has a CTEP Institution code and is pulled into NCORP SYS from the NCI Enterprise Core Module (ECM) provide the following information: • 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 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).
NMCCA Project Specialist	Once verification of a NCTN group site number is received, forward the information on to the NMCCA regulatory coordinator, NMCCA Executive Director, Velos database manager and the NMCCA CRS.
NMCCA Coordinator	Confirm with the NMCCA participant site that the NCTN group trial participation has been approved for the requested physician(s), and that specific NCTN group trials may be requested for that participant site.

	Remind the investigator that until the participant site registration is complete, the site may enroll patients in NCTN group trials only under the institution number for the UNMCCC. Arrange for any necessary training of research personnel in NCTN trial participation