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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: PRESTUDY SITE VISIT (PSSV) (Please note, this policy is pharmaceutical trials specific)

SOP No.: 2.2	Version No.: 7	Effective Date: 2-26-2004

Owner: NMCCA Clinical Research Manager

Name: Leslie Byatt

Leslie Byatt — 3/19/18

Signature — Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

Signature — 3/18/2018 Date

INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at New Mexico Cancer Care Alliance participant sites when the sponsor of a study requires a pre-study site visit, to:

Meet with study personnel and review their qualifications for the study,

Assess the facilities of the research site for implementing the study,

Evaluate the possibility of collaborating on the study.

Determine if the study will be opened at this site.

Grant formal site selection, allowing access to regulatory materials and initiation of contract activities.

SCOPE

This SOP applies to the procedures for conducting the Pre-Study Site Visit (PSSV) for potential clinical studies subject to investigational new drug (IND) or new device (IDE) regulations for drugs, biologics, and device during all investigational phases of development. It describes the steps followed by UNM Comprehensive Cancer Center (UNM CCC) and New Mexico Cancer Care Alliance (NMCCA participant sites from the time a PSSV is scheduled by a sponsor until all follow-up activities associated with the visit have been completed.

Whenever possible, these visits are conducted only after obtaining clinical working group (CWG) approval of the study. However, if a study sponsor requires site selection earlier as a requirement for consideration of our sites we will conduct an earlier PSSV, if approved by the potential Principal Investigator. In this event, the NMCCA clinical research manager or designee will arrange for and conduct the visit.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.52	Transfer of obligations to a contract research organization
21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.66	Assurance of HRRC review
21 CFR 312.68	Inspection of investigator's records and reports
January 1988	Guidelines for the Monitoring of Clinical Investigations

REFERENCES TO OTHER APPLICABLE SOPs

SOP 3.1 Regulatory Files and Subject Records

RESPONSIBILITY

This SOP applies to those members of the regulatory and clinical research team involved in organizing and participating in the pre-study site visit. This includes the following:

Principal Investigator (PI)

NMCCA/CRO Executive Director

Research coordinator

Regulatory coordinator

Study pharmacist

NMCCA CRS

Research technicians

Data managers

PROCEDURES

Preparing for the pre-study site visit -

. Owner	Criteria / Steps
NMCCA /CRO Director	Ensure that the sponsor's Confidentiality Agreement is complete and has been appropriately signed and returned to the sponsor.
Protocol & Outreach Coordinator	Provide the pharmaceutical company or Contract Research Organization (CRO) monitor with contact information for the NMCCA clinical research manager if a pre-study site visit is required.
NMCCA Clinical Research Manager	PRE PSSV: • Coordinate completion of Feasibility Questionnaires (FQ), Site Assessment Forms (SARs) and other sponsor-required tools. • Contact the local study PI and research team to arrange for a mutually agreeable meeting date and time. • Confirm the sponsor's preferred areas of interest for the visit and develop an agenda including meeting schedules for various areas. • Reserve a room (for UNM CCC visits) for the PSSV and schedule a PSSV at NMCCA sites as required. • Send written confirmation of the PSSV date, time, location and agenda to all invitees. • Prepare a participation log

NMCCA Clinical Research Manager	DURING PSSV: • Information regarding clinical working group and PRMC review and approval Information regarding contracted Institutional Review Boards (IRBs) • Contact for contract and budget negotiations • Business card(s) of staff member conducting visit • Provide a tour of the facilities including, as applicable based on affiliate site, the patient treatment area (clinic or hospital), pharmacy, translational laboratory, TriCore laboratory area, medical records department and Clinical Trials Office areas. • As needed, coordinate collection of additional information following the visit and submit to the sponsor/CRO monitor. • For all UNM FDA 483 report requests, refer contact to UNM Legal Department • Notify the Executive Director, and (if assigned) Primary Regulatory Coordinator of official site selection and maintain hard copies of confirmation. Enter a note in Velos confirming site selection. • Include meeting agenda, meeting participation log and documentation of formal site selection in the study regulatory binder • Scan completed Delegation of Authority log and current FDA 1572 form and upload to study database.