SOP2.4 - Study Activation
Approved Date: 02-26-04
Reviewed/Revised Date: 2/06; 08/08, 10/13. 9/17
Owner: NMCCA CRS

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

STANDARD OPERATING PROCEDURE

Clinical Research Office

Title: STUDY ACTIVATION		
SOP No.: 2.4	**Version No.: 5**	**Effective Date: 2-26-2004**

Owner: NMCCA CRS

Name: Kaylee Deutsch

Signature 12/19/17 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 processes followed at the UNM Comprehensive Cancer Center (UNM CC) and New Mexico Cancer Care Alliance (NMCCA) Participant Sites when a study is activated:

- Review of all regulatory and IRB files and documents for completeness;
- Review accuracy of case report forms (CRFs);
- Obtain completed SIV Checklist/Obtain all applicable signatures
- Complete the CTO Post SIV Checklist/Obtain PI signature
- Obtain minutes of study initiation meeting, as applicable
- Obtain study investigational article
- Confirm legal and financial contracts are complete

SCOPE

This SOP applies to the procedures for conducting the study activation for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all investigational phases of development. It describes the steps followed by the UNM Cancer Center (UNM CC) and New Mexico Cancer Care Alliance (NMCCA) clinical research sites to activate a new clinical study

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.66	Assurance of HRRC review
January 1988	Guidelines for the Monitoring of Clinical Investigations
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline
SOP 2.2	Pre Study Site Visit
SOP 2.3	Site Initiation Meetings and Visits

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in arranging, managing, participating in or following up after the study initiation visit. This includes the following:

- Principal investigator
- Sub-investigator
- Executive Director
- UNM CCC Clinical Research Operations Manager
- NMCCA Clinical Research Manager
- Clinical Research Supervisor
- Business manager
- Data manager
- Research coordinator
- Regulatory coordinator
- Data coordinator
- Study pharmacist
- Research technician
- Quality assurance auditor
- Study monitor
- Information specialists

PROCEDURES

Preparing for the Study Activation

. Owner	Criteria / Steps
Regulatory Coordinator	Ensure that all regulatory documentation is complete and all authorizations (site selection, staff training) have been obtained. Ensure that sponsor has approved each site for activation. Ensure that study agents shipping procedures have been confirmed by the study pharmacist. Ensure that minutes of the initiation visit have been received from sponsor as applicable Ensure that the research team has been trained through site initiation meetings (SIM) or visits (SIV) Ensure that study activities have been delegated. Confirm that all contracts and site budgets are complete and posted to eVelos as appropriate As necessary, ensure that imaging facility certification has been obtained.
Research Coordinator Data Coordinator	Ensure that case report forms are available. Ensure that EDC and IWRS database access has been received and activated, as applicable. Complete CTO SIV Checklist and give it to regulatory coordinator once complete.
Study Pharmacist /PI/Radiology	Ensure that the study agent has been received and accounted for. Ensure that IWRS database access has bene received and activated, as applicable. Complete CTO SIV Checklist and give it to regulatory coordinator once complete

Managing the study activation

. Owner	Criteria / Steps
Regulatory Coordinator	Complete CTO SIV checklist by acknowledging that the study is ready for activation. Give the Executive Director and/or the Clinical Research Supervisor the CTO SIV checklist to complete activation.
NMCCA Executive Director	For industry and externally funded investigator-initiated trials: confirm completeness of site study tracking form in information database. Sign CTO SIV checklist to confirm activation. Update clinical trial management software (CMS) database status to reflect study activation.
Clinical Research Supervisor	For NCI and other trials as directed: confirm completeness of site study tracking form in information database. Sign CTO SIV checklist to confirm activation. Update clinical trial management software (CMS) status to reflect study activation
Regulatory Coordinator	Upload study consent forms and corresponding IRB approved documents to CMS database. Email a notification to all UNM CCC and/or New Mexico Cancer Care Alliance participating clinical research team members indicating that the study is open for accrual.